

Combatting Falsification and Counterfeiting Of Medicinal Products in the European Union

A Legal Analysis

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COMBATTING FALSIFICATION AND COUNTERFEITING OF MEDICINAL PRODUCTS IN THE EUROPEAN UNION - A LEGAL ANALYSIS

PhD Series 01-2018

Vishv Priya Kohli

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Doctoral School of Business and Management

PhD Series 01.2018

CBS  COPENHAGEN BUSINESS SCHOOL
HANDELSHØJSKOLEN

Combatting Falsification and Counterfeiting Of Medicinal Products in the European Union - A Legal Analysis

Vishv Priya Kohli

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Copenhagen, January 2018

Vishv Priya Kohli

Abstract

The study of counterfeiting and falsification of medicinal products, from a legal perspective, is a relatively new area in the EU. Specific regulations that focus on falsification of medicines came as recently as 2011. Therefore, this discipline is also new for research.

There are two primary objectives of the thesis. The first is to analyse how EU law addresses counterfeiting and falsification of medicinal products, (Directive 2011/62/EU, Directive 2004/48/EC, and Regulation 608/2013) – *de lege lata*. The second is to analyse whether the law containing tools to combat counterfeiting and falsification of medicinal products meets the social objectives of public health (Articles 9 and 168) and consumer protection (Articles 12 and 169), as envisaged by the Treaty on the Function of the European Union.

The thesis establishes that the problem of counterfeiting and falsification of medicinal products lies at the intersection of three spheres of law - IP law, Medicine law, and Criminal law. This insight provides the foundation for the understanding of the weaknesses in the legal regime that contains tools for combatting counterfeiting and falsification of medicines in the EU.

In order to set the context and illustrate the main problem of counterfeiting and falsification of medicinal products, three cases are analysed - Operation Robin (Sweden), Operation Singapore (the UK), and Operation Volcano (Italy). Through the case studies, the common challenges confronting the law are identified, such as the infiltration of the legal supply chain, manipulation of medicinal products, insufficient control over online sale of counterfeit medicines, and the use of small

consignments to transport such products. These issues underline the gaps that exist in the legal framework in the EU and serve as the basis for the analysis of the legal framework.

The legal analysis reveals that counterfeiting and falsification of medicines is addressed in a compartmentalised and mutually exclusive manner by the different streams of law. As a result, the legal framework does not operate at the most effective level possible.

In order to draw inspiration to strengthen the current legal framework in the EU, initiatives taken at the international level with particular emphasis on the Medicrime Convention, the ACTA, and multilateral and bilateral agreements are also analysed.

Thereafter, on the basis of the issues identified in the case studies and the analysis of the law, it is examined whether the law containing tools to combat counterfeiting and falsification of medicinal products meets the social objectives of public health and consumer protection, as envisaged by the TFEU.

In conclusion, it is reasserted that the problem of counterfeiting and falsification of medicinal products lies at the intersection of IP law, Medicine law, and Criminal law. Even though the legal instruments are successful to some extent, there is still scope for improvement, especially in the area of criminal enforcement of counterfeiting and falsification of medicinal products, securing authorisation certificates for the market players and building overall synergies within and amongst authorities representing the three streams of law, within and across the Member States.

Abstract in Danish/Resumé på dansk

Forfalskning af medicin fra et juridisk perspektiv er et relativt nyt område inden for EU. En særregulering af forfalskninger af medicin så dagens lys så sent som i 2011, og som følge deraf er dette emne nyt inden for den juridiske forskning.

Denne afhandling har to primære formål. Det første formål er at analysere, hvordan EU håndterer forfalskning af medicin. I den forbindelse tages der udgangspunkt i direktiv 2011/62/EU, Direktiv 2004/48/EC og forordning 608/2013 – *de lege lata*. Det andet formål er at analysere, hvorvidt det omhandlede lovgrundlag opfylder de sociale mål om dels folkesundhed (artikel 9 og 168) og dels forbrugerbeskyttelse (artikel 12 og 169) som forudsat i traktaten om den Europæiske Unions funktionsmåde.

I afhandlingen konkluderes det, at det juridiske problem vedrørende regulering af forfalskning af medicin ligger i skæringspunktet mellem 3 lovgivningssfærer, immaterialret, lægemiddelret og strafferet. Denne indsigt skaber grundlaget for at forstå svaghederne i lovgivningen med midlerne til bekæmpelse af forfalskning af medicin i EU.

For at illustrere problemstillingen indeholder afhandlingen en analyse af tre sager - Operation Robin (Sverige), Operation Singapore (Det Forenede Kongerige), og Operation Volcano (Italien). Gennemgangen af sagerne identificerer de problemstillinger, som lovgivningen står over for, såsom infiltration af den legale forsyningskæde, manipulation af produkterne, utilstrækkelig kontrol med online salg af forfalsket medicin og brugen af små forsendelser.

Den juridiske analyse af immaterialretten, lægemiddelretten og strafferetten afdækker, at forfalskning af medicin håndteres isoleret i de forskellige lovgivninger, og at der ikke er tænkt i synergier. Det konkluderes på den baggrund, at den juridiske regulering som følge heraf ikke er optimal. Dernæst analyseres en række internationale initiativer – særligt Medicrime konventionen og ACTA samt en række andre multilaterale og bilaterale initiativer - med henblik på at undersøge, om de kan give inspiration til en styrkelse af den gældende EU regulering på området.

På grundlag af sagsgennemgangene og den juridiske analyse vurderes det, hvorvidt lovgivningen indeholder de nødvendige midler til bekæmpelse af forfalskning af medicin og dermed hvorvidt de sociale mål om folkesundhed og forbrugerbeskyttelse som forudsat i traktaten om den Europæiske Unions funktionsmåde kan anses som opfyldt.

Som konklusion konsolideres udgangspunktet om, at problemet med forfalskning af medicin ligger i skæringspunktet mellem immaterialret, lægemiddelret og strafferet. Skønt lovgivningen i nogen grad kan anses som effektiv, konkluderes det, at der stadig er potentiale for forbedringer, særligt i relation til strafferetlig håndhævelse, forhøjelse af sikkerheden omkring certifikater for markedsaktører samt i tilvejebringelse af synergier mellem myndigheder inden for de tre lovområder, både inden for hver enkel medlemsstat og på tværs af medlemsstaterne.

Abbreviations

ACTA:	Anti-Counterfeiting Trade Agreement
AH:	Authorisation Holder
AIFA:	Italian Medicines Agency
API:	Active Pharmaceutical Ingredient
CAP:	Centrally Authorised Product
CFM:	Counterfeit and Falsified Medicines
CFREU:	Charter of Fundamental Rights of the European Union
DRA:	Drug Regulatory Authority
EMA:	European Medicines Agency
EU:	European Union
FDA:	U.S. Food and Drug Administration
FIP:	International Pharmaceutical Federation
FMD:	Falsified Medicines Agency
GDP:	Good Distribution Practice
GMP:	Good Manufacturing Practice
GMDP:	Good Manufacturing and Distribution Practice
HMA:	Heads of Medicines Agencies

IMPACT:	International Medical Products Anti-Counterfeiting Taskforce
IP:	Intellectual Property
IPR:	Intellectual Property Rights
ICH:	International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use
IWG:	Inspectors Working Group
MA:	Manufacturing Authorisation
MAH:	Market Authorisation Holder
MHRA:	Medicines and Healthcare Products Regulatory Agency (U.K.)
MS:	Member States of the European Union
NABP:	National Association of Boards of Pharmacy
NCA:	National Competent Authority
NUI:	Non Urgent Information
OECD:	Organisation for Economic Cooperation and Development
OTC:	Over the Counter
PSI:	Pharmaceutical Security Institute
RA:	Rapid Alert
RAS:	Rapid Alert System
SSFFC:	Substandard, Spurious, Falsely labelled, Falsified, Counterfeit
TEU:	Treaty on European Union

TFEU:	Treaty on the Functioning of the European Union
TRIPS:	Trade Related Aspects of Intellectual Property Rights
UNODC:	United Nations Office on Drug and Crime
VIPPS:	Verified Internet Pharmacy Practice Sites
WCO:	World Customs Organisation
WGEO:	Working Group of Enforcement Officers
WHA:	World Health Assembly
WHO:	World Health Organisation
WIPO:	World Intellectual Property Organisation
WTO:	World Trade Organisation

Glossary

Adulteration:	The process of altering a product by intentionally manipulating the product by adding something that ordinarily is not supposed to be in the product.
API:	Active Pharmaceutical Ingredient is that part of the drug that contains the healing or disease preventive or curing agent of the pharmaceutical product.
Counterfeit drug:	A drug having an unauthorised representation of a registered trademark on a product identical or similar to one for which the trademark is registered.
Drug Recall:	A drug recall means removal of a prescription or over-the-counter drug from the market by the national competent authority, usually a medicines agency.
Drug:	A medication or a substance used in the preparation of medication.
Excipient:	A pharmacologically inactive substance like a colouring agent, filler or a preservative that is used with other active substances in a medicinal product.

Fake drug:	A synonym used for the falsified or counterfeit drug.
Falsified drug:	A drug that falsely represents a product's origin or sources or history.
GDP:	Good Distribution Practice are the guidelines regarding quality control, warranty system, requirements for purchase, receiving, storing, and exporting medicinal products that must be upheld for distribution of medicinal products for human use.
Generic medicines:	Generic medicines are copies of brand-name drugs, which have the same pharmacological effect as the brand-name drugs. The generic drugs, therefore, have equivalent risks, safety, and strength, side effects, route of administration and dosage as the brand-name drugs.
GMP:	Good Manufacturing Practice is a system to ascertain that pharmaceutical products adhere to a quality standard. It is formulated with an aim of reducing the risk concerning pharmaceutical products that cannot be done away with by means of testing the finished product.
Illegal medicine:	Illegal medicine is a medicine not authorised by law.
Lifesaving drugs:	Life-saving medicines are the antibiotics that help in saving lives, such as drugs that treat cancer, etc.

Lifestyle drugs:	A lifestyle drug is a term used to describe medications that treat conditions like wrinkles, erectile dysfunction, or acne, which are not life-threatening and non-painful.
Medicines:	A substance or preparation used for treating a disease.
NUI:	Non-Urgent Information.
Over-the-counter:	An OTC is a pharmaceutical drug that does not require a prescription in order to be dispensed.
Parallel import:	A parallel import, often referred to as grey product is a non-counterfeit product imported without the authorisation of the intellectual property owner.
Pharmaceutical:	A drug with medicinal property.
Prescription drug:	A prescription medicine is a pharmaceutical drug that requires a medical prescription by law, to be dispensed. .
Substandard:	A drug that does not meet the national specification outlines by a national competent authority. These drugs are manufactured by legitimate manufacturers but are substandard because of quality failures.
Market	An official document issued by the competent medicines

authorisation: regulatory authority for the purpose of marketing after conducting evaluations for safety, efficacy, and quality. It sets out the name of the product, the dosage form, the quantitative formula, the shelf life and storage conditions required along with packaging characteristics.

Manufacturing authorisation: It is part of the series of controls which the legislation states in the form of requirements pertaining to market authorisation, distribution authorisation or market authorisation depending upon the precise activity being discharged.

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Part I: Introduction

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Part I consists of two chapters and lays down the foundation of the thesis. In the first chapter, the topic is introduced by providing the background, establishing the relevance and stating the objectives of the thesis. Next, the perspective of the thesis is indicated followed by delimitations of the areas that are relevant but are not addressed in the thesis. The first chapter ends with the structure of presentation of the thesis, which serves as a roadmap to the thesis, and provides the practical direction. Subsequently, in the second chapter of Part I, the theory of law that is considered and employed in the thesis is discussed, followed by the sources of law that are utilised in the legal analysis. Thereafter, the methods that are used in the various parts of the thesis are discussed. Thus, Part I provides the basis on which the rest of the thesis stands.

Chapter 1: Introduction

1.1. Relevance

Counterfeiting¹ is not a new phenomenon; in fact, it has been known to exist for at least the past 2000 years. Pliny The Elder described counterfeit coins as popular collectors' items for Romans.² Counterfeiting existed then and it exists now, but the forms of counterfeiting have transformed and multiplied. All kinds of counterfeiting have a negative effect on economy, growth, jobs and innovation – be it counterfeiting of currency, wine, fine arts or of luxury goods. The latest survey conducted by the Organisation for Economic Co-operation and Development (OECD) & European Union Intellectual Property Office (EUIPO) reported that the global trade in fake goods was worth almost half a trillion dollars per year.³ Other more serious types of counterfeit products, including falsified

¹ Counterfeiting is commonly understood to mean – “to forge; to copy or imitate, without authority or right, and with a view to deceive or defraud, by passing the copy or tiling forged for that which is original or genuine.” See more in Black, H.C., Nolan, J.R., & Nolan-Haley, J.M. (1990). *Black's Law Dictionary*. (Sixth Edition). St. Paul, Minn. West Publishing Co. 349.

² Barry, K. (2007). Counterfeits and counterfeiters: The ancient world. In Chaudhry, P. E., & Zimmerman, A. (2009). *The economics of counterfeit trade: governments, consumers, pirates and intellectual property rights*. Springer Science & Business Media.7.

³ OECD/EUIPO (2016), *Trade in Counterfeit and Pirated Goods: Mapping the Economic Impact*, OECD Publishing, Paris. It was estimated that the value of imported fake goods worldwide was estimated to be USD 461 million in 2013, compared to the total imports in world trade at USD 17.9 trillion. It was also reported that up to 5% of goods imported into the European Union are fakes.

medicines, fake automobile spare-parts, and counterfeit toys have led to a large number of avoidable deaths across the globe.⁴

Medicine counterfeiting also has a long history.⁵ Dioscorides, a Greek physician, pharmacologist and botanist wrote about the detection of counterfeit drugs in his 'Materia Medica', in 40-90 A.D. The other Greco-Roman medical and natural history writers who have written about falsification of medicine include Theophrastus and Galen.⁶ In the nineteenth century, because of the rapid pace of technological and economic development, there was a parallel rise in production and distribution of counterfeit goods.⁷ In 1985, the World Health Organisation (WHO) recognised counterfeit medicines as a global problem.⁸ The exponential increase in worldwide trade of counterfeit goods has been noticed by the WHO,⁹ the International Police Organisation (INTERPOL),¹⁰ and the academic circles.¹¹

In this thesis, the focus is on counterfeiting and falsification in the pharmaceutical sector of the EU as this can lead to life threatening incidents. The pharmaceutical sector is especially vulnerable and lucrative for the criminals. Firstly, with relatively little investment, it is possible to make huge profits. Also, the cost associated with the manufacturing of fake pills is negligible as compared to the profits that are made by the sale of each counterfeit pill. The International Institute

⁴ The result of use of counterfeit medicines has resulted in death of patients around the world. Such deaths were reported, for instance, in the USA, Canada and New Zealand. Wertheimer, A. I., & Wang, P. G. (2012). *Counterfeit Medicines: Policy, economics, and countermeasures (Vol. 1)*. ILM Publications. 75-76.

⁵ See further in Stieb, E.W. (1966). *Drug Adulteration: Detection and Control in the 19th century Britain*, Madison, WI. The University of Wisconsin Press.

⁶ See further in Stieb, E.W. (1966). *Drug Adulteration: Detection and Control in the 19th century Britain*, Madison, WI. The University of Wisconsin Press.

⁷ Bate, R. (2008). *Making a killing: the deadly implications of the counterfeit drug trade*. AEI Press, Washington, D.C.

⁸ World Health Organization (WHO). (2012). Substandard/spurious/falsely labelled/falsified/counterfeit medical products: report of the working group of member states. WHO. Geneva.

⁹ *ibid.*

¹⁰ INTERPOL. (2014). Operation Pangea VII report. INTERPOL, Lyon.

¹¹ Blackstone, E. A., Fuhr Jr, J. P., & Pociask, S. (2014). The health and economic effects of counterfeit drugs. *American health & drug benefits*, 7(4).

of Research against Counterfeit Medicine (IRACM) has reported that an investment of USD 1,000 generates USD 20,000 in the trafficking of heroin or a return of USD 43,000 for counterfeit cigarettes. However, with the investment of USD 1,000 in counterfeit pharmaceuticals, a return of USD 500,000 can be expected. In fact, the INTERPOL evaluates the annual turnover from pharmaceutical crime at USD 75 million.¹² Secondly, counterfeiting in the pharmaceutical sector is attractive for the criminals, not only because of the relatively easy profits associated with counterfeiting but also due to the low probability of getting caught. Also, even if the counterfeiters are found, the penalty for counterfeiting of medicines is minimal as compared to other offences. In the EU, the average sentence for a pharmaceutical crime is less than three years in prison.¹³

Another significant reason to thoroughly deal with counterfeiting of medicines is the fact that, contrary to popular belief, it is not only lifestyle drugs, such as weight loss tablets, erectile dysfunction medication, or steroids for muscle enhancement, but also life-saving medicines that are targeted by counterfeiters. The lifesaving medicines, such as cancer treatment medications, diabetes medicines, as well as equipment, remain in demand for a longer period of time and are highly essential medicines, and, therefore, they always tend to be consumed.¹⁴

The rising numbers of counterfeit products in the pharmaceutical industry put the public health and safety at risk, as is evident from the rising number of counterfeit

¹² Office of Harmonisation in the Internal Market & Europol. (2015). Situation Report on Counterfeiting in the European Union – A joint project between Europol and the Office for Harmonization in the Internal Market. 11.

¹³ In Slovakia, the penalty is three years and in Poland the prison sentence for pharma crime is currently only two years, as reported in the Office of Harmonisation in the Internal Market & EUROPOL. See EUROPOL & OHIM. (2015). Situation Report on Counterfeiting in the European Union – A joint project between Europol and the Office for Harmonization in the Internal Market. 39.

¹⁴ *ibid.*, 13.

medicines all across the globe¹⁵ also reported by the INTERPOL in 2014,¹⁶ and the WHO in 2012.¹⁷ In 1985, the WHO recognised the public health issues connected with counterfeit medicines and by 2010, they had revealed that the global counterfeit market had a turnover of USD 75 billion.¹⁸ Recent estimates peg the global market share in counterfeit pharmaceuticals at USD 200 million, emphasising a 90% increase in the revenues since 2005.¹⁹ Moreover, in the EU, a recent study conducted on 5000 European citizens in five countries cast light on the fact that 5% of the consumers suspected that they had been at the receiving end of counterfeit prescription drugs, whereas 1% of the consumers were sure that they had actually received a counterfeit prescription medicine. This estimate implies that nearly 12.8 million consumers were at risk of consuming counterfeit medicines in these countries.²⁰

The issue of counterfeit medicine has been addressed in various fora. For instance, since the 1980s, a global congress on combatting counterfeiting and piracy was organised at the WHO²¹ by a public private partnership with representatives from the INTERPOL; World Customs Organisation (WCO); the World Intellectual Property Rights Organisation (WIPO); the International Chamber of Commerce/ Business Action to Stop Counterfeiting and Piracy (ICC /BASCAP Initiative); and the International Trademark Association (INTA).²² As will also become apparent

¹⁵ Blackstone, E. A., Fuhr Jr, J. P., & Pociask, S. (2014). The health and economic effects of counterfeit drugs. *American health & drug benefits*, 7(4).

¹⁶ INTERPOL (2014) Operation Pangea VII report, INTERPOL, Lyon.

¹⁷ World Health Organization (WHO) (2012) Substandard/spurious/falsely labelled/falsified/ counterfeit medical products: report of the working group of Member States. WHO. Geneva.

¹⁸ *ibid.*

¹⁹ IRACM (2013) Counterfeit medicines and criminal organizations, IRACM, Paris.

²⁰ Jackson, G., Patel, S., & Khan, S. (2012). Assessing the problem of counterfeit medications in the United Kingdom. *International journal of clinical practice*, 66(3), 241-250.

²¹ WHO. (2006). WHO launches task force to fight counterfeit drugs. *In Bulletin of the World Health Organization*, Volume 84, (9), September 2006. 685-764.

²² The Global Congress on Combating Counterfeiting and Piracy, where business leaders, law enforcement officers, inter-governmental authorities and non-governmental organisations were represented to discuss vital questions

from the subsequent chapters, efforts have been made at international, regional, and national levels to counter this problem. However, the efforts have not proven to be adequate.

In the EU, the regulation of pharmaceutical sector became stricter as an aftermath of the Thalidomide tragedy²³ when the potential harm from inadequately regulated medicinal products was revealed. Thalidomide was a drug that was marketed under the trade-name *Contergan* in West Germany in 1957 and thereafter, was also marketed in Austria. This drug was prescribed to pregnant women to alleviate morning sickness and resulted in around 7,000 infants being born with a malformation of the limbs (phocomelia).²⁴ Approximately 10,000 cases of infants born with phocomelia were reported around the world, and only 50% of these infants survived. Moreover, the surviving children lived with severe limb²⁵ and other organ defects.²⁶ This case led to stricter and more comprehensive regulation of medicines including over-the-counter (OTC) drugs. Consequently, in the 1960s and 1970s, safety and efficacy began to form the bedrock of authorisation criteria for medicines in Europe.²⁷ There was the introduction of stricter liability standards at the national level,²⁸ and also at the supranational level. At the EU level, Public Health Protection Guidelines were introduced in 1965 followed by 65/65/EEC rules regarding authorisation for drugs.²⁹ In 1995, an independent EU agency,

pertaining to counterfeiting, including the question about the evolving nature of counterfeiting and the impact on future of public health and safety.

²³ Dally, A. (1998). Thalidomide: was the tragedy preventable? *The Lancet*, 351(9110). 1197-1199.

²⁴ McBride, W. G. (1961). Thalidomide and congenital abnormalities. *The Lancet*, 278(7216), 1358.

²⁵ Annas, G. J., & Elias, S. (1999). Thalidomide and the Titanic: reconstructing the technology tragedies of the twentieth century. *American journal of public health*, 89(1), 98-101.

²⁶ Koren, G., Pastuszak, A., & Ito, S. (1998). Drugs in pregnancy. *New England Journal of Medicine*, 338(16), 1128-1137.

²⁷ Permanand, G. (2006). *EU pharmaceutical regulation: the politics of policy-making*. Manchester University Press.

²⁸ In the UK, The Medicines Act was introduced in 1968 and in West Germany, a new drug law was introduced in 1961.

²⁹ Council Directive, 65/65/EEC, of 26 January 1965 on the approximation of provisions laid down by law, regulation or administrative action relating to proprietary medicinal products. OJ L 178, 17.07.2000. 1-16.

European Medicines Agency (EMA) was established to oversee approvals of medicines and other related tasks.³⁰ According to the European Commission, the EMA's establishment was a significant part of the overall strategy for the creation of a Single Market for pharmaceuticals. It was anticipated that the EMA would facilitate free movement within the Single Market.³¹

However, despite being the most highly regulated sector at EU level, there is still no Single Market for pharmaceutical products in the EU, more than twenty years after the establishment of the EMA.³² This is due to the unique character of the pharmaceutical market and the nature of EU competences. Firstly, the pharmaceutical sector is atypical as compared to other sectors. This is because the patients are dependent on the doctors, as regards to prescription.³³ The patients cannot usually purchase a prescription medicine as only OTC medications are available to consumers without a prescription. Secondly, the State is the largest purchaser of medicines and besides Defence sector, no other sector is financed to such a great extent by public expenditure as the pharmaceuticals. The interest of the State also lies in the fact that public health and safety is a State responsibility. Therefore, the high level of regulation in the pharmaceutical sector is not unusual due to the public health and safety being at stake. Also, the State has a key involvement in healthcare budgets, as well as social security measures. Therefore, three different angles are in constant attrition - public health issues of drug quality, safety and efficacy; healthcare perspective pertaining to financing and reimbursement; and industrial policy such as ensuring successful, competitive and productive pharmaceutical sector.

³⁰ Inauguration of the European Agency for the evaluation of Medicinal Products. (January 1995). Press release, DN: IP/95/64, 26, Brussels: Commission of the European Communities. CEC (IP 1995).

³¹ *ibid.*

³² Permanand, G. (2006). *EU pharmaceutical regulation: the politics of policy-making*. Manchester University Press.

³³ *ibid.*

EU derives its healthcare mandate from Article 168 of the (Treaty on the Functioning of the European Union) TFEU,³⁴ which authorizes the EMA for deciding on the authorisation of new drugs. However, Article 168, TFEU also requires the EU to respect the responsibility of the Member States for the organisation and delivery of health services and medical care. The policy trade-off between community's legal and policy frameworks is obvious.³⁵ The friction between the principle of subsidiarity on the one hand, and free movement of goods, persons, services and capital of the Single Market, on the other, is evident. The principle of subsidiarity stipulates that the competence lies at the lowest level at which it can be effectively carried out.³⁶ This allows the Member States to determine the healthcare policy and the pharmaceutical policy. However, the free movement of goods, services, people and capital treats the pharmaceutical products as industrial goods and in this way, the pharmaceutical products fall under the competence of the EU governing the Single Market. Consequently, the responsibility of the pharmaceutical policy is divided between the EU and the individual Member States. Due to the principle of subsidiarity and EU's limited competence in this area, the harmonisation in the pharmaceutical sector has not been at the same rapid pace as in other sectors.³⁷

³⁴ Consolidated version of the Treaty on the European Union and the Treaty on the Functioning of the European (TFEU), Union O. J. 2012, C - 326/13.

³⁵ Permanand, G. (2006). *EU pharmaceutical regulation: the politics of policy-making*. Manchester University Press.

³⁶ See Articles 4(2)(k) and 6(2) of the TFEU.

³⁷ Permanand, G. (2006). *EU pharmaceutical regulation: the politics of policy-making*. Manchester University Press.

1.2. Intersection of laws

It is significant to indicate why the efforts made to fight against counterfeiting and falsifications of medicinal products seem to be inadequate and insufficient. The reasons that will be elaborated in the subsequent chapters, boil down to the fact that counterfeiting lies at the intersection of three different streams of law. Firstly, a large part of issues relating to counterfeiting of medicines concerns the Intellectual Property (IP) law area. For instance, a counterfeit or falsified medicine packaged in a manner aimed at imitating an authentic medicinal product would be counterfeit, as well as falsified, as provided for in the provisions of the Trademarks Directive (Directive 2015/2436/EU)³⁸ and the Falsified Medicines Directive (Directive 2011/62/EU).³⁹ Both the legal instruments concern the packaging of a product in addition to other provisions. Whereas the Falsified Medicines Directive concerns the packaging of a falsified medicinal product, the Trade Marks Directive relates to packaging of any product, which would also include medicinal products. Therefore, in the context of the counterfeiting and falsification of medicine, it is always more than an IP rights violation as the medicines sold in a false packaging are inevitably tampered with.⁴⁰ In August 2017, the Danish Medicines Agency reported a counterfeit product that was discovered in the legal supply chain, *Xeplion 150 mg*, which is primarily used to treat schizophrenia.⁴¹ This report illustrates how the provisions of Medicine law

³⁸ See Article 10 and 11 of the Directive (EU) 2015/2436 of the European Parliament and of the Council of 16 December 2015 to approximate the laws of the Member States relating to trade marks. OJ L 336, 23.12.2015, 1–2.

³⁹ See Article 1(1) (c), Directive, 2011/62/EU, of 8 June 2011 amending Directive 2001/83/EC on the Community code relating to medicinal products for human use, as regards the prevention of the entry into the legal supply chain of falsified medicinal products. OJ L 174, 1.7.2011, 74–87. Henceforth, referred to as, ‘Directive 2011/62/EU’.

⁴⁰ An example is that of Herceptin, a cancer treatment drug being manufactured by Roche, which was intercepted in Germany in false packaging. It was later found out that the drug was manufactured in Italy, and was stolen from an Italian hospital and was tampered with and re-introduced in the legal supply chain. (See Chapter 3, Section 3.2., Operation Volcano).

⁴¹ Danish Medicines Agency. (August 1, 2017). *Withdrawal of one more batch of counterfeit packs of the schizophrenia medicine Xeplion 150 mg*. Retrieved from

will usually find application besides IP law.

Thus, the second stream of law that deals with the problem of counterfeiting is Medicine law. In the EU, it is specifically the Falsified Medicines Directive that deals with the issues of falsified medicine. The Falsified Medicines Directive primarily addresses the Medicine law aspect and does not address the IP law related to counterfeiting. This is also clearly stated in the preamble to the Falsified Medicines Directive.⁴² The line of demarcation between the Medicine law perception of a counterfeit medicinal product and the IP law perception of a counterfeit product is marked from the very name of the directive, which uses the term ‘falsified’ rather than ‘counterfeit’. The choice of ‘term’ is like opening a Pandora’s Box and will be shortly addressed in Section 1.6.

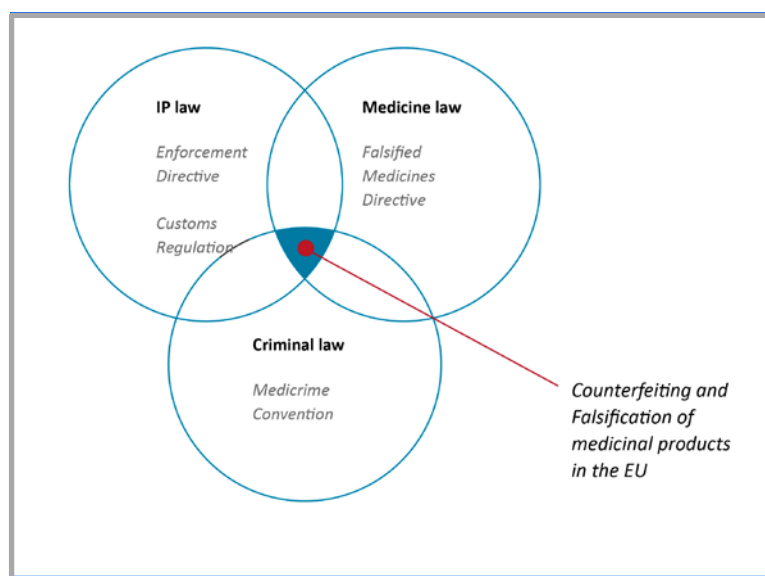


Figure 1

The third stream of law, besides IP and Medicine law that is related to counterfeiting and falsification is the Criminal law. The role of national and/or

<https://laegemiddelstyrelsen.dk/en/news/2017/withdrawal-of-one-more-batch-of-counterfeit-packs-of-the-schizophrenia-medicine-xeplion-150-mg/> last accessed 8 August 2017.

⁴² Recital 5, Directive 2011/62/EU.

transnational organised crime has been established in the counterfeiting of medicines⁴³ and the harmonisation of criminal measures for counterfeiting has been discussed at various fora in the EU as well as at international level. A directive on criminal measures aimed at ensuring the enforcement of intellectual property right (popularly known as (IPRED II)⁴⁴ was proposed in 2005, but was later withdrawn. Also, Anti-Counterfeiting Trade Agreement (ACTA)⁴⁵, which contained provisions of criminal measures against acts of counterfeiting, failed. In 2011, the Medicrime Convention was proposed by the Council of Europe and has been signed by many and ratified by at least four Member States by June 2017.⁴⁶ The Medicrime Convention's primary contribution is the criminalisation of the act of counterfeiting of medicines.⁴⁷ Therefore, it contains measures that should be adopted to criminalise the act of counterfeiting of medicines and other related crimes.⁴⁸

The intersection of the three different streams of law has proved to be problematic as the issue of counterfeit and falsified medicine is dealt with under different types of law, depending on where the problem is detected at first. If the medicines authorities detect the issue, the Medicines law is applied and if the customs authorities discover the problem, the IP law is activated. If the proprietor of a trade marks becomes acquainted with the violation first, then the proprietor would report the case to the police authorities and Criminal law may be applied.

⁴³ See Chapter 3, Section 3.5.2., for more details. *Also see* in Chapter 3, Section 3.2. Operation Volcano, the legitimate medicines were stolen from a truck supplying medicines to an Italian hospital by organized criminals, which were later tampered with and re-introduced in the legal supply chain. *See also* Chapter 3, Section 3.4. is Operation Robin, where the organized structure of the criminal network was discovered. Similar examples have been witnessed in the United States as well.

⁴⁴ Proposed Directive on criminal measures aimed at ensuring the enforcement of intellectual property rights (2005/0127/COD) was aimed at supplementing the Directive 2004/48/EC.

⁴⁵ Anti-counterfeiting Trade Agreement, 2011.

⁴⁶ The Medicrime Convention has been ratified by Albania, Armenia, Belgium, France, Hungary, Spain, Moldova, Ukraine from amongst the Members of the Council of Europe. (Status as of 14.7.2017).

⁴⁷ See discussion in Section 7.2.

⁴⁸ *ibid.*

Theoretically, it should not be difficult to earmark the areas that should be dealt with, under a particular type of law. However, in practice, it has been challenging because it is yet to be recognised that counterfeiting and falsification of medicines are two sides of the same coin. Any act of falsification of medicines essentially involves an act of counterfeiting, and hence, is a violation of IP laws, as well. Therefore, it is neither prudent nor expedient to divide the responsibilities of the authorities representing the different streams of law into mutually exclusive watertight compartments.

As a result of the fact that counterfeiting and falsification of medicinal products lies at the intersection of laws, and this context is not taken into consideration while dealing with the cases of counterfeiting and falsification of medicinal products, on the one hand, there is a risk that the right holders or the aggrieved patient's complaints fail to be addressed. On the other hand, the people engaging in counterfeiting and falsification of medicinal products are able to take advantage of the state of the legal framework in the EU.

This also creates practical institutional problems for the health regulators, customs authorities and enforcement officers as it leads to the cases vacillating between the different authorities, due to lack of clarity pertaining to what constitutes purely 'falsification' of a medicinal product and what entails 'counterfeiting' of a medicinal product. Therefore, the authority that would lead the investigation of a case is not always clear. For instance, in Operation Volcano,⁴⁹ the Italian Medicines Agency led the Operation whereas, in Sweden, in the case of Operation Robin,⁵⁰ it was the Swedish Customs and Law Enforcement Authority that steered the operation. This problem of lack of clarity regarding the institution responsible for dealing with the crime and other institutions' coordination does create

⁴⁹ See Chapter 3, Section 3.2.

⁵⁰ See Chapter 3, Section 3.4.

obstructions for an effective enforcement of the law concerning the counterfeit and falsified medicines.

1.3. Objectives of the thesis

In this thesis, a holistic picture of the problem concerning regulation of counterfeit and falsified medicinal products⁵¹ in the EU is presented. In the thesis, the legal framework dealing with counterfeit and falsified medicines is outlined in the beginning. This is followed by an illustration of the practical manner in which counterfeiting and falsification occurs in the pharmaceutical sector in the EU through three case studies. The relevant legal instruments are thereafter, analysed in the light of the case studies. Thereafter, the extent to which legal instruments are successful in meeting the social objectives of public health and consumer protection of the TFEU is assessed.

The thesis asserts that counterfeiting and falsification of medicines lie at the intersection of Medicine law, Intellectual Property law and Criminal law. In the EU, the falsification of medicinal products is governed by the Falsified Medicines Directive (Directive 2011/62/EU) and counterfeit medicinal products are dealt with under IP law (Directive 2004/48/EC and Regulation 608/2013). However, the Criminal law aspect is not harmonised in the EU as yet.

In the light of the above, the primary objectives of the thesis are:

⁵¹ A medicinal product is understood, as defined in Article 1 (2) of Directive 2001/83/EC, to mean any substance or combination of substances that have the properties for treatment or prevention of disease in human beings. The definition of a medicinal product also includes any substance or a combination thereof that may be employed in administering the substances with the goal of restoring, correcting, or modifying physiological functions.

1. To analyse how counterfeiting and falsification of medicinal products is addressed by the law (Directive 2011/62/EU, Directive 2004/48/EC, and Regulation 608/2013) in the EU (*de lege lata*).
2. To analyse whether the law containing tools to combat counterfeiting and falsification of medicinal products meets the social objectives of public health (Articles 9 and 168, TFEU) and consumer protection (Articles 12 and 169, TFEU) as envisaged by the Treaty on the Functioning of the European Union.

In the thesis, the measures against falsification and counterfeiting of medicines are identified in three different legal instruments in the EU - the Directive 2011/62/EU (Falsified Medicines Directive, henceforth, referred to as, ‘the FMD’),⁵² Directive 2004/48/EC (henceforth, referred to as, ‘the Enforcement Directive’)⁵³ and Regulation (EU) No. 608/2013 (henceforth, referred to as, ‘the Customs Regulation’).⁵⁴ The FMD addresses the regulation of health and medicinal law with respect to prevention of entry of falsified medicines in the EU. It makes a distinction between ‘counterfeit medicines’ and ‘falsified medicine’ and the focus is entirely on the ‘falsified medicines’. The FMD contains specific measures that aim at securing the legal supply chain in the pharmaceutical sector in the EU.

The Enforcement Directive and the Customs Regulation primarily address the aspects related to IP law. It also contains some important general anti-counterfeiting measures that find application in the pharmaceutical sector, especially when the violation is IP related, such as false packaging. In addition to the FMD and the Enforcement Directive, the Customs regulation also contains important anti-counterfeiting measures. The Customs Regulation is especially

⁵² Directive 2011/62/EU.

⁵³ Directive 2004/48/EC of the European Parliament and of the Council of 29 April 2004 on the enforcement of intellectual property rights OJ L 157, 30.4.2004.

⁵⁴ Regulation, 608/2013/EU, of 12 June 2013 concerning customs enforcement of intellectual property rights and repealing Council Regulation (EC) No 1383/2003. OJ L 181, 29.6.2013, 15–34.

activated when the counterfeit medicines or counterfeit APIs are imported from other countries.

The research objectives indicate that the focus of the thesis is exclusively in the context of the European Union. Contrary to the popular belief that counterfeit medicine is mostly associated with Asia and Africa, it is illustrated in this thesis that counterfeit and falsified medicine also prevail in the EU. In fact, counterfeit and falsified medicines are widespread in the EU, and EU citizens are just as vulnerable as citizens in other parts of the world. Therefore, counterfeiting and falsification in the pharmaceutical industry in the EU needs to be addressed. While it may be true that the Asian and the African continents are more vulnerable⁵⁵ to counterfeit and falsified medicines, the developed world – the US, the EU, and Australia are also susceptible. Many of the similar problems exist in the EU, though on a different scale. There are instances of the problem of sale of counterfeit medicine on the internet through parallel imports, illegal supply chain and infiltration of the legal supply chain also in the EU.

1.4. Perspective

The activity of falsification and counterfeiting of medicinal products has a far reaching impact. It affects the patients (access to safe, effective and good quality drugs), the pharmaceutical industry (manufacturing, research and development, innovation, etc.) and the State (public health and safety). The patients are directly

⁵⁵ From the perspective of developing countries, substandard medicine is better than no medicine. Due to poverty, there is demand for medicine in the black market. From the perspective of a poor person, it would make sense to get some medicine, which would be partly effective rather than have no access to medicine at all. Therefore, when there is more demand for medicines in the black market – it is extremely difficult to decipher whether the medicine that is being sold in the black market is substandard medicine; or illegal medicine by virtue of the illegal channel of sale, which has all the correct ingredients and is not typical counterfeit medicine; or adulterated medicine or ‘just falsely labelled’ medicine.

affected as they may become the victims of the falsification and counterfeiting of medicinal products. The patient community can stand to suffer direct loss, ranging from not being cured of the disease to building drug resistance to losing their life. The pharmaceutical industry also endures an economic loss because of falsification and counterfeiting of medicinal products especially the pharmaceutical companies that invest in innovation, Research & Development, run clinical trials, manufacture drugs and apply for authorisations and approvals.⁵⁶ The State also confronts challenges because of the falsification and counterfeiting of medicinal products, especially because the States have the responsibility of safeguarding public health and safety on the one hand, and need to assure safe, most cost effective medicines are delivered to the public, on the other hand. Therefore, each of these interest groups is affected by the falsification and counterfeiting of medicinal products and have a vested interest. Essentially, the patients would like safe and cost effective medicines to be available, while the pharmaceutical industry lobbies for a competitive business environment, with enough safeguards against counterfeit products that are a threat to their reputation and goodwill. The State needs to prioritise protection of public health and safety,⁵⁷ as well as ensure maintenance of affordable prices of the medicines for the common public.

The perspective of each of the stakeholder group – patients, the pharmaceutical industry and the State– is significant. However, this is a legal thesis and the focus is on the legal instruments that are employed to combat the falsification and counterfeiting of medicinal products at the EU level. Therefore, the perspective of the concern of the State as regards maintenance of public health and safety is predominant in the thesis. The legal instruments, specifically, the FMD (Directive

⁵⁶ Permanand, G. (2006). *EU pharmaceutical regulation the politics of policy-making*. Manchester University Press.

⁵⁷ See Article 168, TFEU.

2011/62/EU), the Enforcement Directive (Directive 2004/48/EC) and the Customs Regulation (Regulation 608/2013) are analysed, which contain measures that provide tools to combat falsified and counterfeit medicines in the EU.

1.5. Delimitation

Counterfeiting and falsification in the pharmaceutical sector is a worldwide problem. However, this thesis concentrates on counterfeiting and falsification in the pharmaceutical sector in the EU. It needs to be recognised that falsification and counterfeiting of medicinal products has been accorded serious attention by law makers only in the past two decades in the EU. Therefore, the case law and scholarly works available on this subject are limited.

An important element about counterfeiting, in general that also applies to counterfeiting in the pharmaceutical sector is the fact that counterfeiting is an illegal activity by nature. Therefore, it is difficult to accurately account for, for an activity, which is primarily conducted in the dark. Any statistics and figures that represent counterfeiting or falsification of medicinal products are, therefore, not exact. At best, these statistics can provide a rough estimate, and in all likelihood, the reality is larger and greater than what is visible in the statistics. Therefore, even though all the figures and statistics are gathered from reputable sources like the OECD; WHO; INTERPOL; and Europol, these must be used only as indicators.

It is also important to specify that while exploring IP law, the focus is not on substantive law. Therefore the detailed provisions of, for instance, trade mark law, will not be addressed. An overview of the enforcement of IP law in the EU, particularly with respect to enforcement of trademarks, which is directly relevant to counterfeiting of medicines, will be explored.

As will become apparent, the act of counterfeiting and falsification of medicinal products is generally accompanied by associated crimes like money laundering, smuggling, theft, forgery of documents, fraud and IP violations.⁵⁸ Even though the exploration of these associated crimes is relevant and important, in this thesis, the focus remains exclusively on the crime of counterfeiting and falsification of medicinal products. The accompanying crimes are mentioned but not explored further.

It is also acknowledged that the thesis would have benefitted with a comparative analysis with another country, such as the US. However, a comparative analysis was not done as an in-depth analysis would also require an in-depth discussion on the legal framework existing in the US and the analysis of cases from that jurisdiction. Even though a few references have been made at relevant points, a thorough analysis has not been undertaken.

Another important aspect that may have contributed would have been a discussion on the role of the private sector and other stakeholders in the fight against counterfeiting. However, other stakeholders' role has been left out on purpose as the focus is primarily on the legal framework. It is recognised that in order to effectively control the problem of counterfeiting in the pharmaceutical sector, all stakeholders need to make a collective effort. There are instances where collective action against counterfeiting of medicine has been fruitful, such as Operation Pangea,⁵⁹ wherein an annual initiative is taken by INTERPOL in collaboration with customs authorities, health regulators, and national police and private sector organisations of the countries involved. It is conducted for one week's duration every year, when all the countries that participate in the operation conduct raids on

⁵⁸ See Section 3.3 and 3.4, Operation Singapore and Operation Robin for more details.

⁵⁹ INTERPOL. (2017). INTERPOL Operation Pangea Factsheet on Illicit goods and global health. COM/FS/2017-03/GHS-01.

online sellers of counterfeit medicines.⁶⁰ The stakeholders include not only the manufacturers of pharmaceutical products, but also innovators, patients, and consumers, in addition to many others. However, the primary focus in the thesis is on the legal framework dealing with falsification and counterfeiting in the pharmaceutical sector in the EU, and the private stakeholder initiatives are not addressed.

In any discussion on counterfeiting in any sector, besides the legal framework, the policy and political discussions are equally vital. As this is a legal thesis, the political discussions have been left out of the scope of the thesis, even though, wherever it was deemed vital for the thesis, references have been made to policy issues, but are not discussed further.

1.6. Terminology

While considering counterfeiting in the pharmaceutical sector, a number of terms are employed in the academic literature. The most frequently used terms are ‘counterfeit’⁶¹ ‘falsified’,⁶² ‘falsely labelled’,⁶³ ‘substandard’,⁶⁴ ‘spurious’⁶⁵,

⁶⁰ Nine such operations have been conducted under the leadership of INTERPOL, so far. In addition to Operation Pangea, the INTERPOL also led the Operation Storm (Southeast Asia) and Operation Mamba (Eastern Africa) which aim to sell not only on illicit websites but also physical outlets, in order to disrupt transnational criminal networks involved in pharmaceutical crime. These operations underline the success of multidisciplinary enforcement action. See more at Operation Pangea, INTERPOL Factsheet on Illicit goods and global health. See COM/FS/2017-03/GHS-01.

⁶¹ TRIPS: Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 1869 U.N.T.S. 299, 33 I.L.M. 1197 (1994) [hereinafter TRIPS Agreement]. Footnote 14 to Article 51; See Council of Europe. (2011). Council of Europe convention on counterfeiting of medical products and similar crimes involving threats to public health. Strasbourg. Council of Europe. (Also known as the Medicrime Convention). Council of Europe Treaty Series. No.211. Henceforth, referred to as ‘the Medicrime Convention, 2011’; See also Definition of a counterfeit drug, US Food, Drug and Cosmetic Act, 21 U.S.C. 321 Section 201 (g) (2).

⁶² Article 1 (1) (c), Directive 2011/62/EU.

⁶³ WHO. (2012). Substandard/spurious/falsely labelled/falsified/counterfeit medical products: report of the working group of member states. WHO, Geneva.

⁶⁴ *ibid.*

⁶⁵ *ibid.*

‘fake’⁶⁶, ‘adulterated’⁶⁷, ‘illicit’ and ‘illegal’. It is important to clarify the meaning and scope of the different terms in order to address the problem of counterfeiting and falsification in the pharmaceutical sector in the EU. Therefore, the different terms utilised are discussed in this section.

The term ‘counterfeit’ in general, has been used for the goods that use an identical or confusingly similar trademark, without authorisation, either on the goods or on the packaging of goods, in a manner that rights of an authorised right holder are violated.⁶⁸ This definition extends to all types of goods, including pharmaceutical products. This general understanding of the term distilled into the EU legal instruments from the TRIPS Agreement.⁶⁹ It is evident in the application of the Enforcement Directive, Directive 2004/48/EC,⁷⁰ as well as the Customs Regulation, Regulation 608/2013.⁷¹ However, specifically, ‘counterfeit medicine’ is not defined in the EU legal instruments, except for in the Preamble to the Falsified Medicines Directive and Directive 2011/62/EU, which states that counterfeit medicines are construed to be the medicines that are in violation of IP laws.⁷² The Medicrime Convention, which has been signed and ratified by a few Member States of the EU, has defined counterfeit medicine as a “...*medicinal product with a false representation regarding identity and/or source*”.⁷³ This

⁶⁶ Isles, M. (2017). What’s in a word? Falsified/counterfeit/fake medicines—the definitions debate; *Also see* used by EMA, in public communications, for instance, European Commission. (2015). ‘*Buying Medicines Online, Think you know what you are getting?*’ Brussels. European Commission.

⁶⁷ Wertheimer, A. I., & Wang, P. G. (2012). *Counterfeit medicines volume I: Policy, economics and countermeasures*. ILM Publications. 114.

⁶⁸ TRIPS Agreement. Footnote 14 to Article 51.

⁶⁹ *ibid.*

⁷⁰ Directive 2004/48/EC of the European Parliament and of the Council of 29 April 2004 on the enforcement of intellectual property rights.

⁷¹ Regulation, 608/2013/EU, of 12 June 2013 concerning customs enforcement of intellectual property rights and repealing Council Regulation (EC) No 1383/2003. OJ L 181, 29.6.2013, 15–34.

⁷² Recitals 5 and 29, Directive 2011/62/EU of the European Parliament and of the Council of 8 June 2011 amending Directive 2001/83/EC on the Community code relating to medicinal products for human use, as regards the prevention of the entry into the legal supply chain of falsified medicinal products. Henceforth referred to as ‘Directive 2011/62/EU’.

⁷³ Article 4 (j), The Medicrime Convention, 2011.

definition put forth by the Medicrime Convention is extremely close to the definition of a falsified medicinal product according to the Falsified Medicines Directive.⁷⁴

From the aforementioned, it can be deduced that usually the term counterfeiting is used in the context of IP Law, as reflected in the Enforcement Directive⁷⁵ and the Customs Regulation⁷⁶ in the EU. However, at times, counterfeit can also be employed in the context of medicines with a false representation regarding identity and/or source, as indicated in the Medicrime Convention.⁷⁷ The understanding of counterfeit and falsified medicines gets complicated as the WHO continued to employ the term SSFFC (spurious, falsely labelled, falsified, and counterfeit)⁷⁸ until May 2017. In addition to ‘counterfeit’ and ‘falsified’, ‘spurious’ and ‘falsely labelled’ were introduced in the academic literature by this definition put forward by the WHO. However, in the latest policy document, distinctions have been made between substandard, unregistered/unlicensed, and falsified medicinal products. The move to do away with SSFFC definition and use only substandard and falsified as the terms of reference have been approved by the World Health Assembly in May 2017.⁷⁹ While spurious, falsely labelled and falsified medicines can be encompassed under the umbrella of falsified medicines and be addressed by Medicines Law, ‘counterfeit medicines’ will usually fall under the umbrella of IP law, have been left out of the scope by the WHO, since the WHO only looks at the public health implications of medicinal products.

⁷⁴ Article 1 (1) (c), Directive 2011/62/EU.

⁷⁵ Directive 2004/48/EC.

⁷⁶ Regulation 608/2013.

⁷⁷ Article 4 (j), The Medicrime Convention, 2011.

⁷⁸ WHO. (2012). Substandard/spurious/falsely labelled/falsified/counterfeit medical products: report of the working group of Member States. WHO, Geneva.

⁷⁹ WHO. (2012). Appendix 3, WHO Member State Mechanism on substandard/ spurious/ falsely labelled/ counterfeit (SSFFC) medical products working definitions. WHO. Geneva.

Besides the WHO (until May 2017), the Medicrime Convention, there are other international organisations that use the term ‘counterfeit medicine’ for what is known as ‘falsified medicine’ in the EU, such as the IRACM.⁸⁰ Even the pharmaceutical companies prefer the general term ‘counterfeit medicine’.⁸¹ In addition, many other countries also still use the term ‘counterfeit medicine’, which the EU now calls ‘falsified medicines’. For instance, the US Food and Drug Administration (FDA) uses the term ‘counterfeit medicine’ and not ‘falsified’ medicine. In fact, counterfeit medicine is defined as a fake medicine, which may be contaminated or contain the wrong dosage, and could be illegal.⁸² The term ‘fake’ medicine is also used in the awareness raising campaigns conducted in the EU. The European Commission produced awareness raising material⁸³ regarding the new EU logo that is required to be affixed by all legitimate websites offering medicines for sale over the internet in the EU. Herein, the terms that are used include ‘fake medicine’, ‘false medicine’, and illegal medicine’.⁸⁴ The term ‘fake’ medicine is used by the US FDA to refer to ‘counterfeit’ medicines and in the EU, the term fake medicine is used to denote ‘false medicine’ that does not contain the active ingredient that is required in the medicinal product; or may contain harmful or fatal substances.⁸⁵ Thus, the confusion regarding the most appropriate term continues amongst the regulatory authorities, where a counterfeit medicine can be understood as fake medicine or falsified medicine.

⁸⁰ IRACM. (2013). Counterfeit medicines and criminal organisations, IRACM, PARIS.

⁸¹ See Sanofi. (May 2017). The fight against counterfeit medicines. Press Book. Sanofi; See also Roche. (April 2011, reviewed April 2017). Position paper – Roche position on counterfeiting. 1-7.

⁸² U.S. Food & Drug Administration. (2016). *Counterfeit Medicine*, US Food & Drug Administration. Silver Spring. Human Drug Information.

⁸³ European Commission. (2015). ‘*Buying Medicines Online, Think you know what you are getting?*’ Brussels. European Commission.

⁸⁴ *ibid.*

⁸⁵ *ibid.*

In addition to the above, term ‘substandard’ medicine is also used in academic literature,⁸⁶ and also by the WHO.⁸⁷ A substandard medicine, also known as ‘out of specification’ (OOS) products, is perceived to be the medicine, which is an original product manufactured by an authorised manufacturer but may not live up to the requirements of the National Medicines Regulatory Authority. A substandard drug is no less dangerous than a falsified medicine.⁸⁸ Another term that is frequently used in academic literature and is sometimes confused with counterfeit/falsified medicines is ‘adulterated’ medicines. An adulterated medicine is the one wherein the composition of the medicine is altered by the deliberate addition of a component that is not ordinarily a part of that substance, which usually leads to the debasement of that substance.⁸⁹

There are two umbrella terms that are also commonly used in the context of counterfeit and falsified medicines, which are ‘illicit medicines’ and ‘illegal medicines’. Usually, these medicines may or may not be medicines that are authentic but appear in the illegal supply chain. In other words, illegal and illicit⁹⁰ medicines refer more to the channel of trade rather than the quality of the medicinal product in question. However, these medicines can also be counterfeit and falsified. For instance, in the EU illegal medicine has been referred to as either counterfeit or fake medicine.⁹¹

⁸⁶ Attaran, A., Barry, D., Basheer, S., Bate, R., Benton, D., Chauvin, J., & Newton, P. N. (2012). How to achieve international action on falsified and substandard medicines. *BMJ*, 345, e7381.

⁸⁷ WHO. (2012). Appendix 3, WHO Member State Mechanism on substandard/ spurious/ falsely labelled/ counterfeit (SSFFC) medical products working definitions. WHO. Geneva.

⁸⁸ Johnston, A., & Holt, D. W. (2014). Substandard drugs: a potential crisis for public health. *British Journal of Clinical Pharmacology*, 78(2), 218–243.

⁸⁹ Miller-Keane. (2009). *Encyclopedia and Dictionary of Medicine, Nursing, and Allied Health*, Seventh Revised Edition. London. Elsevier Health Science. Inc.

⁹⁰ UNDOC. (2016). *Terminology and Information on Drugs*, 3rd ed., Vienna. UNODC.

⁹¹ European Commission. (2015). ‘*Buying Medicines Online, Think you know what you are getting?*’ Brussels. European Commission.

It is vital to indicate that authentic and original medicines can be found in the illegal supply chain. The reason for their appearance in the illegal supply chain is usually linked to lack of required authorisations and approvals because of the non-fulfilment of requirements of the National Competent Authorities (NCA) provisions. Therefore, it will be incorrect to state that all illegal and illicit medicines are counterfeit medicines. Likewise, it needs to be reiterated that substandard drugs are not counterfeit drugs. They are authentic drugs, manufactured by authorised market authorisation holders. They are considered substandard because they do not meet the requirements of the NCAs.

It is apparent from the foregoing discussion that clarification of the terminology that is used in the context of counterfeit and falsified medicines is significant. At the EU level, there is an apparent agreement that the IP law perspective of counterfeiting revolves around the enforcement of the private rights of the right holders of a trademark. In other words, the term counterfeiting indicates only IP violations and infringements,⁹² and the public health and safety aspect is not dealt with. For instance, as regards to the definition of ‘counterfeit goods’ in the Customs Regulation (Regulation 608/2013),⁹³ the focus is on infringement of trademarks.

On the other hand, whenever the term ‘falsified medicine’ is employed, the health and medicine law perspective comes into play, whereby the public law perspective of safeguarding public health and safety being the primary goal takes the centre stage. The Falsified Medicines Directive defines a falsified medicine and focuses on the identity, sources and history of the medicinal product. The Falsified

⁹² As used in, for instance, Article 2(5), Regulation 608/2013; *See also* Recital 5 of Directive 2011/62/EU.

⁹³ Article 2 (5) Regulation 608/2013.

Medicines Directive clearly leaves out the IP law related aspects,⁹⁴ because it differentiates between counterfeit medicine and falsified medicine.⁹⁵

When law and policy documents and academic literature use the terminology interchangeably, not only does it lead to confusion, but it also has bearing on how the authorities interpret a particular offence. The interpretation of the offence would subsequently determine the applicable law. Whether it would be IP law or Medicine law would depend upon the type of violation involved. For instance, if fake packaging material is intercepted – it is an IP infringement as it is a violation of the right holder's right with respect to trademarks rights.⁹⁶ However, the crucial link between IP violation and Medicines law violation is that a trademark violation, which is of the nature of the false packaging, is also a violation of the Falsified Medicines Directive, Article 1(1) (c).⁹⁷ In this way, an IP violation related to pharmaceuticals is closely linked to Medicines law violation.

For the purposes of this thesis, the terms falsified medicine will be used in the context of Falsified Medicines Directive and the term counterfeit medicine will be used in the context of the Enforcement Directive and Customs Regulation, as determined by the respective legal instruments.

1.7. Structure of the thesis

In the light of the legal case studies, the legal instruments providing tools to combat counterfeiting and falsification of medicines in the EU are analysed. This is followed by a chapter on global initiatives for the purpose of assessing the

⁹⁴ See Article 1(1) (c) Directive 2011/62/EU.

⁹⁵ Recital 5, preamble of Directive 2011/62/EU.

⁹⁶ See Articles 10 and 11, Directive (EU) 2015/2436.

⁹⁷ See Article 1(1) (c), Directive 2011/62/EU.

measures being undertaken at the international level. Thereafter, it is analysed whether the law governing counterfeiting and falsification of medicinal products meets the social objectives of public health and consumer protection as envisaged by the TFEU.

To summarise (also see *Figure 2*), the thesis will be presented in the following manner:

Part I (Introduction)

Part I presents the relevance of the thesis, states the parameters and establishes that the thesis stands at the intersection of the IP law, Medicine law and Criminal law. The objectives of the thesis are presented and analysed to highlight the focus of the thesis. It also explains the philosophy of law that is used in the thesis – legal positivism. In consonance with the philosophy of law, the methods – legal dogmatic method and case studies method, used in the thesis are discussed. Thereafter, the relevant primary sources of law – the TEU, the TFEU and, the CFREU, and the secondary sources of law - Falsified Medicines Directive (Directive 2011/62/EU), Enforcement Directive (Directive 2004/48/EC) and Customs Regulation (Regulation 608/2013), are discussed with regard to their relevance, scope and application in context of the thesis.

Part II (Legal case studies)

Part II of the thesis illustrates the problem of counterfeiting and falsification of medicinal products. By setting the context and providing an insight into the real life examples through case law, the gaps in the legal framework dealing with counterfeiting in the EU emerge to the surface. Three operations are discussed in this regard – Operation Robin, Operation Singapore, and Operation Volcano.

These three operations highlight the problems associated with overlapping and intersection of IP law and Medicine law along with the lack of criminal sanctions and penalties. The common issues of concern are identified in Part II, such as the inability to keep the legal supply clear of infiltration by the illegal supply chain and insufficient control over the online sale of counterfeit medicine.

Part III (Legal analysis)

Part III of the thesis is divided into four chapters. In chapters 4, 5 and 6, the analysis of the legal instruments is conducted in the light of the issues identified in Chapter 3. In Chapter 4, an analysis of the Falsified Medicines Directive is conducted with focus on the legal supply chain, the online sale of medicines and the safety of the medicinal product. In Chapter 5, the Enforcement Directive is analysed with special focus on the provisions for enforcement of IP as well as those issues that have not been addressed. The Customs Regulation is analysed in Chapter 6, wherein the analysis of Customs Regulation is carried out with special reference to measures that may be taken by the authorities at the borders to prevent entry of counterfeit and falsified medicines. A chapter on global initiatives forms the last chapter of Part III that analyses how the problem of counterfeiting and falsification of medicinal products has been and is being tackled at the international level, with a focus on the Medicrime Convention, ACTA, and multilateral and bilateral agreements such as TPP, TTIP, RCEP.

Part IV (Evaluation & Conclusion)

Part IV of the thesis is divided into two chapters. In Chapter 8, it is analysed whether the law (Directive 2011/62/EU, Directive 2004/48/EC, and Regulation 608/2013) providing tools to combat counterfeiting and falsification of medicinal

products in the EU meets the social objectives of public health (Article 9 and 168, TFEU) and consumer protection (Article 12 and 169, TFEU), as envisaged by the TFEU. This is followed by Chapter 9 that presents the summary and conclusion of the thesis.

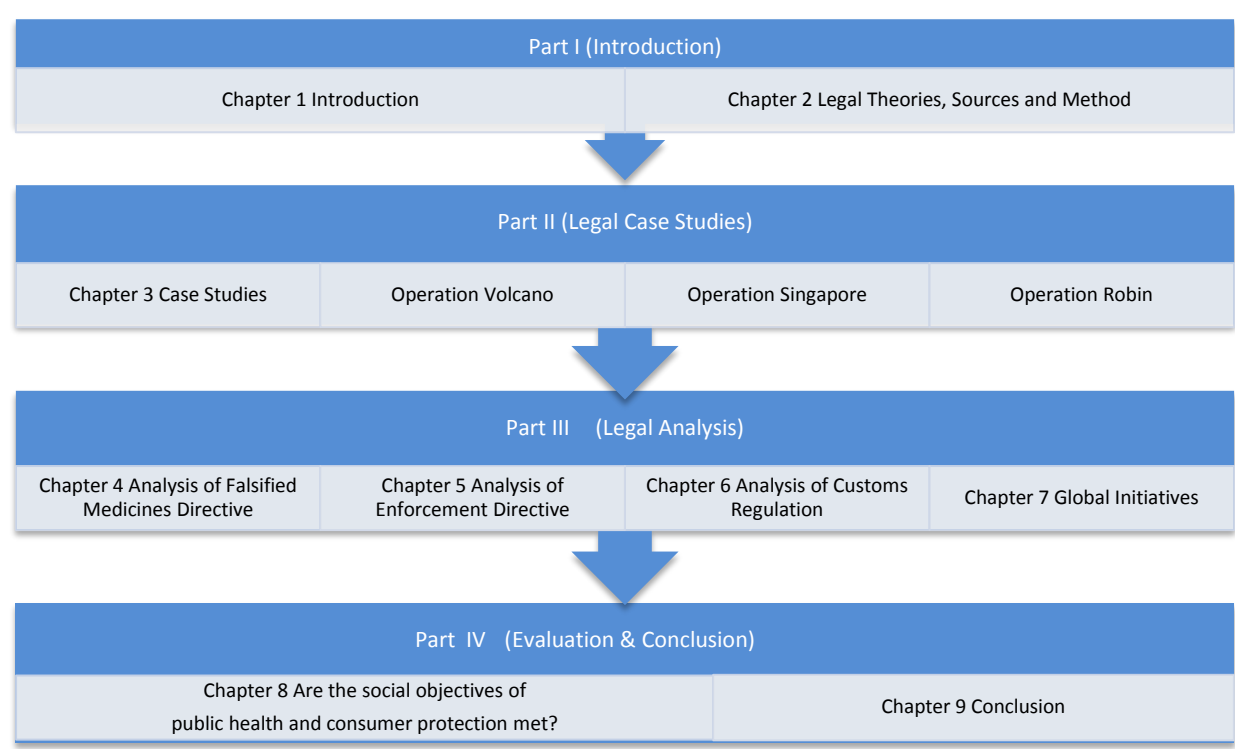


Figure 2

Chapter 2: Legal Theory, Sources and Method

2.1. Introduction

This chapter explains the philosophy of law, which is employed, the legal method that is used and the sources of law consulted in order to deal with the primary issues raised in the thesis. The main objectives of the thesis are to analyse how counterfeiting and falsification of medicinal products are addressed by the law (Directive 2011/62/EU, Directive 2004/48/EC, and Regulation 608/2013) in the EU - *de lege lata*- and to analyse whether the law that provides tools to combat counterfeiting and falsification of medicinal products in the EU meets the social objectives of public health (Article 9 and 168) and consumer protection (Article 12 and 169) of the Treaty on the Functioning of the European Union (TFEU).

Essentially, the purpose of explaining the theoretical and methodological approach used in the thesis is to explain the scientific method used to arrive at the criteria for determining the valid law, and the interpretation of sources of law employed in

this thesis.⁹⁸ An analysis of the black letter law is conducted and how the law ‘is’ (*de lege lata*), is analysed as regards to measures dealing with counterfeiting and falsification of medicinal products in the EU. Thereafter, it is analysed if the law meets the social objectives of public health and consumer protection in the EU.

2.2 Legal Theory - Legal Positivism and EU law

A legal theory provides the philosophical basis and sets the relevant parameters for a body of academic work. In the EU, there are two main prevailing of legal theories that are employed – the theory of legal positivism and the theory of legal realism.⁹⁹ The theory of legal realism believes the valid law to be the rule of courts or the State apparatus in general who establish the legal norm. Legal positivist such as Hans Kelsen, H.L.A. Hart and Tuori, believe in the importance of measuring each legal instrument against a higher norm. This is contrary to the legal realists, like Ross,¹⁰⁰ who directly look at the legal instrument and not beyond. The legal positivists believe in man-made laws and a higher norm that grants legitimacy to the lower norms.

In the EU, the theory of legal positivism and the theory legal realism are the most commonly applied theories. In the context of this thesis, EU law is the focus of analysis, wherein three legal instruments belonging to the body of secondary legislation will be measured against ‘higher norms’ of public health and consumer protection, identified in the TFEU, which is the part of primary legislation.

⁹⁸ Nielsen, R. New European Legal Realism – New Problems, New Solutions? in Neergaard, U., & Nielsen, R. (Eds.). (2013). *European Legal Method - towards a new European Legal Realism?* Copenhagen. Jurist-og Økonomforbundets Forlag. 78-79.

⁹⁹ Nielsen, R. New European Legal Realism – New Problems, New Solutions? In Neergaard, U., & Nielsen, R. (Eds.). (2013). *European Legal Method - towards a new European Legal Realism?* Jurist-og Økonomforbundets Forlag. 75.

¹⁰⁰ Ross, A. (1959). *On law and justice*. Berkeley. University of California Press.

Therefore, the theory of legal realism is inapplicable because it does not believe in the existence of a norm higher than the legal instrument in question.

In this thesis, the guiding philosophy is that of legal positivism as the higher norm is perceived to be residing in the EU Treaties. The higher norm being that of public health and consumer protection as envisaged in the TFEU. In that light, the legal instruments are analysed at first and subsequently, they are assessed against the higher norm identified in the TFEU. In this thesis, EU law is the unit of analysis and in the EU, the valid law is recognised law as articulated in the primary and secondary legislations. In the EU, the secondary legislation does not exist independently of the primary legislation. It is provided by law that the secondary legislation has to take cognisance of the primary legislation. In other words, the EU treaties house the higher norms. The theory of legal realism does not accord importance to a 'highest norm' over and above the legal instrument in consideration, as in legal positivism. It is important to clarify that in this thesis, legal cases are used in Chapter 3 as illustrations and for setting the context of the problem of counterfeiting and falsification of medicines, and not as 'higher norms'. Therefore, the most suitable theory for this thesis is the theory of legal positivism.

This is because legal positivism primarily focuses on 'how the law is'. The legal positivists believed that 'law is law' and it should be upheld. The law is not interdependent on contemporary morals, ethics or religion.¹⁰¹ Therefore, a positive law can be unfair or unreasonable.¹⁰² The thesis is concerned with the analysis of the legal instruments (Directive 2011/62/EU, Directive 2004/48/EC, and

¹⁰¹ As perceived in the theory Natural Law, Jens Evald og Sten Schaumburg-Müller, *Retsfilosofi, retsvidenskab og retskildere*, Kbhvn. 9. In Tvarnø, C.D. & Nielsen, R. (2014). *Retskilder & Retsteorier*. 4. Reviderede udgave. Jurist- og Økonomforbundets Forlag. 389.

¹⁰² Tvarnø, C. D., Nielsen, R.. (2014) *Retskilder & Retsteorier*. 4. Reviderede Udgave, Kbhvn Jurist- og Økonomforbundets Forlag. 390.

Regulation 608/2013) that contain provisions, which are used to combat counterfeiting and falsification of medicines in the EU. The legal analysis of ‘how the law is’, being guided by the philosophy of legal positivism is the core of the legal analysis of the thesis, discussed in Chapters 4, 5, 6 and 7.

This school of thought has a long history that can be traced back to the nineteenth century to thinkers like Jeremy Bentham (1784-1832) and John Austin (1790-1869).¹⁰³ Hans Kelsen and H.L.A. Hart¹⁰⁴ were the most well-known figures in the 20th century and are the pillars of classical legal positivism. Kelsen was a monoist and believed that a *legal order* can be defined as a plurality of general and individual norms, which would constitute a unity if all those norms conformed to a single basis of validity.¹⁰⁵ Regarding the validity of norms, Kelsen claimed that a high norm served as a basis of validity for a lower norm. Kelsen believed that all law can be traced back to a basic norm, i.e. a constitution in a nation state. Moreover, all legal norms needed to be in tune with the basic norm and if it were so, it would be a valid law. This belief fits well with the way EU law is interpreted, as is the case in this thesis, where three EU legal instruments are analysed. In this thesis, Kelsens’ brand of legal positivism is utilised, where the valid law is recognised as the law made by a recognised law making the body and can be traced back to one basic norm.

Kelsens’ norm approach has been further developed in the 21st century by Tuori, who has developed legal positivism into critical legal positivism,¹⁰⁶ wherein law is seen as having two sides. On the one hand, the law is considered as a *legal order*,

¹⁰³ Nielsen, R. New European Legal Realism – New Problems, New Solutions? in Neergaard, U., & Nielsen, R. (Eds.). (2013). *European Legal Method - towards a new European Legal Realism?* Jurist-og Økonomforbundets Forlag. 81.

¹⁰⁴ Hart, H. L. (1994). *The Concept of Law* (with a postscript). Oxford, 21994, 238-276.

¹⁰⁵ Kelsen, H., Paulson, B. L., & Paulson, S. L. (1992). *Introduction to the problems of legal theory*. Oxford: Clarendon Press. 37.

¹⁰⁶ Kaarlo, T. (2002). *Critical legal positivism*. London, Routledge.; Tuori, K. (2016). *Ratio and voluntas: the tension between reason and will in law*. London. Routledge.

a symbolic normative being, comprising a set of norms and on the other hand, it is seen as a *legal practice*, consisting of a set of social practices. These two phenomena of law continuously interplay.¹⁰⁷ In critical legal positivism, it is believed that law is composed of three levels¹⁰⁸ – the surface level of law, the legal culture and the deep structure of law.¹⁰⁹ Moreover, the surface level is claimed to be in a perpetual state of flux,¹¹⁰ as a consequence of new regulations and new court decisions, as well as new articles and books by legal scholars. Therefore, on the surface, the changes are apparent and occur most frequently, but the legal culture takes more time to change while the deep structures of the law take the longest to transform and are the most stable part of the edifice of law.¹¹¹

Kaarlo Tuori maintained that the EU's legal order was primarily concerned with laws and individual decision at the surface level. He accepted that fundamental rights, democracy and the rule of law could ultimately constitute a Union-wide deep structure but claimed that a legal structure and deep culture had not yet developed. This view was later challenged and explained in the joined cases C – 402/05 and C – 415/05 Yassin Abdullah Kadi and others v Council.¹¹² It was stated that Tuori's layered model is not incompatible with pluralist perceptions of European law, where on the one hand the EU Treaties and law influence domestic law and vice versa. There is a shared common deep-rooted understanding of fundamental rights, rule of law and other such values that serve as a reference point for the entire community.

¹⁰⁷ *ibid.*

¹⁰⁸ See more in Tvarnø & Nielsen. (Forthcoming 2017). *Retskilder & Retsteorier*. Kbhvn Jurist- og Økonomforbundets Forlag. 22.

¹⁰⁹ See Kaarlo, T. (2002). *Critical legal positivism*. London, Routledge.

¹¹⁰ Neergaard, U., Nielsen, R., & Roseberry, L. (2011). *European Legal Method-Paradoxes and Revitalisation*. Djøf/Jurist-og Økonomforbundet. 101.

¹¹¹ Kaarlo, T. (2002). *Critical legal positivism*. London, Routledge. 191-192 and 316-317.

¹¹² More in Case C – 465/07 Elgafaji v Staatssecretaris van Justitie; and Gráinne de Búrca. *The Evolution of EU Human Rights Law*. In Paul Craig and Gráinne de Búrca (Eds.). *The Evolution of EU Law*. (2011). 488-489.

In the thesis, the issue of counterfeiting and falsification of medicines has led to changes in laws occurring rapidly over the past seven years, especially in the field of Medicine law, wherein a new directive, several implementing regulations and guidelines giving effect to the directive have emerged.¹¹³ Consequently, the guiding theory of critical legal positivism, providing the parameters to explore (using the legal dogmatic method, discussed in Section 2.4.1.) the legal framework containing tools to combat counterfeiting and falsification of medicines in the EU, would be the most compatible choice for the thesis.

2.3. Sources of Law

2.3.1. Introduction

The purpose of this section is to introduce the sources of law that have been utilised in this thesis. As established in Section 2.1, the valid law is identified according to the legal positivist approach to law. Hence, valid sources of law are the laws that have been adopted by a recognised law-making body, whether national, regional or international. As primarily EU sources of law are used in this thesis, the focus of this section will be on the EU sources. It must be stated at the outset that in the thesis, legal instruments from different streams of law are discussed. For instance, the legal instruments belong to the realm of Medicine law (Directive 2011/62/EU) and IP law (Directive 2004/48/EC and Regulation 608/2013). One of the challenges of attempting an analysis addressing different fields of law is that the goals of each stream are essentially different. While the

¹¹³ See Commission Delegated regulation (EU) 2016/161 of 2 October 2015; Commission Implementing Regulation (EU) No. 699/2014 of 24 June 2014. See more in *Table 1* in Chapter 4, which lists out in detail.

sphere of Medicine law falls within the scope of the public law, the legal instruments protecting IP law enforce private rights. This basic difference between the legal instruments added to the complexity of the analysis.

The genesis of EU lies against the backdrop of World War II and is based on international treaties entered by its Member States. Initially, the European Coal and Steel Community (ECSC)¹¹⁴ was formed in 1951. Thereafter, the Treaty of Rome (1957) led to the formation of the European Economic Community (EEC).¹¹⁵ The next big step towards the formation of the EU in its current form was the Treaty on the European Union at Maastricht¹¹⁶ in 1992, followed by the Reform Treaty of Lisbon that re-named the EC Treaty to the Treaty on the Functioning of the European Union¹¹⁷ (TFEU) in 2007, which subsequently came into force in 2009.

The sources of law in the EU can be divided into two broad categories – the primary sources and the secondary sources. The primary sources of law include the Treaty on the European Union (TEU), the Treaty on the Functioning of the European Union (TFEU), the Charter of Fundamental Rights of the European Union (CFREU) and General Principles of Union Law. On the other hand, the secondary sources of EU law include international agreements and secondary legislations, which consist of regulations, directives and decisions. Besides these

¹¹⁴ The European Coal and Steel Community (ECSC) consisted of six countries - Belgium, France, Germany, Italy, Luxembourg and the Netherlands. The main goal of the ECSC was to control coal and steel production. Treaty Establishing the European Coal and Steel Community. (April 18, 1951). 261 U.N.T.S. 140 [hereinafter ECSC Treaty].

¹¹⁵ Treaty Establishing the European Economic Community. (March 25, 1957). 298 U.N.T.S. 11.

¹¹⁶ Streit, Manfred E., and Werner Mussler. (1995).The Economic Constitution of the European Community: From 'Rome' to 'Maastricht'. *European Law Journal* 1.1. 5-30.

¹¹⁷ Consolidated versions of the Treaty on European Union and the Treaty on the Functioning of the European Union - Consolidated version of the Treaty on the Functioning of the European Union - Protocols - Annexes - Declarations annexed to the Final Act of the Intergovernmental Conference which adopted the Treaty of Lisbon, signed on 13 December 2007 - Tables of equivalences; OJ C 326, 26.10.2012, 1 – 390.

two main categories, the case law from the (Court of Justice of the European Union) CJEU is also another significant source of EU law.

The preparatory works such as EU commission reports, proposals, communications, white papers, green papers, reports authorised by the EU bodies, and the reports of national agencies of the Member States are also a vital resource and provide supplementary information. In this thesis, the primary and secondary sources are supplemented by official preparatory reports and works.¹¹⁸

2.3.2. Doctrine of the sources of law

The doctrine of the sources of law is primarily used to arrive at the hierarchy of sources of law. The doctrine of sources of law applies to national law, EU law and also international law. In the context of globalisation, international law, in the form of treaties and agreements, has an impact and is incorporated at the regional level,¹¹⁹ for example, in EU law. It is translated or recognised in national laws, and therefore, clarity regarding sources of law is pertinent. Although the national, international and EU law have their own sources of law, they cannot be independent of each other. There is interaction and influence of one law on the other. Since in this thesis, the sources of law that are used, are primarily EU law sources, only the EU doctrine of sources of law is being discussed.

In the EU, there is a distinct doctrine of sources of law. At the apex, lies the Treaty of the European Union¹²⁰ (TEU) and the Treaty on the Functioning of the European Union (TFEU),¹²¹ which serve as the primary sources of law. In this

¹¹⁸ See Appendix II for a detailed list of primary, secondary and preparatory works used in the thesis.

¹¹⁹ The TRIPS Agreement has been recognised and implemented through the Enforcement Directive 2004/48/EC and further in the national legislations of the Member States.

¹²⁰ European Union. (1992) *Treaty on European Union (Consolidated Version)*, *Treaty of Maastricht*, 7 February 1992, OJ C 325, 24.12.2002, 5-32. Henceforth, referred to as 'TEU'.

¹²¹ Consolidated version of the Treaty on the Functioning of the European Union. O. J. 2012, C - 326/13.

thesis, specific emphasis is on the public health (Articles 9 and 168) and consumer protection (Articles 12 and 169) provisions of the TFEU. The Directives and Regulations form the second tier and are considered the secondary sources of law. In the thesis, two directives (Directive 2011/62/EU and Directive 2004/48/EC) and one regulation (Regulation 608/2013) are the units of legal analysis. In practice, it implies that the secondary sources must always abide by, and give precedence to the primary sources of law. Moreover, the directives and regulations must not be in conflict with the treaties.

In the hierarchy of doctrine of sources of law for the EU, the Court of Justice of the European Union (CJEU) has asserted that the international treaties entered into by the EU and the customary law is to be considered above secondary EU law.¹²² Therefore, it can be construed that the secondary law must be compatible with the international treaties and agreements entered by the EU.¹²³

2.3.3. Primary sources of law

Broadly, the TEU and the TFEU form the legal bases of the European Union¹²⁴ and the foundation of the EU.¹²⁵ These two treaties are complementary in nature

Henceforth, referred to as 'TFEU'.

¹²² See Case: C -366/10, *Air Transport Association of America and others v. Secretary of State for Energy and Climate Change* (2011) E.C.R. I- 13755, paras 28-29 and 51-54. In this case the question was raised as to whether EU Directive including aviation activities (in context of the scheme for greenhouse gas emission allowance) trading within the Community, was consistent with International treaty law and customs. In this case, the CJEU listed out the requirements that needed to be fulfilled for an international treaty to take precedence over secondary EU law. It was further stated that the EU was bound by a treaty, which was sufficiently precise.

¹²³ See joined cases C 320/11, C330/11, C- 382/11 and C – 383/11, *Digitalnet and Others* (2011) E.C.R. I-00167, para.39. The cases were regarding payment of customs duties concerning the import of set-top boxes having a communication function from Korea to Bulgaria. The EU had entered into an international agreement regarding trade in information technology (ITA) and the CJEU held that EU Regulations regarding the classification of goods for the goal of settling the rate of customs applicable to those goods were to be understood in consonance with the international agreement.

¹²⁴ Article 1, TEU. See also Geiger, R., Khan, D. E., & Kotzur, M. (Eds.). (2015). *European Union Treaties; a Commentary: Treaty on European Union: Treaty on the Functioning of the European Union*. Hart.12.

¹²⁵ Article 1 (2), TFEU. See also Tsoukalis, L., & Emmanouilidis, J. A. (2011). *The Delphic oracle on Europe: is there a future for the European Union?* Oxford University Press.

and there is no explicit form of hierarchy and along with the CFREU, the three documents form the primary law of the EU.

2.3.3.1 The Treaty of the European Union

The TEU established the legal personality of the EU¹²⁶ and created a legal order *sui generis*.¹²⁷ It also states the common values of the Member States, such as respect for human dignity, freedom, democracy, equality, and the rule of law.¹²⁸ These values underline the self-conception of the Union, as well as underpin the obligations of Union and the Member States as regards to the common values.¹²⁹ Under Article 3, the aims of the Union are established wherein the primary goal of promotion of peace, common values and well-being of the people is paramount. The establishment of the area of freedom, security and justice emanates from this provision, whereby the right to free movement of persons within the Union is granted to every EU citizen.

While considering the EU doctrine of the sources of law, it is vital to discuss the synergy between the EU law and the national laws of the Member States. There are two fundamental doctrines that steer the relationship between the EU law and national laws – the doctrine of supremacy and the doctrine of direct effect.¹³⁰ These two principles are essential and are the measures that facilitate the maintenance of uniformity in the EU. Also, the doctrine of supremacy primarily relates to the acknowledgement of the fact that the primary and secondary EU law takes precedence over national laws of the Member States.¹³¹ The doctrine of

¹²⁶ Article 47, TEU.

¹²⁷ Piris, J. C. (2011). *The future of Europe: towards a two-speed EU?* Cambridge University Press.

¹²⁸ Article 2, TEU.

¹²⁹ Biondi, Eeckhout, Ripley (Eds.). (2012). *EU Law after Lisbon*. Oxford. Oxford University Press.

¹³⁰ Articles 4 and 288, TFEU.

¹³¹ See Cases: C-26/62, *Van Gen den Loos v Nederlandse Administratie der Belastingen* [1970]E.C.R. 1- The CJEU referred to the supremacy of the EU law over National laws of the Member States for the first time in this case. The CJEU held that “(...) ... *the Community constitutes a new legal order of international law for the benefit of which*

direct effect implies that the provisions of the EU Treaty can have a direct effect on the Member States and the individuals can employ them.¹³² The primary purpose of establishing the supremacy of the EU law over the national law is to ensure uniformity in the EU. The doctrine of supremacy and the doctrine of direct effect have been accepted by the national courts, except in very rare incidents, when national courts challenged the doctrine of supremacy.¹³³

The TEU establishes the competences of the Union and the Member States under Article 4, where it is stated that the competences that are not conferred upon the Union by the Treaties, lie within the purview of Member States. In this manner, the basic State functions are protected and the respect for the unique national identity of the Member State is also maintained. The duty of sincere cooperation¹³⁴ is established by this provision, whereby the Union institutions are obliged to respect the fundamental interests of the Member States¹³⁵ and the Member States are obliged to assist the Union.¹³⁶ From this provision, flows the application of Union law in the domestic sphere, and is applicable in its entirety, otherwise known as the principle of ‘direct effect’. It has also been established that the Union law precedes national law.

the states have limited their sovereign rights, albeit within limited fields, and the subjects of which comprise not only Member States, but also their nationals.. (...)” and C-6/64, Flaminio Costa v E.N.E.L. [1964] E.C.R. 585, when the doctrine of supremacy was firmly settled.

¹³² See C 26/62, *Van Gen den Loos*, It was the landmark case wherein the principle of direct effect originated. It was held by the CJEU, “It follows from the foregoing considerations that, according to the spirit, the general scheme and the wording of the Treaty, Article 12 must be interpreted as producing direct effects and creating individual rights which national courts must protect.”

¹³³ In German case law in the *Solange* decision from 1974 and 1986 (BVerfGE 37, 271 case no.2 BvL 52/71, case no: 2 BvR 197/83), the *Maastricht* decision in 1993 (BVerfGE 89, 155 case no: 2 BVR 2142 and 2 BvR 2159/92), and the *Honeywell* (BVerfGE 126.286, case no: 2 BVR 2661/06) decision in 2010. These decisions show that the German Constitutional Court has reserved the right to question the supremacy of the EU law over the German Constitution.

¹³⁴ Geiger, R., Khan, D. E., & Kotzur, M. (Eds.). (2015). *European Union Treaties; a Commentary: Treaty on European Union: Treaty on the Functioning of the European Union*. Hart. p.12.

¹³⁵ *ibid.*

¹³⁶ ECJ cases C -45/93 C v Spain (1994) ECR I- 935; C 40/92 C v UK (1994) ECR I - 989.

Article 5 of the TEU provides for limits of the competences of the Union. The limitations include the principle of conferral of competences¹³⁷ and the principle of subsidiarity and proportionality. These principles are binding by Union law and are cumulative in nature whereby, application of all the principles is necessary. Therefore, these principles are applicable to all legal instruments in the EU since these are binding principles. For instance, the Falsified Medicines Directive (Directive 2011/62/EU) contains provisions on specific reference to Article 5, TEU.

The principle of limited conferral implies that the Union may act in a limited manner and only in a manner so as to achieve the objective of the relevant provision. The aim of this provision is to avoid intrusion on the competences of the Member States while at the same time achieving the objectives. In other words, the EU is not endowed with powers to extend its competences and secondly, the EU is not bestowed with general law-making capacity.¹³⁸ Every EU action needs to have one or more legal bases in the Treaties and is subject to judicial review.¹³⁹ The principle of conferral determines vertical (determination of the question whether the Union has the competence) as well as horizontal (if the Union has the competence, which institution may carry out the competences) bifurcation of competences.¹⁴⁰

The principle of subsidiarity is considered an ‘architectural principle in Europe’¹⁴¹

¹³⁷ Craig, P. P. (2009). Competence and member state autonomy: causality, consequence and legitimacy.

¹³⁸ Barnard, C., & De Baere, G. (2014). Towards a European social union: achievements and possibilities under the current EU constitutional framework. 6.

¹³⁹ Case C-658/11 Parliament v Council EU:C:2014:2025, para 43.

¹⁴⁰ See Case C-301/06 Ireland v Parliament and Council EU:C:2009:68, para 56.

¹⁴¹ See resolution of the conference on ‘Europe of the Regions of 19 October 1989.

and defined as a fundamental principle of the Union Law,¹⁴² whereby it is stated that a larger unit must not undertake a task that a smaller unit can successfully execute. In other words, there is a binding guideline on how competences are to be used. In specific subject areas like education (Article 165, para 4, TFEU), culture (Article 165, para 5, TFEU) and public health (Article 168, TFEU), which is the primary concern of the thesis, specific rules exist, which set limitation on the Union activities and the Union is relegated to play a supporting role and there is explicit exclusion of harmonisation of domestic laws in such cases.¹⁴³ The principle of proportionality is one of the most significant general principles of Union law¹⁴⁴ that states that the measures must be appropriate and necessary for the legitimate aim to be achieved. It relates to the type of measures that are used (a recommendation is preferable to a directive and a directive is preferable to a regulation) and the density of the content (replacing a measure by a statement of principles, a regulation by mere cooperation of the Member States).

2.3.3.2. The Treaty on the Functioning of the European Union

The Treaty on the Functioning of the European Union (TFEU), formed by the Reform Treaty of Lisbon 2007, substantiates and elaborates on the provisions of the TEU.¹⁴⁵ It is an international treaty concluded by the Member States and therefore is recognised under Public International law and the Vienna Conventions on the Law of Treaties. One of the objectives of the thesis is to assess how far the legal instruments employed in the thesis are successful in meeting the objectives

¹⁴² Article 5, para 3. TEU.

¹⁴³ Geiger, R., Khan, D. E., & Kotzur, M. (Eds.). (2015). *European Union Treaties; a Commentary: Treaty on European Union: Treaty on the Functioning of the European Union*. Hart. 37.

¹⁴⁴ Sauter, W. (2012-13). Proportionality in EU law: A Balancing Act? *Cambridge Yearbook of European Legal Studies*. 439.

¹⁴⁵ Article 1, TFEU.

of the public health as envisaged in Articles 9 and 168 of the TFEU and the aim of protection of consumers under Article 12 and 169. In order to conduct this assessment, the goals of public health and consumer protection, as conceived in the TFEU, need to be ascertained.¹⁴⁶

Counterfeit and falsified medicines have the potential to inflict direct harm on the consumers. Therefore, the Union has horizontal rules as well as specific rules on the protection of consumers and public health and safety in the TFEU. In addition to conducting this assessment, it is also important to assess the goals of the Single Market of free movement of goods, services, people and capital. The attainment¹⁴⁷ of these objectives is a recognised aim of all legal instruments in the EU, including the legal instruments being employed in the thesis.

The concept of an internal market was conceived by the Commission (White Paper 1985),¹⁴⁸ with the primary goal of doing away with trade barriers in product markets and formulation of policies that would encourage competition and bring about economic integration. The proposed Single Market Program (SMP) listed three main objectives – the removal of physical, technical and fiscal barriers.¹⁴⁹ The SMP developed over a period of time and exhibited consistent development. It began with the Maastricht Treaty, 1992; Action Plan 1997; formation of the Economic and Monetary Union, 1999; strategy for Europe's Internal Market, 1999; expansion of EU 2002; Internal Market Strategy 2003-2006; and expansion of the EU Membership, 2007 and developed into the concept that is now

¹⁴⁶ Hervey, T. K., & McHale, J. V. (2004). *Health law and the European Union*. Cambridge. Cambridge University Press.

¹⁴⁷ Craig, P. P. (2012). The stability, coordination and governance treaty: principle, politics and pragmatism; *See also* Mossialos, E. (2010). *Health systems governance in Europe: the role of European Union law and policy*. Cambridge University Press.

¹⁴⁸ Completing the Internal Market, COM (1985) 310 final.

¹⁴⁹ Completing the Internal Market, COM (1985) 310 final.

recognised and defined under Article 26 of the TFEU. The ultimate goal of the internal market is to achieve an overall integration and absence of barriers to intra-EU trade.¹⁵⁰ Even though the differences between the Member States are recognised in terms of legal systems, economic policies, the level of economic development, and cultural and historical diversity, Article 26 para. 1 stipulates the development of the internal market to achieve the overall goal of further integration.¹⁵¹

The internal market as defined in Article 26 of the TFEU refers to the area without ‘internal frontiers’ and where there is free movement of goods, services, capital and people.¹⁵² The four freedoms are extended to all EU citizens and are elucidated in the secondary legislation. For example, the free movement of goods is ensured in both the harmonised sectors as well as the non-harmonised sectors. The harmonised sectors are subject to common rules all over the EU, thereby providing predictable, common legal framework for facilitating free movement of goods, by virtue of shared competences between the Union and the Member States, under Article 4, TFEU and Article 3 (3) TEU. In non-harmonised sectors, such as healthcare, there is an absence of common rules in the EU as they fall under the purview of the Member States, under provisions of Article 4, TFEU and the EU plays a supporting and supplementary role, as envisaged in Article 6, TFEU.

The competences regarding governing public health¹⁵³ and consumer protection¹⁵⁴

¹⁵⁰ ECJ Case 15/81 *Gaston Schul* (1982) ECR 1409; *See also* Radaelli, C. M. (2007). Whither better regulation for the Lisbon agenda? *Journal of European public policy*, 14(2), 190-207.

¹⁵¹ Gabel, M. J. (2009). *Interests and integration: Market liberalization, public opinion, and European Union*. University of Michigan Press.

¹⁵² Article 26, para 2, TFEU.

¹⁵³ Article 168, Title XIV, Public Health (contribution of the Union to public health, ensuring a high level of protection)

are shared between the Union and the Member States as provided for in the Article 4 para 2 lit k. TFEU (shared competences) and Article 6 para 2, TFEU (competence to support, coordinate or supplement). In other words, the Union does not have the authority to pursue its own health policies. While the Union has a supplementary role to the Member States,¹⁵⁵ the EU can encourage and support cooperation between the Member States in the area of public health.

One of the objectives of the thesis is to analyse whether the legal instruments containing provisions to combat counterfeiting and falsification of medicines in the EU meet the social objectives of public health (Articles 9 and 168, TFEU) and consumer protection (Article 12 and 169).¹⁵⁶ Therefore, it is imperative to explain the goals of Article 168, which is done in greater detail in Chapter 8.¹⁵⁷

Article 9

Through Article 9 of the TFEU, human health has been included in the general horizontal health policy in addition to other basic qualities.¹⁵⁸ Besides having an area of general health under its purview, there are also specific provisions dealing with protection of health and safety of workers.¹⁵⁹

¹⁵⁴ Article 169, Consumer Protection, TFEU.

¹⁵⁵ Geiger, R., Khan, D. E., & Kotzur, M. (Eds.). (2015). *European Union Treaties; a Commentary: Treaty on European Union: Treaty on the Functioning of the European Union*. Hart. 679.

¹⁵⁶ See detailed analysis in Chapter 8.

¹⁵⁷ Chapter 8.

¹⁵⁸ See Article 9, TFEU which introduces a horizontal clause on social protection, whereby the Union is required to promote high level of employment, guarantee adequate social protection, fight against social exclusion, high level of education, training and protection of human health.

¹⁵⁹ Articles 153 para 1, 115, 36, 53 para 2, 62 TFEU.

Article 168

Article 168, TFEU clarifies, specifies, and enlarges the competence of the Union in the public health sphere. The specific significance of public health is underlined by Article 168(1), wherein it is required that all Union policies and activities ensure a high level of protection of public health, while determining and implementing Union policies. This is required at the horizontal level and implies that public health concerns are to be ensured in all policies and activities and not just in health regulations.¹⁶⁰

Although Article 168 provides for the targets that must be achieved in the EU with respect to public health, there are some restrictions in achieving the goals. As explained above, public health is a shared competence between the Member States and the Union. While the Member States are the primary architects of their respective national healthcare systems and policies, the Union has a supporting role and steps in only when there is an aspect involving and affecting all Member States and it is deemed expedient to undertake steps at the Union level. Therefore, in the area of public health, the Union cannot formulate a Union health policy. Consequently, the effectiveness of Article 168 is difficult to assess in isolation. Its primary contribution is that secondary legislation needs to uphold the provisions of Article 168 and strive to attain the objectives.

Article 169

In addition to provisions of explicitly stating the importance of public health in the

¹⁶⁰ Cabezas, M. D. (2012). Current trend in pharmaceutical law in EU. *Pharmaceuticals Policy and Law*, 14(2-4), 195-207.

TFEU, there are provisions related to protection of consumers¹⁶¹ that are also relevant for the thesis. The protection of the consumers against counterfeit and falsified medicines also falls under the goals of consumer protection. The TFEU also explicitly provides for consumer protection in Article 12, where it is introduced as a horizontal clause. In addition to Article 12, TFEU, the issue of consumer protection is also exclusively governed in Title XV, Article 169, TFEU. It provides for the promotion of interests of the consumers and that the Union shall contribute to the protection of the health, safety and economic interests of the consumers as well as promoting the right to information, education and to organize themselves in order to safeguard their interests.¹⁶²

Article 118

The thesis analyses the provisions governing counterfeiting of medicines and in this regard employs the Enforcement Directive (Directive 2004/48/EC) and Customs Regulation (Regulation 608/2013). These two legal instruments deal with Intellectual Property Rights (IPRs). Also, Article 118 of the TFEU is important to consider because it provides for the protection of the IPRs in the context of the internal market.¹⁶³ It states the European IPRs should be established for uniform protection of IPR in the EU. The protection of IP is recognised as a fundamental right in the CFREU, Article 17 (2). It is further acknowledged that success of the internal market is affected by the protection of IP¹⁶⁴ because of its bearing on

¹⁶¹ Micklitz, H. W., Reich, N., & Weatherill, S. (2004). EU Treaty revision and consumer protection. *Journal of Consumer Policy*, 27(4), 367-399.

¹⁶² Geiger, R., Khan, D. E., & Kotzur, M. (Eds.). (2015). *European Union Treaties; a Commentary: Treaty on European Union: Treaty on the Functioning of the European Union*. Hart. 682.

¹⁶³ Hilty, R. M. (2004). Intellectual Property and the European Community's Internal Market Legislation-Copyright in the Internal Market-Harmonisation vs. Community Copyright Law. *IIC-international review of intellectual property and competition law*, 35(7), 760-775.

¹⁶⁴ Geiger, R., Khan, D. E., & Kotzur, M. (Eds.). (2015). *European Union Treaties; a Commentary: Treaty on European Union: Treaty on the Functioning of the European Union*. Hart. 569.

innovation and investment. Moreover, uniform Union-wide level of protection of IP was deemed important. Therefore, Article 118 is especially relevant while considering the protection of IP of the owners of pharmaceutical trademarks and patents that are violated because of counterfeiting and falsification of medicine.

Article 288 (Legal acts)

There are many legal instruments that may be used in the EU, such as Directives, Regulations, Decisions, Recommendations, Opinions, and Guidelines.¹⁶⁵ Article 288, TFEU defines the different legal instruments that are utilized in the EU.¹⁶⁶ An EU directive is a type of legislation that is aimed at the Member States. It is a legally binding instrument¹⁶⁷ that sets out the objectives that need to be achieved by the Member States (normally in the preamble of the directive, in the form of recitals). In addition to the general goals of the directive, there are specific provisions that need to be integrated into the domestic legislation, which are usually written in the Articles of the directive. The Member States are required to transpose the provisions of the directive into their national legislation within a provided time frame, which is normally two years.¹⁶⁸ The directives are commonly used to realise the goals of the free movement, free trade and competition. They

¹⁶⁵ Bast, J. (2012). New Categories of Acts after the Lisbon Reform: Dynamics of Parliamentarisation in EU Law. *Common Market L. Rev.*, 49, 885; Best, E. (2007). Legislative procedures after Lisbon: fewer, simpler, clearer? *Maastricht Journal of European and Comparative Law*, 15(1), 85-96.

¹⁶⁶ A 'Decision' can be issued in the context of one or more parties, for example, an EU Member State or an individual company. A decision can be issued by a body such as the Commission and is directly applicable. An important feature of a decision is that it is binding only in the context of the parties that are involved and not in general on all Member States. Amongst the non-binding instruments, 'Opinions' and 'Recommendations' are the most frequently used. While an 'Opinion' allows the institutions to make statements in a non-binding manner and without imposing any legal obligations, it is usually issued by one of the main EU institutions, such as the Commission, the Council or the Parliament. Another important but non-binding legal instrument that is used is 'Recommendations'. This type of instrument does not impose any legal obligations on the EU Member States. It is helpful because it allows sharing of practices that may have successfully worked in some Member States and the other Member States could benefit without encountering any legal consequences.

¹⁶⁷ Article 288, para 3 TFEU.

¹⁶⁸ Once the EU Directive is adopted and passed into EU law, it can have force of law, even when it has not been enacted into national legislation.

may also be utilized to establish common social policies and lay down minimum EU standards. In this thesis, the Falsified Medicines Directive (2011/62/EU) and the Enforcement Directive (2004/48/EC) are closely examined.

Another legal instrument used in the EU to realise common goals is using a regulation.¹⁶⁹ A regulation is understood to mean a legal act that becomes enforceable as soon as it comes into existence. In other words, a regulation is binding and does not need to be transposed into national law but simultaneously becomes enforceable in all Member States upon being approved as a law at the EU level. In this thesis, the subject of Customs Regulation (608/2013) will be analysed.

2.3.3.3. Charter of Fundamental Rights of the European Union

In the thesis, the legal instruments governing counterfeiting and falsification of medicines are analysed because of the serious consequences they can have on human life, causing serious illness, development of drug resistance or even death.¹⁷⁰ In the light of these circumstances, it becomes imperative to underline the importance that is bestowed upon the right to life, and right to health in the CFREU.¹⁷¹ The CFREU was initially proclaimed in 2000 and became legally binding on the EU institutions and on national governments like the EU Treaties in 2009 when the Treaty of Lisbon came into force.¹⁷² The CFREU combines the fundamental rights and freedoms, which are extended to each individual in the EU

¹⁶⁹ Article 288, para 2, TFEU.

¹⁷⁰ Mackey, T. K., & Liang, B. A. (2011). The global counterfeit drug trade: patient safety and public health risks. *Journal of pharmaceutical sciences*, 100(11), 4571- 4579.

¹⁷¹ Kokott, J., & Sobotta, C. (2010). The Charter of Fundamental Rights of the European Union after Lisbon; Morano- Foadi, S., & Andreadakis, S. (2011). Reflections on the architecture of the EU after the Treaty of Lisbon: the European judicial approach to fundamental rights. *European Law Journal*, 17(5), 595-610.

¹⁷² European Union. (2012). *Charter of Fundamental Rights of the European Union*. OJ C 326, 26.10.2012, 391-407.

into a single document. These freedoms are entitled to Dignity, Freedoms, Equality, Solidarity, Citizen's Rights and Justice. These rights emerged from the case law of the CJEU — the rights and freedoms as guaranteed in the European Convention on human rights and other rights and principles as enshrined in international instruments. The Charter is primarily addressed to the EU institutions and bodies and extends due respect to the principle of subsidiarity and to national authorities, while the national authorities implement EU law. The Charter applies only to the areas that are mentioned in the EU Treaties and does not have competence beyond the EU Treaties.

Under Article 2 (1), the Right to life is guaranteed to all. Furthermore, under Article 35 of the CRFEU, everyone is entitled to right health care. Also, a horizontal provision is provided for to ensure a high level of human health protection in definition and implementation of all Union policies and activities.¹⁷³

It is vital to state that the CFREU also recognises the protection of IP as an important goal under Article 17(2), which is important because the thesis is addressing both IP law and Medicine law perspective.

2.3.4. Secondary sources of law

In this thesis, the focus is on the secondary sources of law, which must be interpreted in consonance with the primary sources of law¹⁷⁴ and international agreements. As discussed in Chapter 1,¹⁷⁵ the problem of counterfeiting and falsification in the pharmaceutical sector in the EU lies at the intersection of IP law, Medicines law and Criminal law, there is no one legal instrument that

¹⁷³ Lenaerts, K. (2012). Exploring the limits of the EU charter of fundamental rights. *European Constitutional Law Review*, 8(03), 375-403.

¹⁷⁴ See ECJ Case C-168/01 Bosal Holding (2003) ECR I 9409.

¹⁷⁵ Chapter 1, Section 1.2.

exclusively addresses the issue of counterfeit medicine. As health policy only has the broadest outlines in the Treaties, it has been necessary to pass a number of laws covering both health and Single Market aspects of the issue. The provisions are found in various legal instruments. The secondary legal instruments that are employed while dealing with the broad problem of counterfeiting in the EU are the Falsified Medicines Directive,¹⁷⁶ the Enforcement Directive¹⁷⁷, and the Customs Regulation.¹⁷⁸ It also needs to be mentioned at the outset that each discussed legal instrument has its own purpose of origin, and the aim of one legal instrument may not necessarily be in consonance with the aim of another instrument. For instance, the primary objective of the Falsified Medicines Directive is to safeguard public health and safety by ensuring the authenticity of medicines. On the other hand, the Enforcement Directive aims at streamlining the protection of rights and interests of the IPR holders. Elimination of counterfeit and falsified medicine happens to be a common goal because interests intersect concerning the containment of the problem of counterfeit medicines. However, this may not always be the case. Therefore, it is vital to establish that the reasons as to why these legal instruments came into being, and what these instruments try to resolve, support or implement, which may not always be a common goal.

2.3.4.1. The Falsified Medicines Directive (Directive 2011/62/EU)

The FMD came into being as an amendment to the Medicines Directive (Directive 2001/83/EC)¹⁷⁹ in the light of an enormous increase in the number of falsified

¹⁷⁶ Directive 2011/62/EU.

¹⁷⁷ Directive 2004/48/EC.

¹⁷⁸ Regulation (EU) No. 608/2013.

¹⁷⁹ Directive 2001/83/EC, on the Community code relating to medicinal products for human use, as regards the prevention of the entry into the legal supply chain of falsified medicinal products. OJ L 311, 28.11.2001, p. 67.

pharmaceutical products entering the EU.¹⁸⁰ The Medicines Directive was developed in 2001 to even out the disparities in the provisions relating to medicinal products between the Member States as it was having a direct impact on the functioning of the Single Market. It harmonised the Community code relating to medicinal products for human use in the EU. In tune with the primary sources of law concerning the maintenance of the sanctity of the Single Market and Public health concerns in Articles 168, 114, and 169 of the TFEU, Articles 4, 5, and 9 of the TEU and Article 2, 17, and 35 of the CFREU, the Falsified Medicines Directive, Directive 2011/62/EU¹⁸¹ forms the core legislation as regard to falsification of medicines in the EU. Due to the common concern for public health in the EU, and in accordance with the principle of subsidiarity and proportionality,¹⁸² it was deemed appropriate that the crucial nature of the matter of public health must be partially dealt with at the Union level, even though healthcare policies are generally left to the Member States.¹⁸³

Objectives and Scope

The main objective of the FMD, as stated in Recital 33 of the FMD¹⁸⁴ is to ensure that the Internal Market functions smoothly with respect to medicinal products and overall to combat falsification of medicines in the EU. The safety of the type of medicinal products that enter and are sold¹⁸⁵ in the EU,¹⁸⁶ take into consideration the risk profiles that threaten to disturb the flow of medicine in the internal market. In this regard, the FMD introduces safety features to be employed on the

¹⁸⁰ Recital 2, Directive 2011/62/EU; In 2011, 30 million counterfeit medicines were intercepted at EU borders, EFPIA, Stamping out Falsified Medicines, www.efpia.eu/topics/industry-economy/falsified-medicines, accessed April 2016.

¹⁸¹ Directive 2011/62/EU.

¹⁸² See Article 5, TEU.

¹⁸³ Taaffe, T. (2012). European Union has the falsified medicines directive. *BMJ*, 345, e8356.

¹⁸⁴ *ibid.*

¹⁸⁵ Recital 11, Directive 2011/62/EU.

¹⁸⁶ Recital 10, Directive 2011/62/EU.

medicinal products.¹⁸⁷ The FMD aims to prevent falsified medicines from entering the legal supply chain and ensure that EU citizens are able to buy high-quality medicines through pharmacies across the EU and online through verifiable sources in the European Union.¹⁸⁸ The FMD aims to overcome potential market distortions that might hamper competition in the internal market¹⁸⁹ through its provisions concerning harmonised principles and guidelines for inspections of manufacturers and wholesale distributors of medicinal products.¹⁹⁰

Essentially, the FMD only deals with falsified medicines entering the legal supply chain and illegal supply chain, where the counterfeit and falsified medicines find a huge market is not governed by it. However, this illegal supply chain is regulated by other provisions of the Medicines Directive (Directive 2001/83/EC).¹⁹¹ Moreover, the FMD does not govern the impact on IPRs¹⁹² in any manner, which is categorically stated in the Preamble to the FMD. The FMD clearly underlines its focus on the ‘public health and safety’ perspective while dealing with falsified medicines. This line of demarcation is strong as the FMD does not use the term ‘counterfeit’ but utilizes the term ‘falsified’ medicines’.¹⁹³ The term falsified is defined so as to include any medicinal product with a false representation of identity, source, or history of the product.¹⁹⁴ The FMD emphasizes that the term counterfeit medicine is used to indicate when a medicinal product does not uphold

¹⁸⁷ Bogaert, P. B. C., & Burton, C. (2015). The mysteries of the Falsified Medicines Directive-where is the logic on safety features. *London: Script Regulatory Affairs*, 1-3.

¹⁸⁸ Lavorgna, A. (2015). The online trade in counterfeit pharmaceuticals: new criminal opportunities, trends and challenges. *European Journal of Criminology*, 12(2), 226-241.

¹⁸⁹ Recital 18, Directive 2011/62/EU.

¹⁹⁰ See Commission Directive 2003/94/EC of 8 October 2003 laying down the principles and guidelines of good manufacturing practice in respect of medicinal products for human use and investigational medicinal products for human use.

¹⁹¹ Tremblay, M. (2013). Medicines counterfeiting is a complex problem: a review of key challenges across the supply chain. *Current drug safety*, 8(1), 43-55.

¹⁹² Recital 29, Directive 2011/62/EU.

¹⁹³ See discussion on the term in Chapter 1

¹⁹⁴ Article 1 (3), Directive 2011/62/EU.

the IP laws. These situations could relate to an infringement of a trademark. As asserted in Chapter one,¹⁹⁵ falsification of medicine inevitably leads to violation of an IP right, resulting in violations of medicine law and IP law. However, the issues relating to IP violations do not fall within the scope of the FMD.

Relevance

The FMD needs to be considered in this thesis as it is the FMD that sets out the rules and regulations pertaining to falsified medicinal products.¹⁹⁶ As will become apparent, counterfeit medicines can be introduced at any point in the legal supply chain. For the purposes of understanding, the entire process can be divided into four stages. A falsified medicinal product can enter the supply chain at stage 1 (when the active ingredient is imported, which can be a counterfeit and/or falsified ingredient), stage 2 (manufacturing stage, where counterfeit and/or falsified medicine can be injected into original packaging), stage 3 (distribution stage, where distributors can knowingly or unknowingly introduce counterfeit and/or falsified medicines) or stage 4 (sale through pharmacies or online pharmacies or websites,¹⁹⁷ when counterfeit and/or falsified medicines can be offered for sale). The FMD addresses each of these stages, where counterfeiting and falsification can occur.

¹⁹⁵ See Chapter 1, Section 1.2.

¹⁹⁶ Jones, G. (2014). The Falsified Medicines Directive: time to get it right. *The Pharmaceutical Journal*, 293, 7832.

¹⁹⁷ Hall, A., & Antonopoulos, G. A. (2016). Introduction. In *Fake Meds Online* (1-17). Palgrave Macmillan UK.

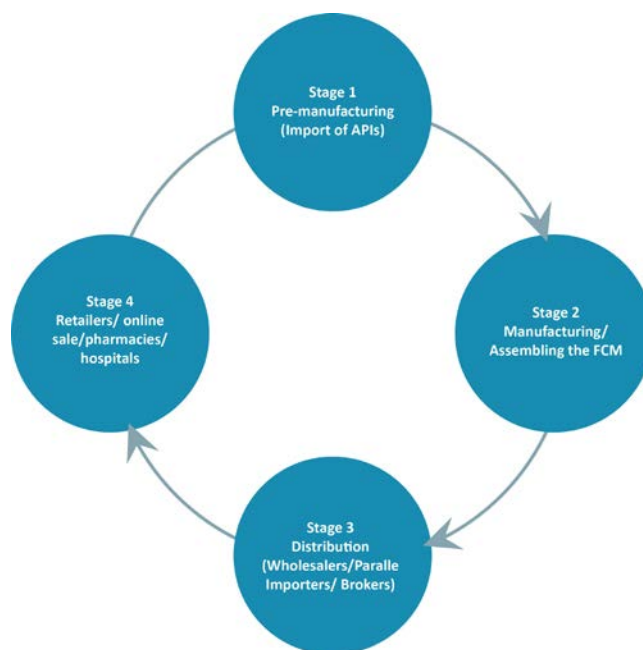


Figure 3

The FMD recognises its primary purpose, which is to harmonise and strengthen safety and control measures in Europe,¹⁹⁸ in four specific areas — safety features of medicines, the supply chain¹⁹⁹ including application of Good Distribution Practices (GDP) for active substances and excipients, and sale over the Internet. These areas encompass the entire life cycle of a medicine, from the time of conception (pre-manufacturing stage) to the last stage of sale by a retailer to a potential consumer. Therefore, the FMD is extremely relevant for the thesis as it especially came into being to address the issue of falsification of medicines in the EU.

¹⁹⁸ Naughton, B. D., Vadher, B., Smith, J., Smith, G., Chapman, S. R., Dopson, S., & Brindley, D. A. (2015). EU Falsified Medicines Directive mandatory requirements for secondary care: a concise review. *Journal of Generic Medicines*, 12(3-4), 95-101.

¹⁹⁹ Smith, G., Smith, J. A., & Brindley, D. A. (2014). The Falsified Medicines Directive: How to secure your supply chain.

2.3.4.2. The Enforcement Directive (Directive 2004/48/EC)

Objectives and Scope

Directive 2004/48/EC of the European Parliament and of the Council of 29 April 2004 on the enforcement of intellectual property rights (also known as "IPR Enforcement Directive" or "IPRED") is a European Union directive in the field of IP law, made under the internal market provisions of the Treaty of Rome.²⁰⁰ A more efficient IP enforcement is a primary goal of the Enforcement Directive²⁰¹ as it also ensures freedom of movement²⁰² and eradication of distortions of competition. The goal of enforcement of IP is also in tune with provisions of Right to Property as mentioned in the Charter of Fundamental Rights of the European Union.²⁰³ In this regard, the protection of IP cannot be underestimated, especially with reference to the promotion of innovation and improvement of competitiveness.²⁰⁴ The type of covered IP rights include trademark rights, copyrights, sui generis right of a database maker, rights of the creator of the topographies of a semiconductor product, patent rights, including rights derived from supplementary protection certificates, geographical indicators, design rights, utility model rights, plant variety rights, trade names, in so far as these are protected as exclusive property rights in the Union law or in the concerned national law.²⁰⁵

²⁰⁰ The Treaty of Rome, officially the Treaty establishing the European Economic Community (TEEC), is an international agreement that led to the founding of the European Economic Community (EEC) on 1 January 1958. It was signed on 25 March 1957 by Belgium, France, Italy, Luxembourg, the Netherlands and West Germany.

²⁰¹ See Recital 1, Directive 2004/48/EC.

²⁰² See Article 26, TFEU.

²⁰³ See Article 17(2), CFREU and Recital 32, Directive 2004/48/EC.

²⁰⁴ Ellard, D. (2004). The EU's IPR Enforcement directive: Origin, key provisions and future of the EU's IPR Enforcement Directive. *Computer law review international*, (3), 65-71.

²⁰⁵ Statement by the Commission concerning Article 2 of Directive 2004/48/EC of the European Parliament and of the Council on the enforcement of intellectual property rights (2009/295/EC).

The scope of application of the Enforcement Directive,²⁰⁶ thus, extends to IP law and does not have a public health orientation. The scope of protection includes the IP rights mentioned in the previous paragraph. As it is a protection of private rights, the goals are in consonance with the nature of private rights, which can be asserted by the right holder or a representative of the right holder.

The Enforcement Directive seeks to achieve an internal market, where IP is not only protected but is part of facilitating an environment²⁰⁷ that is conducive for investment and innovation, coupled with developing employment and improving competitiveness.²⁰⁸ The goals of encouraging innovation and investment in the internal market can be realised if the IPRs are effectively protected in the Community. Therefore, through the Enforcement Directive, it is anticipated that the disparities concerning substantive law on IP in the Member States can be minimized.²⁰⁹

The objective of the Enforcement Directive²¹⁰ is to approximate legislative systems with the aim to achieve an equivalent and homogeneous level of protection of IP in the internal market, as also indicated in Recital 10 of the Directive.²¹¹ This is in tune with the goals of the TFEU, particularly the goal of approximation of laws in Article 114.²¹² The overall goal is to provide justice by way of measures, procedures and remedies that are effective, proportionate and

²⁰⁶ Cook, T. (2015). Enforcement Directive and Harmonization of Remedies for Intellectual Property Infringement in the EU.

²⁰⁷ Massa, C. H., & Strowel, A. (2004). *The scope of the proposed IP Enforcement Directive: torn between the desire to harmonise remedies and the need to combat piracy.*

²⁰⁸ Recitals 1-3, Directive 2004/48/EC.

²⁰⁹ Recital 8, Directive 2004/48/EC.

²¹⁰ Kur, A. (2004). The Enforcement Directive-Rough Start, Happy Landing? *IIC-international review of intellectual property and competition law*, 35(7), 821-830.

²¹¹ Recital 10, Directive 2004/48/EC.

²¹² See Article 114, TFEU in consonance with Article 26 of TFEU.

dissuasive. The Directive, by way of the provisions, seeks to avoid creation of barriers to legitimate trade.

Relevance

The Enforcement Directive is relevant to the thesis as while addressing the problem of counterfeiting and falsification of medicines, IP law related issues pertain to counterfeit medicine, such as false packaging, which is usually related to trademark rights infringement. When IP rights are infringed due to counterfeiting, Enforcement Directive provisions assist in enforcing the rights through the provisions of civil measures, which are transposed into the national legislations.²¹³ The Enforcement Directive is concerned with enforcement of all IP rights, including trademark rights. The Directive is not sector specific, therefore, the Enforcement Directive houses the anti-counterfeiting measures that need to be employed in order to deal with the problem of counterfeiting²¹⁴ when it also concerns the pharmaceutical sector.²¹⁵ Since the Enforcement Directive does not have the specific goal of protection of public health, it does not focus on the repercussions of falsified medicines on health and safety and only stresses on the enforcement of the private rights of the IP right holder.

The Enforcement Directive addresses in specific terms, evidence-gathering powers of judicial authorities²¹⁶ to force offenders or other parties commercially involved in an infringement matter for providing information on the origin of infringing

²¹³ Cook, T. (2015). Enforcement Directive and Harmonisation of Remedies for Intellectual Property Infringement in the EU.

²¹⁴ Kierkegaard, S. M. (2005). Taking a sledgehammer to crack the nut: The EU Enforcement Directive. *Computer Law & Security Review*, 21(6), 488-495.

²¹⁵ Shrivastava, S. R., Shrivastava, P. S., & Ramasamy, J. (2014). Public health measures to fight counterfeit medicine market. *International journal of preventive medicine*, 5(3).

²¹⁶ Article 9, Directive 2004/48/EC.

goods. It further contains provisions for dealing with the distribution networks, provisional and precautionary measures,²¹⁷ for instance, measures like interlocutory injunctions,²¹⁸ or seizure of suspected goods and corrective measures²¹⁹ including permanent injunctions,²²⁰ recall and removal of infringing goods from trade channels. In addition, the Directive deals with powers to force offenders for paying damages.²²¹ Also, it concerns itself with only civil measures. However, it does acknowledge that in addition to civil measures and administrative procedures, criminal measures can also be introduced in appropriate situations.²²²

2.3.4.3. The Customs Regulation (Regulation 608/2013)

Objectives and Scope

The EU Regulation 608/2013,²²³ henceforth called the ‘Customs Regulation’, concerning customs enforcement of IPRs, bolsters and consolidates customs procedures pertaining to the enforcement of IP rights in Europe. The Regulation is a result of the Council Regulation No. 1383/2003 review, which was requested by the Council’s resolution of 25th September 2008 on a comprehensive European

²¹⁷ Article 9, Directive 2004/48/EC.

²¹⁸ See more in Black, H.C., Nolan, J.R., & Nolan-Haley, J.M. (1990). *Black’s Law Dictionary*. (Sixth Edition). St. Paul, Minn. West Publishing Co. “An interlocutory injunction is an injunction that may be issued at any point in time during the pendency of the litigation for the short-term purpose of preventing irreparable injury to the petitioner prior to the time that the court will be in a position to with grant or deny permanent relief on the merits”. See more in Black, H.C., Nolan, J.R., & Nolan-Haley, J.M. (1990). *Black’s Law Dictionary*. (Sixth Edition). St. Paul, Minn. West Publishing Co. 784.

²¹⁹ Article 10, Directive 2004/48/EC.

²²⁰ A court order prohibiting someone from doing some specific act or commanding someone to undo some wrong or injury. This type of injunction is intended to be in force until the end of the specific law suit. See more in Black, H.C., Nolan, J.R., & Nolan-Haley, J.M. (1990). *Black’s Law Dictionary*. (Sixth Edition). St. Paul, Minn. West Publishing Co. 784.

²²¹ Article 13, Directive 2004/48/EC.

²²² Recital 28, Directive 2004/48/EC.

²²³ Regulation (EU) No. 608/2013.

anti-counterfeiting and anti-piracy plan²²⁴. The review of the previous regulation sheds light on the legal framework, which had to be strengthened in order to impart legal certainty and better enforcement of IPRs by customs authorities.²²⁵ The Regulation came into existence to set out the conditions and procedures to be followed by the customs authorities when they come across suspect goods of infringing character.²²⁶

The Regulation governs the customs enforcement of IPRs²²⁷ at the border in the EU. The customs authorities play a significant role at the borders²²⁸ in intercepting goods that are suspected to be infringing in nature. The customs authorities execute the crucial task of facilitating enforcement of IPR, deriving their authority from the EU primary legislation,²²⁹ further strengthened by the EU action plan.²³⁰ The primary goals of the action plan are an improvement in customs control, improving cooperation between the different sectors like industry and the international partners, and bringing about greater awareness amongst the end users regarding the negative impact of the purchase of counterfeit goods. As is evident from the statistics, in 2014, the customs authorities intercepted 35.5 million articles with an overall total value of over €617 million.²³¹ The main purpose of the Customs Regulation, in its amended form, is to give the customs authorities teeth to bite, in order to take action against counterfeiters.

²²⁴ Recital 1, Regulation (EU) No 608/2013.

²²⁵ Recital 3, Regulation (EU) No 608/2013.

²²⁶ De Meyer, C., & Gommers, C. (2013). The transit dilemma revisited: the new Customs Regulation and the legislative package on trade marks. *Journal of Intellectual Property Law & Practice*, 8(10), 771-775.

²²⁷ Chaudhry, P. E. (2006). Changing levels of intellectual property rights protection for global firms: A synopsis of recent US and EU trade enforcement strategies. *Business Horizons*, 49(6), 463-472.

²²⁸ Regulation 608/2013.

²²⁹ See Articles 26, 114, 118, and 169 of the TFEU.

²³⁰ Communication from the Commission to the European Parliament, the Council and the European economic and Social Committee 'Towards a renewed consensus on the enforcement of Intellectual Property Rights: An EU Action Plan', COM (2014) 392 final.

²³¹ European Commission. (27 October 2015). New report highlights crucial role of EU customs authorities in fighting against counterfeit goods. Brussels. European Commission. IP/15/ 5919.

It is also one of the goals of the Regulation to assist in keeping goods that can have a harmful impact on the health and safety of the EU citizens outside the EU borders.²³² Hence, the Regulation also gives priority to protect public health, specifically, with reference to goods in transit²³³ when there is a risk their entering the internal market.

The Customs Regulations²³⁴ has IP violations within its scope and has the perspective of IP law enforcement. The Regulation contains procedural rules to be applied by the Customs authorities in case a product violating the IP law is detected. However, the Regulation does not contain any criteria for determining the existence of an infringement of an IPR.²³⁵ Although, it is stated in the preamble that the protection of public health and safety is an important goal but it does not govern the pharmaceutical sector exclusively and is applicable to all sectors.

Relevance

The counterfeiting medicinal products enter the EU borders through various means – over land, by air and sometimes in the luggage of passengers as also indicated in the legal case studies discussed in chapter 3,²³⁶ which indicate that an international element is usually involved in counterfeiting in the pharmaceutical sector. The Customs Regulation is extremely relevant and important for the thesis as customs authorities have the potential to stop the counterfeit and falsified medicine at the point of arrival into the EU borders.

²³² Recital 2, Regulation 608/2013.

²³³ Recital 11, Regulation 608/2013.

²³⁴ Bently, L., & Sherman, B. (2014). *Intellectual property law*. Oxford University Press, USA.

²³⁵ Recital 10, Regulation 608/2013.

²³⁶ See Chapter 3.

The Regulation defines the key terms, such as ‘counterfeit goods’, ‘pirated goods’ and ‘goods suspected of infringing an IPR’.²³⁷ The definition of ‘counterfeit goods’ revolves around the violation of the trade mark and geographical indication of the product. Further, ‘goods suspected of infringing an IPR’ entail goods, devices, products or components, moulds and matrix that may be manufactured for the purpose of aiding in infringement of IPRs.²³⁸ These definitions are relevant for the purposes of this thesis as they spell out the products that may be intercepted at the borders and are connected with falsification and counterfeiting of medicines. False labels, packaging materials, active substances, etc. would also be covered under these categories.²³⁹

The process and possible actions that the customs authorities may take have been simplified and specified clearly. This measure has the objective of strengthening the customs seizure process. It also implies that most of the counterfeit and falsified goods arriving in Europe from other parts of the world can be destroyed by the customs authorities under certain conditions.²⁴⁰ The Regulation also grants wider powers to customs authorities for destroying small consignments of counterfeit or pirated goods, without the consent of the rights holders in certain specific situations.²⁴¹ The Regulation aims at protecting the IPRs of the rights holders by preventing, combatting and addressing the various dimensions of counterfeit trade.

²³⁷ Article 2, Regulation 608/2013.

²³⁸ Article 2 (7), Regulation 608/2013

²³⁹ Article 2, Regulation 608/2013.

²⁴⁰ Martinet, B. (2014). European regulation strengthens IP protection. *Risk Management*, 61(7), 10-12.

²⁴¹ If the rights holder has given the permission in the application and the owner of the goods does not oppose in the stipulated timeframe, the customs authorities may destroy counterfeit/pirated goods without further processing or obtaining explicit consent from the owner of the goods or the rights holder. *See* Article 26, Regulation 608/2013

2.3.4. Interpretation of Sources of law

All tools of interpretation can only serve as general guidelines for interpreting the law since the mindset of the interpreter is bound to have some influence on the interpretation.²⁴² The context of interpretation, such as whether EU, International or national law is being employed can also have a bearing on the final interpretation. Despite the probability of these variations in interpretation of sources of law, there has been and still is a need to have some semblance of uniformity. Therefore, philosophers and scholars have attempted to develop certain tools for interpretation to serve this very purpose.

2.3.4.1. Rules of Interpretation of sources of law - Vienna Convention

In this thesis, the Rules of Interpretation stated in Vienna Convention on the Law of Treaties (VCLT) are applied²⁴³ as the EU treaties are international treaties that bind the Member States to a common purpose. The Rules of Interpretation are enshrined in Articles 31, 32 and 33 of the VCLT²⁴⁴ and serve as the tools of interpretation for these treaties. While Article 31 states the ‘general rules of interpretation’, Article 32 provides ‘supplementary means of interpretation’ and Article 33 provides rules regarding ‘interpretation of treaties authenticated in two or more languages’. Moreover, Article 31 emphasizes the importance of interpreting a treaty in good faith and in consonance with the objectives and purpose of the treaty. The preamble and annexures normally embody the purpose and objectives of a treaty and should be considered in addition to the main provisions of the treaty in question.²⁴⁵ Furthermore, any agreement, instrument or

²⁴² See Kelsen, Hans. (1992) *Introduction to the Problems of Legal Theory* (A translation of the First edition of *Reine Rechtslehre* 1934). Oxford. 77-89; *Also see* Ross, A. (1959). *On law and justice*. Berkeley. University of California Press. 108-109.

²⁴³ Vienna Convention on the Law of Treaties, 1969. Henceforth, referred to as ‘VCLT’.

²⁴⁴ *ibid.*

²⁴⁵ Article 31 (2), VCLT, 1969.

subsequent agreement should be taken into consideration while interpreting the document.²⁴⁶ Article 31 embodies the classic tools of interpretation, which are grammatical interpretation, systematic interpretation and teleological methods of interpretation.²⁴⁷ Grammatical interpretation focuses on the import of the words of the text in question;²⁴⁸ on the other hand, systematic interpretation lays emphasis on the context of law while teleological interpretation stresses on the purpose of the law. In this thesis, these methods of interpretation are applied in the format described below.

2.3.4.2. Travaux préparatoires

The *travaux préparatoires* are considered in Article 32 of the VCLT, wherein it is stated that preparatory works should be resorted to, in case application of Article 31 results in ambiguity of meaning while interpreting the law. It is relevant for the thesis as counterfeiting and falsification is an issue, which has been tackled by the law for a relatively short period of time. Therefore, it is important to refer to preparatory works for fully comprehending the intentions and the background behind the specific provisions in the legislation addressing the issues of counterfeiting and falsification of medicines. In the thesis, the White papers, green papers, public consultation reports, EU customs enforcement reports, WTO reports, OECD reports, and EUIPO reports have been employed as supporting materials. In the legal case studies, for one of the three operations reliance is placed in the White paper produced by the Medicines Agency in Italy. Even though supplementary means of interpretation are pushed back to secondary status

²⁴⁶ Article 31(2) and Article 31(3), VCLT, 1969.

²⁴⁷ See von Savigny, F. C. (1847). *System des heutigen römischen Rechts* (Vol. 6). Veit. 206.

²⁴⁸ Mankowski, P. (2012). *Brussels I Regulation*. Munich. 34-38.

in the interpretation, the preparatory works play a decisive role.²⁴⁹ It mirrors the historical method of interpretation, which is a classic tool of interpretation.²⁵⁰ It gives importance to the aims of the framers of the law as well as the history associated with the development of the law, which is usually found in the preparatory works. If there is a conflict between different language versions of a Treaty, Article 33 of the VCLT is applied. It states that when a treaty is in two or more languages, the text is considered equally authoritative in each language. If differences arise in interpretation, the resolution should be sought by taking into consideration the purpose and object of the treaty.²⁵¹ In the EU, the secondary legislation, which is the focal point of analysis in the various instruments like directives and regulations are made in different languages of the Member States. As the Directives and Regulation that are considered have been developed over the past twenty years and some of the legal instruments are still developing, it is vital to consult the preparatory works like the White Papers and public consultation reports to fully gauge the intention and impact of the legal instruments in question.

Usually, the interpretation of EU law commences with a black letter law analysis, where the way in which the legal text is worded (Article 31(1) of VCLT (ordinary meaning/grammatical interpretation)), is given prominence while interpreting the law. However, it is possible that at times, especially if the law is framed in many different languages, it becomes difficult to interpret the law. This is relevant in the context of the EU, where the law is framed in varied languages.²⁵² A note of caution that is exercised while interpreting EU law is the fact that the EU law exists in different languages of the Member States and each language version

²⁴⁹ Special Focus Issue, Rules of Interpretation (Article 32 of the Vienna Convention on the Law of Treaties), Makane Moïse Mbengue, ICSID Reviews, Vol. 31, No. 2 (2016), 388-412.

²⁵⁰ See von Savigny, F. C. (1847). *System des heutigen römischen Rechts* (Vol. 6). Veit. 206.

²⁵¹ Article 33 (4) VCLT, 1969.

²⁵² For example, the EU Directives and Regulations are framed in all languages of the Member States.

carries equal weight. If a situation arises where confusion occurs as a result of the wording of the legal text, other methods of interpretation may become necessary.

In such circumstances, the teleological method of interpretation is usually employed.²⁵³ The teleological interpretation (Article 31 (1), VCLT) seeks to interpret the law, keeping the goals or original purpose of the text in context. The purpose of the legal texts may be revealed in the preparatory acts, and in the case of the EU law in the recitals of the legal instrument. The recitals of the EU legal instruments, located in the preamble reveal the intentions of the framers of the instruments, as well as set out the goals that are expected to be accomplished through the legal act. Although the recitals do not have any binding effect, they play a significant role, especially in the interpretation of the legal instruments. For the purposes of this thesis, the teleological method is especially relevant for discussing the second objective of the thesis – the analysis of whether the legal instruments containing provisions to combat counterfeiting and falsification of medicines in the EU have been successful in meeting the social objectives of public health and consumer protection in the EU.

It is important to note that the four legal methods of interpretation collectively called the classic tools of interpretation are fluid and are not mutually exclusive. Therefore, in practice, all four methods may be simultaneously employed in the interpretation of EU law in no hierarchical manner. However, in case of any doubt, the Court of the European Union (CJEU) has ruled that the reasonable purpose of the provision in question should be determined.²⁵⁴

²⁵³ Mankowski, P. (2012). *Brussels I Regulation*. Munich. 34-38.

²⁵⁴ Mankowski, P. (2012). *Brussels I Regulation*. Munich.35.

2.3.5. Challenges of the legal sources

The thesis uses both primary and secondary sources of EU Law. Amongst the primary sources of law, the TEU, the TFEU and the CFREU are employed. The provisions in the triad, especially those measures concerning the goals of the Single Market,²⁵⁵ the public health,²⁵⁶ and consumer protection²⁵⁷ aims of the Union and the Fundamental Rights to life,²⁵⁸ health²⁵⁹ and intellectual property²⁶⁰ set the broad parameters for the thesis.

The two Directives (FMD, Enforcement Directive) and one Regulation (Customs Regulation) form the secondary sources of law. As evident, each legal instrument – Falsified Medicines Directive and Enforcement Directive and the Customs Regulation – has its individual goals. The goal of the FMD is to ensure public health and safety, whereas the Enforcement Directive and the Customs Regulation deal with enforcement of IP rights.

This leads to two major considerations; the first vital aspect relates to the fact that the FMD deals with Public law and is concerned with public health and safety, while the Enforcement Directive and Customs Regulation deal with enforcement of private rights, such as trademarks rights. Therefore, fundamentally there are some differences in the sources of law. While ‘private law’ regulates horizontal relationships²⁶¹ between private parties (citizens, companies) or between the State playing the role in private – law capacity, and citizens, the public law regulates

²⁵⁵ Articles 26 and 114 TFEU.

²⁵⁶ Article 168 TFEU.

²⁵⁷ Article 169 TFEU.

²⁵⁸ Article 2, CFREU.

²⁵⁹ Article 35 CFREU.

²⁶⁰ Article 17(2) CFREU.

²⁶¹ Gauttier, P. (2004). Horizontal coherence and the external competences of the European Union. *European law journal*, 10(1), 23-41.

vertical relationships, where the State exercises powers in relation to citizens or companies.²⁶² Also, whenever public law comes into play, the State adopts the responsibility to protect the greater good of the public and takes initiative to prevent public harm. On the other hand, the enforcement of private rights always involves initiative that needs to be taken by the individual.²⁶³

Therefore, there is a clear distinction between the manner in which FMD operates, which is State led and the manner in which the Enforcement Directive and Customs Regulations work, which is enforcement of private rights.²⁶⁴

The second important general consideration is that the anti-counterfeiting measures are deduced from these three legal instruments, none of which aim at explicitly weeding out counterfeiting of medicines from the EU. The Falsified Medicines Directive states that it does not aim at combatting counterfeiting but only falsified medicines from the legal supply chain. The Enforcement Directive and the Customs Regulation deal with enforcement of IP rights. Although the aforementioned legal instruments recognise that counterfeiting and piracy is a problem and the legal instruments have the goal of fighting counterfeiting and piracy in general but only in terms of IP, as a whole.

The sources of law employed in the thesis are diverse and disparate. With specific reference to the secondary legislation, the three different streams of law – IP law, Medicine Law and Criminal law, and specific focus has been on two of the three

²⁶² Study Group on Social Justice in European Contract Law, 'Social Justice in European Contract Law: a Manifesto', *European Law Journal* 10.6(2004).653-674.

²⁶³ It is recognised that the ED states that the actions can be initiated by Groups and organisations.

²⁶⁴ Schulze, R., & Schulte-Nölke, H. (Eds.). (2011). *European Private Law-Current Status and Perspectives* (No. 1). Walter de Gruyter; Sell, S. K. (2003). *Private power, public law: the globalization of intellectual property rights* (Vol. 88). Cambridge University Press.

streams. The challenge has been that the individual goals of the types of law are different. While on the one hand, the FMD falls under the category of public law, the Enforcement Directive and the Customs Regulation enforce private rights of the citizens.

Secondly, there is negligible amount of case law, trustworthy empirical data and authentic statistics on the topic of counterfeiting and falsification of medicines because it is intrinsically a fast moving, behind the closed door type of illegal activity that hardly leaves any paper trail. Therefore, in Chapter 3, in one of the case studies, reliance is placed on a report – White paper on operation Volcano that has been written by the Italian Medicines Agency together with medicines’ agencies of other Member States.²⁶⁵ For the other two case studies, reliance was placed on the case law. These legal case studies were supplemented by discussions with the representatives of the medicines agencies of Italy and the UK and head of investigations of operation Robin, Customs and Law Enforcement Agency in Sweden.²⁶⁶ The case law was supplemented by confidential case notes and preparatory documents made available.

Against the backdrop of these sources of law and in the light of the case studies, the thesis will analyse as to how counterfeiting and falsification of medicinal products are governed by the legal instruments – Falsified Medicines Directive, Enforcement Directive and the Customs Regulation in the EU.

²⁶⁵ White Paper on Operation Volcano, The Herceptin Case: story, lesson learned, proposals, AIFA, AEMPS, AGES, ICZ, MHRA. (2015).

²⁶⁶ Discussions were carried out with Dr. Domenico Di, (AIFA, Italy), Ms. Lina Andersson (Head of investigations, Swedish customs and law enforcement, Sweden) and Mr. Alastair Jeffery (MHRA, UK).

2.4. Method

2.4.1. Legal dogmatic method

The traditional legal method, also known as the legal dogmatic method or doctrinal analysis is essential to the thesis for identifying the relevant sources of law that govern counterfeiting and falsification of medicinal products and is employed in Part III and IV of the thesis. This is followed by analysis of the legal sources, wherein considering issues that are identified in the preceding chapter, these sources are weighed against each other in accordance with the doctrine of sources of law, as traditionally carried out in the legal dogmatic method for analysing whether the legal instruments that govern counterfeiting and falsification of medicines meet the social objectives of public health and consumer protection as envisaged in the TFEU, which are identified as the higher norm.

The legal dogmatic method is in consonance with the theory of legal positivism, which is the guiding philosophy of the thesis as legal dogmatic method typically relates to the elucidation of law as adopted by a recognised the law making body. In Part III of the thesis, the Falsified Medicines Directive (Directive 2011/62/EU), the Enforcement Directive (Directive 2004/48/EC) and the Customs Regulation (Regulation 608/2013) are analysed in the context of combatting counterfeiting and falsification of medicines in the EU using the legal dogmatic method. Initially, the provisions that are relevant for addressing counterfeiting and falsification of medicines are identified in the three legal instruments. Thereafter, the relevant provisions of the legal instruments are analysed with the focus on finding the gaps. Finally, the last chapter in Part III analyses some of the global initiatives that have been taken in the context of combatting counterfeiting and falsification of

medicine, such as the Medicrime Convention, ACTA and a few multilateral and bilateral agreements. The legal dogmatic method is also used in Part IV of the thesis, when the second objective of the thesis is analysed. In Part IV of the thesis, it is analysed if the law governing counterfeiting and falsification of medicines in the EU meets the social objectives of public health (Articles 9 and 168) and consumer protection (Articles 12 and 169) as envisaged in the TFEU. The provisions of the TFEU are identified as the ‘higher norm’ against which the secondary instruments are measured.

In the thesis, three different streams of law (IP law, Medicine law and Criminal law) intersect while dealing with the problem of counterfeit and falsified medicines. Also, there is a plurality of legal sources (Conventions, Directives, Regulations, Guidelines, etc.) and players (medicines agencies, police, customs authorities, IP right holders). The problem of divided competence between different laws and agencies that implement the law while resolving the problem of counterfeit and falsified medicines is difficult to address.

Furthermore, the effect of multi-level and multi-disciplinary regulation of dealing with the issue of counterfeiting and falsification of medicinal products lead to several basic norms (in IP law and Medicine law) that can be dealt with separately or tackled in an integrated manner. The thesis propagates the integrated approach where the issues are collectively tackled rather than individually. By integrated approach, it is implied that the problem of counterfeiting and falsification of medicinal products is looked at as two sides of the same coin, where counterfeiting is one side and falsification is the other. It needs to be asserted that the tools to combat this problem are spread in different legal instruments. However, while analysing, if the social objectives of public health and consumer

protection are met, the legal instruments are analysed collectively in a concurrent manner.

2.4.2. Case study method

The Case studies method is employed in Part II of the thesis, wherein three different legal ‘Operations’ are discussed.

Operation Name	Court case /Report	Country
Operation Volcano	White Paper on Operation Volcano, Herceptin case - Story, lesson learned, proposals, 2014, (AIFA, AEMPS, AGES, ICZ, MHRA)	Italy
Operation Singapore	Court case: R. v Gillespie (Peter Hugh), [2012] 2 Cr. App. R. (S.) 24 (2011)	U.K.
Operation Robin	Court case: Case No. B 6262 -12, Stockholms Tingsrätt Judgment of 2013-06-25.	Sweden

Table 1

Case studies, as a tool for research, have been used in social sciences for a long time and occupy a rather vexed position.²⁶⁷ Some methodologists question the validity of case study research²⁶⁸ as they question how a few examples can be illustrative of a broad reality. On the other hand, a large number of case studies continue to appear and have attained a position of classic works.²⁶⁹ As recent scholarly works indicate, case study research continues to thrive and is not limited to political science, IT or Business Management. Moreover, political economists

²⁶⁷ John, G. (2005). What is a case study and what is it good for? *American Political Science Review*, Vol. 98. No.2.

²⁶⁸ *ibid.*, 341.

²⁶⁹ Allen, William, S. (1965). *The Nazi Seizure of Power: The Experience of a Single German Town, 1930-1935*. New York: Watts. See also Johnson, Chalmers. (1983). *MITI and the Japanese Miracle: The Growth of Industrial Policy, 1925-1975*. Stanford University Press; and Pressman, J. L., & Aron, W. (1973). *Implementation*. Berkeley: University of California Press.

and others²⁷⁰ are also adopting case study research. The reason for the continued use of case studies in different streams of research is because of the added value they generate in the discipline. When the term ‘legal case study method’ is used, it is sometimes confused with legal case study method of teaching, in legal studies. In this thesis, the term used is ‘case study method’ in order to distinguish it from the method of teaching law. In legal research, case study method is encouraged as it has borne significant results.²⁷¹

A case study has been defined in numerous ways. To some, it means that the method is qualitatively small,²⁷² to others it means that the research features tracing a process;²⁷³ and to a few others, it can mean that the research investigates the properties of a single case.²⁷⁴ However, for the purposes of this thesis, the case studies in Chapter 3 are understood “...as complex examples which give an insight into the context of a problem as well as illustrating the main point”.²⁷⁵

The legal case studies used in this thesis serve the purpose of illustrating the most common ways in which counterfeit and falsified medicines enter the legal supply chain and end up in the hands of the consumers. The case studies employed in the thesis are three different ‘operations’ carried out in three different EU Member

²⁷⁰ Acemoglu, Daron, Simon, J., & James, A. R. (2003). An African Success Story: Botswana. *In search of Prosperity: Analytic Narratives on Economic Growth*, ed. Dani Rodrik. Princeton, NJ: Princeton University Press, 80-122; Bates, Robert, H., Avner, G., Margaret, L., Jean-Laurent, R., & Barry, W. (1998). *Analytic Narratives*. Princeton University Press; Rodrik, Dani (ed.). (2003). *In Search of Prosperity: Analytic Narratives on Economic Growth*. Princeton, NJ: Princeton University Press.

²⁷¹ See more in Webley, L. (2016). Stumbling Blocks in Empirical Legal Research: Case Study Research. *Law and Method*.

²⁷² Yin, Robert, K. (1994). *Case Study Research: Design and Methods*, Newbury Park, CA: Sage.

²⁷³ George, Alexander, L., & Andrew, B. (2004). *Case studies and Theory Development*, Cambridge, MA: MIT Press.

²⁷⁴ Campbell, D. T., & Stanley, J. C. (1966). Experimental and quasi-experimental designs for research. *Handbook of research on teaching* (NL Gage, Ed.), 171-246. See also Eckstein, Harry. (1975) 1992. Case Studies and Theory in Political Science. *In Regarding Politics: Essays on Political Theory, Stability, and Change*. Berkeley, University of California Press.

²⁷⁵ Fry, H., Ketteridge, S., & Marshall S. (1999). *A Handbook for Teaching and Learning in Higher Education*, Kogan Page, Glasgow. 408.

States and are based on real court cases, involving surrounding circumstances as well, in order to provide a full picture. Two of the three case studies are based on case law and one of them is based on White Paper produced by the medicines agency. Also, one of the operations revolves around counterfeiting and falsification orchestrated by a specific group of people. The number of medicines involved can vary and, the number of legal cases, if spread in different countries, can also differ.

The information for undertaking the case analysis is based on the case law from within the EU and is supplemented by confidential case notes obtained from the national competent authorities of the respective countries. These case studies were chosen amongst many other cases as these cases are the largest, in terms of scale and are also few of the well-documented cases in the EU.

The case study method is used in order to provide an insight into the context of the typical ways in which counterfeiting and falsification of medicines take place and for identifying the core issues that need to be addressed through the legal framework in the EU. The case study method was particularly chosen to study counterfeiting and falsification of medicines also because being an illegal activity, it typically occurs behind closed doors, and does not leave traces behind.

Therefore, it is difficult to obtain authentic data and statistics on this issue.

However, the lack of case law in the EU does not necessarily indicate that counterfeiting and falsification of medicines do not occur. In fact, it is indicative of the fact that it is extremely difficult to obtain evidence and hence, the cases generally fall through due to the lack of evidence. This activity is usually carried out by people having sophisticated knowledge of the pharmaceutical sector and financial structures, as will become apparent from the case studies. Therefore, the profile of the criminals in counterfeiting and falsification of medicines is unique.

Therefore, case study method facilitates exploring the full picture which will assist in the legal analysis.

Operation Volcano (based on the White Paper produced by the Italian Medicines Agency)

The first operation, ‘Operation Volcano’²⁷⁶ was headed by the Italian authorities, which illustrated the manner in which Herceptin, a cancer treatment drug was stolen from the legal supply chain, involving local organised criminals. After being stolen, the same drug was injected with falsified substances and re-introduced in the legal supply chain. It was intercepted in Germany but by then, the drug had already travelled from Italy to the UK and then to Germany. This case study comprises of several cases and is based on a White Paper produced by the Italian Medicines Agency,²⁷⁷ with contributions and comments by the MHRA and a few other recognised bodies. It is recognised that a Report produced by an Agency can be biased, but its value cannot be underestimated. It exposed the mechanisms that are followed by criminals and the successful measures adopted by the authorities that may be replicated.²⁷⁸

Operation Singapore (R. v Gillespie (Peter Hugh), [2012] 2 Cr. App. R. (S.) 24 (2011))

The second case study, ‘Operation Singapore’²⁷⁹ was led by the MHRA, the British Medicines authority and is based on Crown Court Case.²⁸⁰ This operation

²⁷⁶ See more in Chapter 3, Section 3.2 on Operation Volcano – The Herceptin Case, AIFA (Italian Medicines Agency), 2015.

²⁷⁷ *ibid.*

²⁷⁸ See more in Chapter 3, Section 3.2 on Operation Volcano – The Herceptin Case, AIFA (Italian Medicines Agency), 2015.

²⁷⁹ See more in Chapter 3, Section 3.3 on Operation Singapore is the name given to the case *Regina v Peter Gillespie, Richard Kemp, James Quinn, Ian Gillespie and Ian Harding, The Crown Court sitting at Croydon*, 2010. Confidential case notes.

involved the import of medicines from Asia, which landed in Belgium and were transported over land and arrived in Britain. In Britain, these medicinal products were assembled and then re-introduced in the legal supply chain. It involved a multitude of players, and some of them were aware of the illegal activity. However, there were other players who were hired for specific market activity, such as printing packaging material and were unaware of the counterfeiting process.

Operation Robin (Case No. B 6262 -12, Stockholms Tingsrätt Judgment of 2013-06-25)

The third case study considered in the thesis to illustrate the problem of counterfeiting in the EU is ‘Operation Robin’,²⁸¹ which was spearheaded by the Swedish customs’ authority. This district court case²⁸² exposed a complex, specialised and well-organised network of people executing the crime of counterfeiting. The investigation involved cooperation between more than thirty countries. It also confirmed that small consignments using postal services have become the preferred mode of transporting counterfeit medicine in the EU and also brought other factors to light.

The legal case studies will intrinsically contribute to explain the particulars of the cases, as well as highlight similarities in the cases across different countries in a comparative manner. The three different operations used are illustrative legal case studies²⁸³ that will provide evidence of how three different countries within the

²⁸⁰ *ibid.*

²⁸¹ EUROPOL & OHIM. (June 2013). Reports and Conclusions, Knowledge Building in IP Enforcement, Combating Pharmacrime A knowledge –building Conference on Counterfeit Medicines. Alicante. Spain.16.

²⁸² Case No. B 6262 -12, Stockholms Tingsrätt Judgment of 2013-06-25.

²⁸³ Illustrative case studies are primarily descriptive studies. They typically utilize one or two instances of an event

EU grappled with the problem of counterfeit and falsified medicine and will underline the gaps in the legal framework.

2.5. Concluding remarks

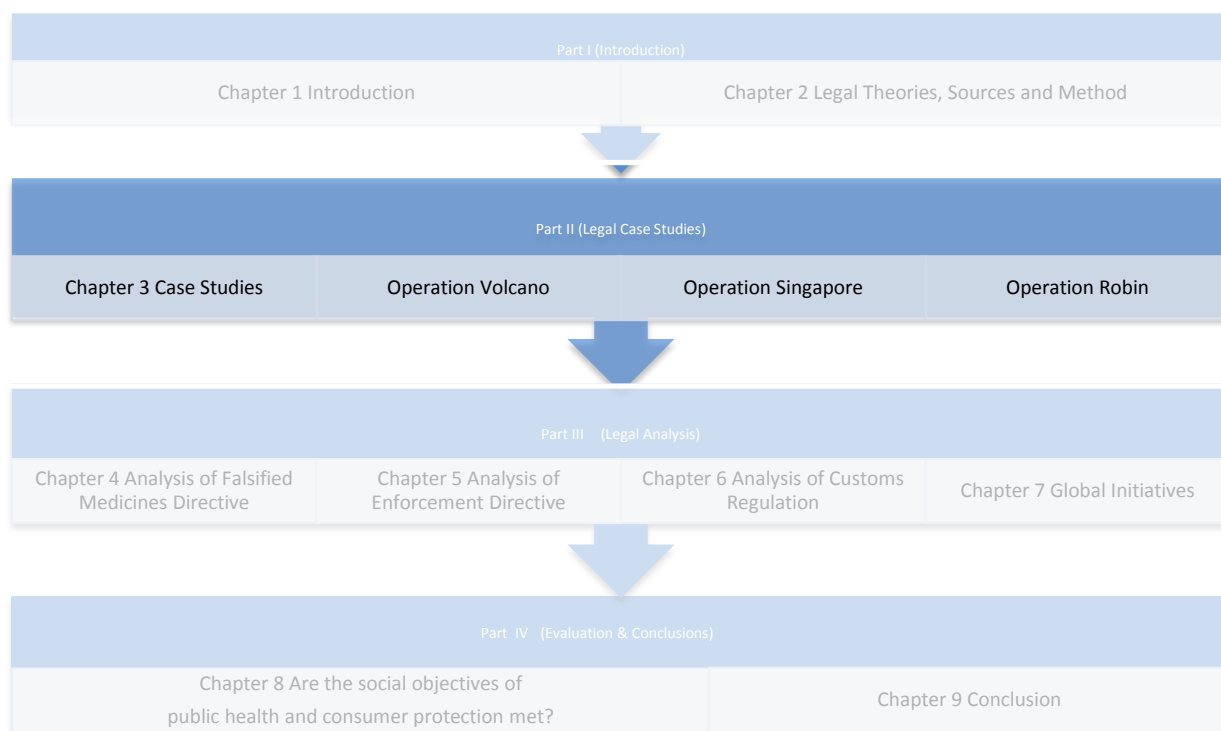
This chapter shed light on the theory that is employed, legal sources of law that are consulted, and the methods that are followed in the thesis. The primary objectives of the thesis are to analyse how counterfeiting and falsification of medicinal products is addressed by law (Directive 2011/62/EU, Directive 2004/48/EC and Regulation 608/2013) in the EU, and to analyse whether the law that contains tools to combat counterfeiting and falsification of medicinal products meets the social objectives of public health (Articles 9 and 168) and consumer protection (Articles 12 and 169) of the Treaty on Functioning of the European Union.

In order to do so, the theory of legal positivism (discussed in Section 2.2) serves as the guiding philosophy in the thesis. In addition, the sources of law relied upon were discussed in this chapter, wherein the primary sources of law – the TEU, the TFEU and the CFREU, which set the overall parameters, and the secondary legislation – the Directive 2011/62/EU, the Directive 2004/48/EC and the Regulation 608/2013 that contains tools to combat counterfeiting and falsification of medicines, were introduced. These legal instruments along with global initiatives taken in context of counterfeiting and falsification of medicines are analysed in Part III, using legal dogmatic method (discussed in Section 2.4.1). The case study method (discussed in Section 2.4.2) is used in the following Part II, in

to demonstrate a situation. Illustrative case studies serve primarily to make the unfamiliar familiar and to give readers a common language about the topic in question.

which the chapter on legal case studies sets the context and illustrates the issue of counterfeiting and falsification of medicinal products in the EU.

Part II: Legal Case studies



Part II is composed of one chapter on the legal case studies. Using the case study method, three different cases are analysed. The primary purpose of this chapter is to set the context of counterfeiting and falsification of medicines in the EU through the use of authentic cases for illustrating how counterfeiting and falsification of medicines transpires. These legal case studies will be instrumental in identifying the common issues and gaps that need to be addressed by the legal framework. The first case study, Operation Volcano is based on the White paper written by the Medicines Agency in Italy and is based on several cases connected to one crime in Italy, involving theft of a cancer treatment drug and how that entered the legal supply chain after being manipulated. The second case study is based on a court case in the UK, also known as Operation Singapore and was led by the Medicines and Healthcare Products Regulatory Agency (MHRA). It

involved counterfeit and falsified medicines entering the EU from China via Belgium into the UK. After repackaging of these medicinal products in the UK, these were planted in the legal supply chain. The third case study is based on a District court case from Sweden, which involved sale of counterfeit medicinal products over the internet. After the medicinal products were manipulated, they were offered for sale through three websites.

Chapter 3: Legal Case Studies

3.1 Introduction

The purpose of this chapter is to illustrate how counterfeit and falsified drugs can find their way into the hands of potential patients, based on legal case studies spanning the past decade within three EU Member States – Italy, Sweden, and the UK. As explained in Chapter 2, in this thesis, the term case study is used, as understood by Fry et al.,²⁸⁴ as ‘an example that provides insight, sets the context of a problem and illustrates the main point.’²⁸⁵ In other words, the legal case studies discussed in this chapter have the primary goal of setting the context of the problem of counterfeiting and falsification of medicines, explaining how it typically transpires from the beginning to the end and underlines the main issues that have not been covered by the legal instruments. Thereby, highlighting the gaps that exist in the legal framework that combats counterfeiting and falsification of medicines in the EU. The larger goal is to utilise the gaps that are discovered in this chapter as guiding parameters for analysing the legal instruments.

The counterfeiting and falsification of medicines take place in diverse ways – as ‘transnational organised crime,’²⁸⁶ involving a well-organised company with decentralised structures and documentation for each action,²⁸⁷ as close knit family

²⁸⁴ Fry, H., Ketteridge, S., & Marshall S. (1999). *A Handbook for Teaching and Learning in Higher Education*, Kogan Page, Glasgow.

²⁸⁵ See further explanation in Chapter 2, section 2.2.

²⁸⁶ Attaran, A., Bate, R., & Kendall, M. (2011). Why and how to make an international crime of medicine counterfeiting. *Journal of International Criminal Justice*, 9(2), 325-354; Bate, R. (2012). *Phake: the deadly world of falsified and substandard medicines*. AEI Press; Lavorgna, A. (2015). The online trade in counterfeit pharmaceuticals: new criminal opportunities, trends and challenges. *European Journal of Criminology*, 12(2), 226 - 241.

²⁸⁷ See Section 3.4. Operation Robin.

business,²⁸⁸ as fake doctor run business,²⁸⁹ as gym business,²⁹⁰ and also as an online business.²⁹¹ Therefore, there is evidence to support the view that the counterfeiting and falsification of medicine is also carried out by small enterprises²⁹² and not only by big organised structures at transnational levels.²⁹³

This chapter highlights some of the common ways in which falsified counterfeit medicines enter the legal supply chain, the actors that are involved and the pathways that are adopted. In order to combat falsification and counterfeiting in the pharmaceutical sector, it is pertinent to understand the entire story from the beginning to the end. This is the first step towards finding a solution. After uncovering ‘what’ the problem is, the current state of laws governing the area of counterfeiting and falsification of medicines will be assessed in Part III.

In this chapter, the focus will be on three case studies that were selected from amongst many instances of counterfeiting of medicines in the EU.²⁹⁴ Between 2007 and 2015, three different operations - Operation Volcano (Italy); Operation Singapore (the UK); and Operation Robin (Sweden), took place in Europe.

²⁸⁸ Case 2 (UK) & Case 4 (the Netherlands) in Hall, A., Koenraadt, R., & Antonopoulos, G. A. (2017). Illicit pharmaceutical networks in Europe: organising the illicit medicine market in the United Kingdom and the Netherlands. *Trends in Organised Crime*, 1-20.

²⁸⁹ Case 3 (Netherlands) *Source*: Dutch prosecution service, Hall, A., Koenraadt, R., & Antonopoulos, G. A. (2017). Illicit pharmaceutical networks in Europe: organising the illicit medicine market in the United Kingdom and the Netherlands. *Trends in Organised Crime*, 1-20.

²⁹⁰ *ibid.*, Case 5 (UK) *Source*: MHRA case files.

²⁹¹ *See* Section 3.4. Operation Robin.

²⁹² Paoli, L. (2016). Towards a Theory of Organised Crime: Some Preliminary Reflections. In *Illegal Entrepreneurship, Organised Crime and Social Control*. Springer International Publishing. 3-17.

²⁹³ Attaran, A., Bate, R., & Kendall, M. (2011). Why and how to make an international crime of medicine counterfeiting. *Journal of International Criminal Justice*, 9(2), 325-354; Bate, R. (2012). *Phake: the deadly world of falsified and substandard medicines*. AEI Press; Lavorgna, A. (2015). The online trade in counterfeit pharmaceuticals: new criminal opportunities, trends and challenges. *European Journal of Criminology*, 12(2), 226-241.

²⁹⁴ A few other examples of counterfeiting and falsification of medicines are available from the (AIFA) communication issued, are Alimta (Germany, Chez Republic, The Netherlands); Avastin (The United Kingdom, Switzerland, Germany, The Netherlands), Avonex (Germany, Sweden, Hungary). *Source*: AIFA case files.

Particularly, these cases were chosen as they were large in scale and comprehensively documented cases. Moreover, these were recent studies led by reliable Member States institutions like Medicines Agencies in Italy (Operation Volcano), MHRA in the UK (Operation Singapore) and the Customs Law Enforcement Authority in Sweden (Operation Robin). The common goal of all the three operations was to weed out counterfeit and falsified medicines from the legal supply chain.

All these operations are discussed in the subsequent sections using the case study method discussed in Chapter 2.²⁹⁵ The study of each of these case studies is called ‘operation’ because the analysis of each of the cases involves more than the one case in the Member State. For instance, though Operation Robin involves only one district court case from Sweden,²⁹⁶ it is more than the District Court case as it also encompasses the sentencing of an accomplice in Thailand. Similarly, in the Operation Singapore, reliance is placed on the Crown Court case and Court of Appeal’s decision in the UK.²⁹⁷ As opposed to Operation Singapore and Operation Robin, where facts are drawn from the proceedings of the court, while studying Operation Volcano (Italy), reliance is placed on the White Paper written by the AIFA²⁹⁸ (Italian Medicines Agency) as the court cases were not accessible. Moreover, the study of each case encompassed also studying the relevant cases that transpired in other countries, supplementary reports and confidential case files. The confidential case files, also employ the term ‘operation’ in the various Member States. The legal analysis conducted by the case law was supplemented

²⁹⁵ Case study method is discussed in Chapter 2, Section 2.4.2.

²⁹⁶ Case No. B 6262 -12, Judgement of Stockholms Tingsrätt of 25 June 2013.

²⁹⁷ *Regina v Gillespie and others* (2010), Crown Court at Croydon, UK; See also *Regina v Peter Hugh Gillespie* No. 2011/02816/B4 Court of Appeal Criminal Division 29 November 2011 [2011] EWCA Crim 3152.

²⁹⁸ Di Giorgio, D. (Director of Publication). (2015). White Paper on Operation Volcano, The Herceptin Case: story, lesson learned, proposals, AIFA, AEMPS, AGES, ICZ, MHRA. Rome, Agenzia Italiana del Farmaco.

by discussions with the representatives of the medicines agencies of Italy and the UK and head of investigations of Operation Robin, Customs and Law Enforcement Agency in Sweden.²⁹⁹ In the following sections these three operations, which are treated as case studies from three different Member States, are discussed.

3.2. Operation Volcano

3.2.1 Introduction

The first operation that will be assessed is Operation Volcano,³⁰⁰ also known as the ‘Herceptin case’³⁰¹ led by the *Agenzia Italiana del Farmaco* (the Italian Medicines Agency, henceforth ‘AIFA’). Herceptin³⁰² or the generic name³⁰³ *Trastuzumab* is a cancer treatment drug available only on prescription by a registered medical practitioner. The Operation was concluded in 2014 and revolves around the theft of legitimate medicines, stolen from a delivery truck on its way to deliver the medicine to an Italian hospital. These medicines were then tampered with and re-introduced in the legitimate supply chain.

²⁹⁹ Discussions were carried out with Dr. Domenico Di Giorgio, Counterfeit Prevention Unit Director, AIFA (Italy), Ms. Lina Andersson, Deputy Chief of Customs investigation. Swedish Customs and Law Enforcement (Sweden) and Mr. Alastair Jeffery, Head of Enforcement, MHRA, U.K.

³⁰⁰ Theft and laundering of medicines: early results of the AIFA project. The Herceptin case. (16 April 2014). Press release no.355.

³⁰¹ Herceptin case due to the name of the medicine – Herceptin that was stolen.

³⁰² Herceptin. (2013). EPAR- sammendrag for offentligheden. European Medicines Agency. EMA/444961/2013. London. U.K.

³⁰³ A generic medicine is a medicine is defined as follows by The World Health Organisation: *A generic drug is a pharmaceutical product, usually intended to be interchangeable with an innovator product that is manufactured without a license from the innovator company and marketed after the expiry date of the patent or other exclusive rights. Generic drugs are marketed under a non-proprietary or approved name rather than a proprietary or brand name. Generic drugs are frequently as effective as, but much cheaper than, brand-name drugs. The Trade-Related Aspects of Intellectual Property Rights (TRIPS) agreement does not prevent governments from requiring accurate labelling or allowing generic substitution. The use of the name is reserved exclusively for its owner.*

Between the year 2011 and 2015,³⁰⁴ there were reports of theft of medicines from hospitals and in the field, such as from delivery trucks, lorries and pharmacies in Italy.³⁰⁵ Such reports made rounds in the media³⁰⁶ and also inspired a University research project.³⁰⁷ As a result of the escalation in the theft of medicines, the AIFA established Counterfeit Prevention Unit with the collaboration of the industry in order to resolve the problem of medicine theft. In 2013, the “Theft project” was established and involved AIFA, *Farmaindustria* (manufacturers association), *ASSORAM* (warehousing services association), *Carabinieri NAS* (specialised police force), and was supported by the Ministry of Health in Italy. The Unit established a network with other similar agencies across Europe for the purpose of sharing information, drawing up blacklists of suspicious companies, lists of drugs that were rumoured to be compromised and lists of stolen batch numbers of drugs. This was done in order to understand the mechanisms of this criminal activity.

3.2.2. Factual background

In 2014, a few batches of Herceptin medicine (for the treatment of breast cancer and stomach cancer)³⁰⁸ were stolen from a truck delivering medicines to a hospital in Italy. In addition to Herceptin, the other medicines that were stolen were Alimta

³⁰⁴ AIFA case files. *Falsified, illegal and stolen medicines*. (2014)

³⁰⁵ Di Giorgio, D. (Director of Publication). (2015). White Paper on Operation Volcano, The Herceptin Case: story, lesson learned, proposals, AIFA, AEMPS, AGES, ICZ, MHRA. Rome, Agenzia Italiana del Farmaco.7.

³⁰⁶ Faucon, B., Plumridge, H. & Falconi, M. (1 May 2014). Italian Officials Probe Criminal Ties to Cancer Drug Theft: Investigators Find an Organised Criminal Ring Is Distributing Stolen Drugs in Western Europe. *In The Wall Street Journal*.

³⁰⁷ Riccardi, M., Dugato, M., Polizzotti, M., & Pecile, V. (2014). The theft of medicines from Italian hospitals. *Milan-Trento, Transcrime–Joint Research Centre on Transnational Crime*.

³⁰⁸ European Medicines Agency update on stolen vials of Herceptin, EU national Authorities and EMA cooperating in response to criminal activities. (17 April 2014). Batch numbers of the stolen Herceptin drug as revealed by the European Medicines Agency (EMA) H4311B07, H4329B01, H4284B04, H4319B02, H4324B03, H4196B01, H4271B01, H4301B09, H4303B01, H4143B01, H4293B01, H4180B01, N1010B02, Press Release, EMA/239072/2014.

(used for the treatment of lung cancer) and Remicade (used for the treatment of Crohn’s disease, ulcerative colitis, etc.).³⁰⁹ Local criminals were specifically hired for the purpose of executing the theft of medicinal products.³¹⁰ This theft of medicines in this precise manner was symptomatic of the general trend in Italy at that time.³¹¹ However, the masterminds behind the complex transaction were not directly involved in the execution of the theft of medicines and merely orchestrated the first step.³¹² The following figure encapsulates how the falsification took place (*Figure 4*).



Figure 4

After the local criminals stole the medicines from the delivery trucks, which were meant to deliver to the hospitals, these batches of Herceptin were transferred to an Italian licensed wholesaler using fake invoices.³¹³ These second level operators tampered with the medicines, which were manipulated in warehouses located in different parts of Italy. Three of such warehouses³¹⁴ were discovered in Naples,

³⁰⁹ *ibid.*

³¹⁰ Di Giorgio, D. (Director of Publication). (2015). White Paper on Operation Volcano, The Herceptin Case: story, lesson learned, proposals, AIFA, AEMPS, AGES, ICZ, MHRA. Rome, Agenzia Italiana del Farmaco.,12.

³¹¹ Thefts of Medicines, Trend of the phenomenon over the years. (2017).AIFA.

³¹² Riccardi, M., Dugato, M., Polizzotti, M., & Pecile, V. (2014). The theft of medicines from Italian hospitals. *Milan-Trento, Transcrime–Joint Research Centre on Transnational Crime*.

³¹³ Di Giorgio, D. (Director of Publication). (2015).White Paper on Operation Volcano, The Herceptin Case: story, lesson learned, proposals, AIFA, AEMPS, AGES, ICZ, MHRA. Rome, Agenzia Italiana del Farmaco.

³¹⁴ *ibid.*, 6.

where manipulations and tampering with the medicines were done on a regular basis. Thereafter, the licensed wholesalers created falsified receipts for shipment and subsequently shipped the products to bogus non-licensed wholesalers set up in the numerous EU Member States like Hungary, Latvia, Cyprus, and the Czech Republic.³¹⁵ It was later confirmed by the Italian authorities that these unlicensed wholesalers were part of a criminal organisation based in Italy and operated in the countries mentioned above.³¹⁶

These fake non-licensed wholesalers were the third level operators. It is believed that these “bogus operators” existed only on paper and the stolen medicines, which were tampered with never left the Italian shores in reality. The primary job of these third link operators was to contact authorised wholesalers in Italy and send them fake invoices. This was a way to “whitewash” the shipments.³¹⁷ The unauthorised operators’ *modus operandi* was aimed at legitimising the supply chain.³¹⁸ Later the investigations revealed the names and addresses of these “bogus wholesalers”, which were available in NUI³¹⁹ issued by the Italian authorities. For instance, Carnela Limited, Cyprus; Mars Distributions KFT, Hungary, Euroriga Med Import Export, Riga, Latvia; Zeapharma S.R.L., Romania, Exim AZ-sros, Slovak Republic; Pyramid D.O.O., Hildons Greece, Nixertron Iberica S.r.L., Italy.

These unauthorised operators, based in Cyprus, Hungary, Romania, Greece, Latvia, Slovak Republic and Italy, issued fake invoices under the pretence of selling the stolen medicines to legally authorised Italian operators – the fourth

³¹⁵ AIFA case files (August 8, 2014). (Rapid Alert issued by Agenzia Italiano del Farmaco,(AIFA).

³¹⁶ Di Giorgio, D. (Director of Publication). (2015). White Paper on Operation Volcano, The Herceptin Case: story, lesson learned, proposals, AIFA, AEMPS, AGES, ICZ, MHRA. Rome, Agenzia Italiana del Farmaco.

³¹⁷ *ibid.*, 11-12.

³¹⁸ *ibid.*

³¹⁹ *ibid.*, 11.

level operators. Investigations revealed the names of these “bogus operators” that directly bought medicines from the “bogus wholesalers”. The names of these fourth level “bogus operators” were revealed in a NUI³²⁰ issued by the Italian authorities - Pharma Global SrL, Napoli; Farmaceutica Internazionale SrL, Avellino; Farmacia Cozzolino di Mario & CIRO, S. N.C. Napoli; Pharma-Trade SPA, Pompei; Pharmasea Ltd, Malta.³²¹

These fourth level operators, based in Italy, who received the whitewashed and legitimised medicines from the “bogus operators”³²² based in the other EU Member States, sold to other authorised dealers in other Member States such as the UK, Germany, and Finland.³²³ In this specific case, the investigations revealed the names of these Italian operators that directly bought medicines from the “bogus wholesalers”. For instance, Pharma Global SrL, Napoli; Farmaceutica Internazionale SrL, Avellino; Farmacia Cozzolino di Mario & CIRO, S. N.C. Napoli; Pharma-Trade SPA, Pompei; and Pharmasea Ltd, Malta.³²⁴

When one such batch arrived in Germany, it was detected in March 2014. The German parallel distributor informed the Italian authorities³²⁵ that a medicine bearing a batch number that was circulated in the blacklist had arrived in Germany. This blacklist had been developed by the Italian Authorities in the wake of escalating theft of medicines from hospitals and pharmacies³²⁶ and as a part of AIFA’s efforts to detect and eliminate trade in counterfeit medicine. This blacklist

³²⁰ Di Giorgio, D. (Director of Publication). (2015). White Paper on Operation Volcano, The Herceptin Case: story, lesson learned, proposals, AIFA, AEMPS, AGES, ICZ, MHRA. Rome, Agenzia Italiana del Farmaco.

³²¹ Di Giorgio, D. (Director of Publication). (2015). White Paper on Operation Volcano, The Herceptin Case: story, lesson learned, proposals, AIFA, AEMPS, AGES, ICZ, MHRA. Rome, Agenzia Italiana del Farmaco.12.

³²² AIFA case files. (8 August 2014). List of bogus operators published by the AIFA.

³²³ AIFA case files. (April 2014). Roche communication, April 2014.

³²⁴ Di Giorgio, D. (Director of Publication). (2015). White Paper on Operation Volcano, The Herceptin Case: story, lesson learned, proposals, AIFA, AEMPS, AGES, ICZ, MHRA. Rome, Agenzia Italiana del Farmaco.12.

³²⁵ Counterfeit Prevention Unit created by AIFA.

³²⁶ As discussed in Section 3.2.1.

of stolen medicinal products from Italian hospitals and pharmacies along with related batch numbers was shared with relevant authorities of the Member States. There was also a watch list that was created for the Member States and an alert procedure was set up by the Italian authorities, which was circulated to interested Drug Regulatory Authorities (DRAs) and stakeholders in Europe, asking to report any suspected incidents involving the listed products to AIFA.³²⁷ Consequently, this particular falsified medicine – ‘Herceptin’ was detected because of this system set in place by the AIFA.

The German parallel distributor informed AIFA that this particular batch of Herceptin, which was received from an authorised wholesale parallel importer based in the U.K. and consisted of Herceptin 150 mg. There were clear signs that the medicines had been tampered with.³²⁸ Firstly, the batch numbers of the primary and secondary packaging were inconsistent. Secondly, even though the original product was in the form of a powder, the product in question was partially liquid. Thirdly, the container of the medicine that was seized revealed that there was some form of residue on the container. The batch numbers³²⁹ of the medicines were communicated and seized samples were sent to the manufacturer, Roche, for further analysis.

The next step was for the U.K. authorities, where the Medicines and Healthcare Regulatory Agency (MHRA)³³⁰ investigated the aspects of the matter pertaining to the U.K. wholesaler and the Italian authorities, NAS (specialised police force in

³²⁷ Database was also made available to industries and operators so that they could report and signals from the field: any suspicion about a medicine could be processed.

³²⁸ Di Giorgio, D. (Director of Publication). (2015). White Paper on Operation Volcano, The Herceptin Case: story, lesson learned, proposals, AIFA, AEMPS, AGES, ICZ, MHRA. Rome, Agenzia Italiana del Farmaco.9.

³²⁹ H4319B02; H4129B01; H4284B04.

³³⁰ The MHRA is an executive agency, sponsored by the Department of Health and regulates medicines, medical devices and blood components for transfusion in the UK.

Italy), to trace the stolen medicine using its database. The UK and Italian authorities worked in close cooperation to resolve the matter. NAS inspected the wholesalers in Italy who supplied to the UK wholesaler by scrutinising the invoices from the UK wholesaler.³³¹ Seizures were also made in Germany, Finland, and the UK.³³² The investigations conducted by the Italian authorities revealed that the batch numbers³³³ of medicine in question could be traced to a theft from a truck in Italy. AIFA further corroborated the evidence that the identification of the products was “illegally exported” and “falsified”.

The Italian authorities requested the authorities in the Member States in a NUI³³⁴ to communicate to the wholesalers, relevant institutions and parallel distributors in their territory to temporarily quarantine medicinal products that were bought from the unauthorised operators listed in the NUIs, until the results of the investigations were reached in accordance with the standard practice of the Medicines Directive.³³⁵

3.2.3 Revelations

The collective evidence revealed that there were significant distribution channels and that this was not a one-time case,³³⁶ in fact, it was a premeditated scheme. The

³³¹ It further came to light that there were also two other medical products that were detected – ALIMTA and Remicade. See Paul- Ehrlich Institut (PEI), an institution of the Federal Ministry of Health, Federal Republic of Germany (April 2014). *Aktuelle Informationen zu gestohlenen Herceptin-Fläschchen, Nach neuen Erkenntnissen sind auch Chargen des Arzneimittels Remicade betroffen*. Germany.

³³² Di Giorgio, D. (Director of Publication). (2015). White Paper on Operation Volcano, The Herceptin Case: story, lesson learned, proposals, AIFA, AEMPS, AGES, ICZ, MHRA. Rome, Agenzia Italiana del Farmaco.10.

³³³ AIFA case files. (14 August 2014). *Farmaci coinvolti in traffici illegali – Aggiornamento 14 agosto 2014*.

³³⁴ See Paul- Ehrlich Institut, an institution of the Federal Ministry of Health, Federal Republic of Germany (4 April 2014). *Aktuelle Informationen zu gestohlenen Herceptin-Fläschchen, Nach neuen Erkenntnissen sind auch Chargen des Arzneimittels Remicade betroffen*. Germany. *Follow-up information on suspected counterfeit of Herceptin 150 mg*.

³³⁵ Article 117(a) Directive 2001/83/EC.

³³⁶ Di Giorgio, D. (Director of Publication). (2015). White Paper on Operation Volcano, The Herceptin Case: story, lesson learned, proposals, AIFA, AEMPS, AGES, ICZ, MHRA. Rome, Agenzia Italiana del Farmaco.11; See also Riccardi, M., Dugato, M., Polizzotti, M., & Pecile, V. (2014). The theft of medicines from Italian hospitals. *Milan-Trento, Transcrime–Joint Research Centre on Transnational Crime*.

non-Italian wholesalers, apparently never questioned anything more than the Italian authorisation of the wholesaler. They apparently believed that they bought from a genuine wholesaler for selling medicines to the other Member States. They also claimed that as stated in the Good Distribution Practices (GDP) guidelines³³⁷ under Article 84 and 85b (3), the Medicines Directive that governs this area requires that wholesalers need to verify only the direct wholesalers they are buying from.

It is also evident from this particular case that life-saving drug for treatment of cancer was the target of counterfeiting and falsification. In the previous decade, the focus of counterfeiting and falsification was believed to be lifestyle drugs, such as weight loss tablets that were the target of counterfeiting.³³⁸ The highly developed and complex method of executing this criminal activity indicates that the motivation for steering this illegal activity was excessive profit and extremely low level of penalty for the commission of this crime.³³⁹ The decentralised system of execution (see *Figure 4*) where specialists were engaged at different steps - local criminals for carrying out the first step of stealing medicines; specialists for tampering with the medicines; unauthorised operators for issuing fake invoices - illustrates that the criminal masterminds had anticipated the way around the system. The path adopted by them made tracking the evidence long-winded, time-consuming and resource craving. There are strong indications that this is not the first case of its kind in Italy.³⁴⁰ Many of the cases went unnoticed because the

³³⁷ Guidelines of 5 November 2013 on Good Distribution Practice of medicinal products for human use (2013/C 343/01). Chapter 5, point 5.2.

³³⁸ Møldrup, C. (2004). The use of the terms 'lifestyle medicines' or 'lifestyle drugs'. *Pharmacy World and Science*, 26(4), 193-196.

³³⁹ Vander Beken, T. (Ed.). (2007). *The European pharmaceutical sector and crime vulnerabilities*. Maklu.

³⁴⁰ Riccardi, M., Dugato, M., Polizzotti, M., & Pecile, V. (2014). The theft of medicines from Italian hospitals. *Milan-Trento, Transcrime-Joint Research Centre on Transnational Crime*; See also Riccardi, M. (2014). When criminals invest in businesses: Are we looking in the right direction? An exploratory analysis of companies

cases were not traceable because of the tactics adopted by the criminals. However, some of the cases³⁴¹ did come to light later and many cases in the rest of Europe were revealed³⁴² as an aftermath of this case.

3.3 Operation Singapore

3.3.1 Introduction

Operation Singapore was one of the most serious breaches of the legitimate supply chain, in terms of the lifesaving drugs that were involved, as well as the sheer economic value of the medicines in the EU.³⁴³ It involved counterfeiting of three prescription only medicines - Plavix³⁴⁴ (*clopidogrel*), Zyprexa³⁴⁵ (*olanzapine*), and Casodex³⁴⁶ (*bicalutamide*), used for the treatment of psychosis, heart disease and prostate cancer, respectively in the UK. The investigation was headed by the MHRA in the U.K. and involved over twelve countries in the process, including the U.S.A., Belgium, China, and Singapore. Operation Singapore involved the counterfeit medicine entering the market disguised as legitimate medicines in the

controlled by mafias. In *Organised crime, corruption and crime prevention*. Springer International Publishing. 197-206.

³⁴¹ AIFA case files. (August 2014). “*The initial focus of the Italian investigation was on a small number of medicinal products; Herceptin, Remicade, Alimta, Avastin & Mabthera. The network was informed that there was no legitimate supply in the wholesaler supply chain for three of these medicinal products from Italian origin (Herceptin, Avastin and Mabthera), hence the initial alert issued by Germany and subsequent press statements by EMA.*”

³⁴² AIFA case files. (2014). A few examples from the AIFA communication issued are Alimta (Germany, Czech Republic, The Netherlands); Avastin (The United Kingdom, Switzerland, Germany, The Netherlands), Avonex (Germany, Sweden, Hungary).

³⁴³ Regina v. Gillespie and others. (2010). Crown Court at Croydon. Confidential case notes. It was discovered that 72,000 packs, 2.1 million doses which stand at a retail value of GBP 4.7 million were involved..

³⁴⁴ Plavix is the trade mark owned by Sanofi Aventis and is also a prescription only medicine and acts as an anti-platelet against and is used in the treatment of heart disease. It was sold at GBP 35.31 per 28 tablet package.

³⁴⁵ Zyprexa is the trade mark of a pharmaceutical owned by Eli Lilly and Company, used for bi-polar disorder and schizophrenia and is a prescription only medicine. It was sold at GBP 79.45 per 28 tablet package.

³⁴⁶ Casodex is the trade mark of a pharmaceutical owned by Astra Zeneca. It is also a prescription only medicine used in the treatment of advanced prostate cancer. It was sold at GBP 128 per 28 tablet package.

legitimate supply chain in the UK in 2006/2007.³⁴⁷ The case hinges upon the illegal importation and distribution of counterfeit medicines, by planting them into the legitimate supply chain with an intention to replace the branded genuine medicines at the pharmacists so that the falsified and counterfeit medicines reach the patient. After arrival in the U.K., from China, the tampering of their packaging began and thereafter, they were planted in the legitimate supply chain in the U.K.

Operation Singapore was a big investigation in magnitude³⁴⁸ to concrete facts and figures regarding trade in counterfeit medicines but also threw light on the social costs³⁴⁹ in the sense of damage to public health and safety. It was discovered that 72,000 packs, 2.1 million doses, which stand at a retail value of GBP 4.7 million were involved.³⁵⁰ The MHRA had to issue four Class 1 Recalls,³⁵¹ which needed immediate action as the product posed a life threatening risk to the patients. Even though the MHRA seized 40,000 packs before reaching pharmacies and 7000 packs were recovered after the recalls were issued, 25,000 packs (700,000 doses) reached the pharmacies and patients. The counterfeit products that were recovered contained between 50 %-80% of Active Pharmaceutical Ingredients (API)³⁵² along with unknown impurities. The counterfeits that were recovered resembled the original products to a great extent and could not be differentiated from the genuine

³⁴⁷ Jackson, G., Patel, S., & Khan, S. (2012). Assessing the problem of counterfeit medications in the United Kingdom. *International journal of clinical practice*, 66(3), 241-250.

³⁴⁸ 93 witnesses from six countries provided evidence at the trial and 205 witnesses made written statements with a four month Crown Court trial. Regina v. Gillespie and others. (2010). Crown Court at Croydon. Confidential case notes.

³⁴⁹ Majid, Y. A. R. (2008). The other global drugs crisis: Assessing the scope, impacts and drivers of the trade in dangerous counterfeit pharmaceuticals. *International journal of social inquiry*, 1, 151-166.

³⁵⁰ Regina v. Gillespie and others. (2010). Crown Court at Croydon. Confidential case notes. 7.

³⁵¹ The MHRA's Defective Medicines Report Centre (DMRC), issues alerts to healthcare professionals, General Practitioners, Hospitals, Surgeries, and wholesalers in order to inform about a medicine that may be a cause of concern with regard to its quality, effectiveness or safety. The alerts are graded with reference to the seriousness of the threat to public health, from Class 1 to Class 4, where Class 1 is the most serious form of recall.

Sources: Defective Medicines Report Centre. (2012). *Medicines & Medical Devices Regulation: What you need to know*. London MHRA. 14; See Glossary for explanation of the term Recall.

³⁵² See Glossary for explanation of the term API.

products on the basis of visual identification.

3.3.2 Factual background

This case³⁵³ involved three key figures- a British national (henceforth referred to as ‘B’), a French National (henceforth referred to as ‘F’) and a Chinese national (henceforth referred to as ‘C’). Amongst the three main players, it was concluded that B was the mastermind of the conspiracy and was the one who orchestrated the purchase, forging of documents, testing, financing, collection, relabelling and delivery of the counterfeit medicines.³⁵⁴ He also created a web of companies in different parts of the world to make the movement of medicines and money possible.³⁵⁵ He was an ex-pharmaceutical parallel importer and a licensed wholesaler. His previous convictions included Medicines Act Offences in mid-1990s.³⁵⁶ In 2005, he was arrested in the context with a £2 million fraud on the Royal Bank of Scotland. B understood the pharmaceutical market well, worked together with a group of people having a variety of skill sets and also tested falsified medicines and exported riskiest products to the United Arab Emirates (UAE).³⁵⁷

B worked together with the French national ‘F’, (who was later arrested in Spain and extradited to France). F was involved in smuggling falsified high-value cancer products from China through Turkey, Switzerland, Germany, Malta and UK. His

³⁵³ See also *R. v Gillespie* (Peter Hugh), Court of Appeal (Criminal Division) 29 November [2011] EWCA Crime 3152; [2012] 2 Cr. App. R. (S.) 24.

³⁵⁴ *R v Gillespie and others*, United Nations Office of Drugs and Crime, UNODC No.: GBRx001.

³⁵⁵ See more in Almuzaini, T., Sammons, H., & Choonara, I. (2013). Substandard and falsified medicines in the UK: a retrospective review of drug alerts (2001–2011). *BMJ open*, 3(7), e002924.

³⁵⁶ *R v Gillespie and others*, United Nations Office of Drugs and Crime, UNODC No.: GBRx001.

³⁵⁷ *ibid.*

methods of operation involved shutting down companies³⁵⁸ and bank accounts, as soon as they were on the radar or were compromised. However, he would readily open new ones in the same city within a radius of 200 meters of the previous company/bank. Besides, F possibly had previous convictions for providing falsified HIV medicines to regions of French speaking West African countries.³⁵⁹

F was hand in glove with C,³⁶⁰ a man of Chinese origin. C was a well-travelled person, especially in Ukraine and had wide business interests, including mining. He traded industrial quantities of APIs and attended International Fine Chemical and API conventions. C also hired a number of specialists and was involved in online business and business forums. He had commenced his business with Viagra and Cialis and moved on to certain specific medical products. It was discovered that C used online chat rooms for communication.³⁶¹

The process started with the purchase of the counterfeit medicines for £1.4 million (the retail value of the medicines was £4.7 million) through a company based in Luxembourg. B was the owner and ran this company. F was the middleman between B (end market) and C (counterfeiter). He would procure genuine medicines and send them to C. C would reverse engineer the medicines and would ask for the batch number, expiry date and language on the packaging. The chatrooms, web based emails and line anonymisers (TOR nodes) were used to communicate, control the movement of medicines and oversee the movement of

³⁵⁸ See Davison, M. (2011). *Pharmaceutical anti-counterfeiting: combating the real danger from fake drugs*. John Wiley & Sons.

³⁵⁹ *R v Gillespie and others*, United Nations Office of Drugs and Crime, UNODC No.: GBRx001.

³⁶⁰ Kevin XU, owner of Orient Pacific International, based in China was caught in an undercover operation by the Immigration and Customs Enforcement (ICE), USA in 2007. The undercover agent was offered an unprecedented amount of medicines in a meeting in March 2007 in Bangkok, Thailand. *Source: R v Gillespie and others*, United Nations Office of Drugs and Crime, UNODC No.: GBRx001.

³⁶¹ *ibid.*

air freights. C³⁶² manufactured the counterfeit medicinal products and sent them from China via Hong Kong, Singapore, Belgium to the UK. They were brought by air to Belgium and via ferry/road to the UK. ³⁶³ There were nine instances of importation through this channel in a period of six months. There was a difference between the actual route that was adopted while transporting the counterfeit medicines and the route that was documented in the paper trail that was left. ³⁶⁴

After arriving in the UK, the medicines reached the warehouse through postal and courier traffic,³⁶⁵ where the medicines were repackaged and relabelled. The repackaging and relabelling process were coordinated by B.³⁶⁶ The goal seemed to be to disguise these counterfeit medicines as parallel traded medicinal products that were of ‘French origin’, including the vignette details,³⁶⁷ the medicine, the cost, the rate of reimbursement and a bar code. The medicines were relabelled and bore the appearance of medicine originating in France by re-packaging with French leaflets and putting the counterfeit vignettes labels used in France.³⁶⁸ Thereafter, these re-packaged medicines were sold to licensed wholesalers, who in good faith sold it to hospitals, clinics and care homes. In this manner, counterfeit

³⁶² C was detected in an undercover operation being carried out by the US authorities concerning falsified medicines. C met the US undercover agents in Bangkok to talk about supplying falsified medicines, where he proposed that he could provide falsified Zyprexa, Plavix and Casodex. US authorities informed the UK authorities about the ongoing investigations, based on which, the UK government recalled the medicines. C travelled to USA to supply the promised falsified medicines and was taken into custody upon arrival. His laptop, which was sent to the UK, for forensic analysis and the laptop revealed evidence of the sale of counterfeit medicine supplied to the UK. C was prosecuted in the US and was given 6 and half years of imprisonment by US District Court for the Southern District of Texas, Houston Division. He was convicted on the charges of conspiracy to traffic counterfeit goods (Zyprexa, Tamiflu, Casodex, Plavix, and Aricept and individual charges of dealing in misbranding drugs and charges of trafficking in counterfeit drugs. *Source: Regina v. Gillespie and others.* (2010). Crown Court at Croydon. Operation Singapore. Confidential case notes, paragraph 240, 81

³⁶³ *Regina v. Gillespie and others.* (2010). Crown Court at Croydon. Operation Singapore. Confidential case notes, paragraph 11(e), 6. paragraphs 238 -239, 79-81.

³⁶⁴ *ibid.*, paragraph 11 (f), 6.

³⁶⁵ *ibid.*, The last batch of counterfeit medicine was recovered at a warehouse in Slough.

³⁶⁶ *ibid.*

³⁶⁷ *ibid.*, The colour of the vignette is determined by reimbursement rate. They are significant and their presence vouches for that the medicinal products are from the French market.

³⁶⁸ *ibid.*, paragraph 68, 21.

medicines infiltrated the legal supply chain. The counterfeiting scam was discovered when a licensed re-packager noticed an error on a batch number and reported to the MHRA. The Trademark right holder, Eli Lilly had already set up an independent investigation into the Chinese manufacturer with the assistance of the US authorities at that time.

Therefore, a coordinated effort of more than twelve countries helped in unearthing the plot. The accused were charged with conspiracy, conspiracy to defraud; conspiracy to money laundering;³⁶⁹ fraudulent trading; trademarks offence,³⁷⁰ marketing authorisation offence, and disqualified director offence.³⁷¹ As a result of four years of investigation into one of the most lethal breach of the regulated supply chain in the U.K., where over 2 million doses of counterfeit medicine were involved, only one person was convicted and sentenced to eight years of imprisonment in the UK.³⁷² The Chinese national was sentenced to six and a half years jail in the US.³⁷³ However, the other accused along with B were cleared of any fraud.³⁷⁴

3.3.3. Revelations

Operation Singapore, led by the MHRA revealed that the legal supply chain in the UK was infiltrated by counterfeit drugs, disguised as parallel imported medicines from France. The medicinal products were falsified products imported from

³⁶⁹ Typically, it is connected to trade in counterfeit medicines. See more in Buckley, G. J., & Gostin, L. O. (Eds.). (2013). *Countering the problem of falsified and substandard drugs*. National Academies Press.

³⁷⁰ See more general explanation in Attaran, A., Bate, R., & Kendall, M. (2011). Why and how to make an international crime of medicine counterfeiting. *Journal of International Criminal Justice*, mqr005.

³⁷¹ MHRA case files, Operation Singapore, 2010, Paragraphs 293-302, 106-111.

³⁷² See for general trend in the UK for comparison: Medicines and Healthcare products Regulatory Agency. (2011); MHRA annual statistics 2010/2011. In *Safeguarding public health*. London. MHRA.

³⁷³ *R v Gillespie and others*, United Nations Office of Drugs and Crime, UNODC No.: GBRx01; See more in U.S. v. Xu, Not Reported in F.Supp.2d (2008).

³⁷⁴ *R. v Gillespie* (Peter Hugh), Court of Appeal (Criminal Division) 29 November [2011] EWCA Crim 3152; [2012] 2 Cr. App. R. (S.) 24; Official Transcript.

China. They were re-packaged and the act of counterfeiting occurred. This was facilitated by insertion of leaflets in French in the medicine boxes as well as by affixing the French vignettes on the packaging. Therefore, when the medicines were sold to unsuspecting wholesalers, the wholesalers could not tell the difference because of the uncanny similarity to the original product. After the counterfeit medicines manufactured in China arrived in the UK, the counterfeit medicines were repackaged and relabelled. This was a well-organised and premeditated operation as is evident in this set up of one mastermind contracting out the job to manufacture a product to a ‘counterfeiter’ in China. This counterfeiter in China supplied not only to Europe but also negotiated a deal to supply this life-saving cancer treatment medicine to the US as well. In the process, he was arrested by the US Customs.³⁷⁵

In addition to violating the Medicines law, the IPRs of the right holders were also violated - Sanofi Aventis (owner of the trademark ‘Plavix’), Elli Lilly (owner of the trademark ‘Zyprexa’, who was already conducting a private inquiry into the counterfeiter based in China) and Astra Zeneca (owner of the trademark ‘Casodex’ and ‘AZ’ and ‘AstraZeneca’). The counterfeit medicines were being portrayed as the authentic product, which is the unlawful adoption of the registered marks on the packaging that was done without the lawful consent of the owners of the registered mark.³⁷⁶

³⁷⁵ See more in *U.S. v. Xu*, Not Reported in F.Supp.2d (2008).

³⁷⁶ *Regina v. Gillespie and others*. (2010). Crown Court at Croydon. Operation Singapore. Confidential case notes, paragraph 300. 109-110.

3.4. Operation Robin

3.4.1 Introduction

Operation Robin,³⁷⁷ a covert operation that lasted for a year and a half was conducted by the Swedish Customs Law Enforcement Department. The investigations covered the period from January 2009 until May 2012. A minor offence of the seizure of cigarettes in June 2009 revealed the link to payments being made for steroids that led to the unravelling of a huge operation in falsified and counterfeit medicines. The analysis of the evidence, surveillance and documentation of bank accounts showed evidence of movement of approximately 450 million euros through Egypt, Hong Kong, Dubai, and Europe.³⁷⁸ Besides the offences of counterfeiting, falsification of medicines, money laundering in UAE, Marshall Islands, and the Cayman Islands, a complex smuggling operation of illegal medicinal products was revealed, employing small packets and parcels encompassing vast geographical expanse from Asia to Egypt to the U.K. to Denmark and then finally to Sweden.³⁷⁹

3.4.2. Factual background

The story began to unfold when a legal aid on a specific mission to Canada gained access to emails from 2007 to mid-2011 revealing that the production of steroids and falsified medicines were a well-organised crime being executed where Sweden and the rest of Scandinavia was the target audience.³⁸⁰ The organisation carrying out the Operation was very well organised, having a semblance of a

³⁷⁷ Case No. B 6262 -12, Judgement of Stockholms Tingsrätt of 25 June 2013.

³⁷⁸ *ibid.*

³⁷⁹ EUROPOL & OHIM. (June 2013). Reports and Conclusions, Knowledge Building in IP Enforcement, Combating Pharmacrime A knowledge –building Conference on Counterfeit Medicines. Alicante. Spain. 16.

³⁸⁰ Case No. B 6262 -12. Judgement of Stockholms Tingsrätt of 25 June 2013. Confidential case notes.

legitimate company.³⁸¹ They had four groups each being led by a head of operations for economy, distribution, sale and marketing. In addition, there was a coordinator, who was meant to oversee that all the different departments worked well together. The production design was specialised with each person having a specialised field of work, taking orders, packaging, production of illegal products, sending threats etc. The organisation was so specialised that there were policy documents for everything, weekly reports, stock reports and accounts were also maintained.

The *modus operandi* revealed that the raw materials or products were sent from Asia, especially China and Hong Kong, which sent APIs.³⁸² The parcels dispatched from Asia and Egypt³⁸³ were received in London, England in mailboxes.³⁸⁴ Thereafter, the parcels were sent to mailboxes in Berlin, Germany, while a few of the parcels ended up in Business Service Frederiksberg, Denmark. Using the UPS services, the parcels were then transported to Sweden. These parcels were driven from one fake address to another.³⁸⁵ In this process, a person was involved who picked up the parcel in person from Brevia, a mailbox company in Stockholm, Sweden. It was deduced that the person who collected the package stored it for a few days before dispatching it off to another address in Sweden.³⁸⁶

In January 2009, 102 kilos of pyrazinamide was seized in Stockholm and one man was apprehended with regard to the seizure. The same person received parcels containing equipment for making steroids, while still in custody. Simultaneously,

³⁸¹ Case No. B 6262 -12. Judgement of Stockholms Tingsrätt of 25 June 2013. Confidential case notes.

³⁸² See explanation in Glossary for APIs.

³⁸³ Case No. B 6262 -12, Judgement of Stockholms Tingsrätt of 25 June 2013, 76.

³⁸⁴ *ibid.*

³⁸⁵ *ibid.*

³⁸⁶ Case No. B 6262 -12, Judgement of Stockholms Tingsrätt of 25 June 2013.

another person received a tablet making machine. The authorities were able to trace every payment to the same bank account, which pointed the authorities in the right direction to resolve the case. An analysis of the bank account revealed transactions of big amounts. In June 2009, two containers filled with 18 million cigarettes were seized in a harbour in Stockholm. The payment of customs fee was traced to two bank accounts, and one of these bank accounts also made the payments for the steroids. The cross-examination of the owner of the container brought to light the fact that he had bought the steroids from an internet website.

In June 2011, a parcel containing 50,000 alprazolam and 20,000 tablets of Stanozolol was seized.³⁸⁷ The parcel was addressed to a fake address that was altered several times before it arrived at its final destination in Sweden. The payment for the transportation of the parcel was facilitated by faceless credit cards. The movement of the parcel was enabled by using postal and courier services such as DHL, UPS, and Swedish postal services. The authorities began tracing the smuggling routes and documented the parcels to see what was in it. The key confiscation was made on September 8, 2011, when the parcel labelled Global Iron Tech was intercepted and 200,000 labels of this brand were discovered. Global Iron Tech offered products for sale on the website called www.steroidakuten.org.

This seizure revealed to the authorities that the products were being manufactured/put together/assembled in Sweden at a warehouse at Borlänge.³⁸⁸ The parcel was sent back to the normal postal channel after the contents of the parcel were documented for. On September 16, 2011, the parcel was collected at

³⁸⁷ Case No. B 6262 -12, Judgement of Stockholms Tingsrätt of 25 June 2013.

³⁸⁸ Case No. B 6262 -12, Judgement of Stockholms Tingsrätt of 25 June 2013, 77.

Brevia³⁸⁹ by an unknown person. After another 12 days, the parcel was picked up at a post office in Borlänge, in the middle of Sweden. On the same day, the parcel arrived at its final destination, the factory producing liquid steroids. The means of transportation and communication was through mailbox companies such as ASA, DHL and UPS because these were faceless companies, where faceless credit cards and identities could be used in order to remain anonymous. Moreover, it would be difficult for the authorities to follow the consignments and discover the final destinations.³⁹⁰ In February 2012, a seizure at a dispatcher's house in Sweden led to the discovery of 700,000 units of steroids, 800 narcotic tablets, 35,000 tablets of falsified medicines, an encrypted computer and addressed envelopes and parcels containing medicines and steroids ready to be dispatched to customers.

The dots were connected when authorities executed an undercover operation to make the final bust. Three test purchases were made by the authorities from the different websites – Steriodakuten.org, Vikingstore.org and Anabolic.cc.³⁹¹ Instructions were strictly followed regarding payment and payment methods that gave further access to new bank accounts to be analysed. As instructed, a mailbox at Brevia was rented and illegal substances were delivered into the mailbox. The final coordinated bust³⁹² that simultaneously took place at several places in Sweden revealed that the illegal organisation had made 450 million euros by selling steroids and fake medicine between January 2009 and May 2012. The leaders and the head of the organisation had earned 350 million euro by selling steroids and fake medicines. The twelve workers had made approximately 50

³⁸⁹ Brevia is a rent a box company, which ensures a high level of confidentiality.

³⁹⁰ Case No. B 6262 -12, Judgement of Stockholms Tingsrätt of 25 June 2013, paragraph 4, 54.

³⁹¹ Case No. B 6262 -12, Judgement of Stockholms Tingsrätt of 25 June 2013, 47 - 50.

³⁹² The final bust took place on May 8, 2012. And assets worth 700,000 Euros were confiscated. *Source:* Case No. B 6262 -12. Judgement of Stockholms Tingsrätt of 25 June 2013. Confidential case notes.

million euros.³⁹³

The total seizures during Operation Robin amounted to 11 million units of active substances,³⁹⁴ 550,000 narcotic tablets and 3 kilos of narcotic powder, 610,000 tablets of falsified medicines, equipment for producing liquid steroids, labels, machines for making tablets and assets worth 70 million euros. In all, 23 people were sentenced³⁹⁵ to prison, with two people receiving 16 and 14 years of imprisonment. The four leaders were awarded life imprisonment in Thailand³⁹⁶ and another one received seven years prison sentence. During the Operation, besides steroids and narcotics, two steroid producing factories were also uncovered. The perpetrators were charged with drug trafficking and gross drug smuggling offence, gross doping crime, smuggling and violating of law on pharmaceuticals trade.

3.4.3. Revelations

Operation Robin led by the Swedish Customs and Law Enforcement Authority revealed that falsified medicines and counterfeit products were offered for sale over the internet by making use of three websites.³⁹⁷ The counterfeit APIs were imported from Asia that arrived in Sweden in small packets using postal and courier services. After arriving in the EU, these packets were sent from one mailbox in one Member State to another mailbox in another Member State several times, before they ended up in the factory in Borlänge.³⁹⁸ In the factory, these

³⁹³ Case No. B 6262 -12, Judgement of Stockholms Tingsrätt of 25 June 2013.

³⁹⁴ 11 million units of active substances imported from China, Hong Kong and Egypt, Case No. B 6262 -12, Judgement of Stockholms Tingsrätt of 25 June 2013, 50.

³⁹⁵ Case No. B 6262 -12, Judgement of Stockholms Tingsrätt of 25 June 2013, 1.

³⁹⁶ Case No. B 6262 -12, Judgement of Stockholms Tingsrätt of 25 June 2013, 90.

³⁹⁷ Case No. B 6262 -12, Judgement of Stockholms Tingsrätt of 25 June 2013: www.steriodakuten.org, www.vikingstore.org, and www.anabolic.cc.

³⁹⁸ Case No. B 6262 -12, Judgement of Stockholms Tingsrätt of 25 June 2013.

products were put together and offered for sale through the websites. They were dispatched using the postal services. Operation Robin also revealed that the management was very well-organised and the structure of the organisation resembled the structure of a legitimate company with described and recorded work programs and flows.

As in other cases of falsification and counterfeiting of medicinal products, Operation Robin also sheds light on the elements of premeditation — well-structured and organised nature; use of small consignments for transportation; use of online method of sale and manipulation of products; and involvement of more than one country in the process of counterfeiting and falsification of the medicinal products.

3.5. Problems highlighted the case studies

An evaluation of Operation Volcano, Operation Singapore and Operation Robin reveals some similarities and certain differences in the manner in which counterfeit and falsified medicines are manufactured, marketed, sold and infiltrated in the legal supply chain. This section aims at detecting these patterns in order to discover the gaps in the legal framework dealing with counterfeit and falsified medicines in the EU. Even though only three case studies are addressed in this chapter, there are reports of more such similar incidents in the EU.³⁹⁹

³⁹⁹ Hall, A., Koenraadt, R., & Antonopoulos, G. A. (2017). Illicit pharmaceutical networks in Europe: organising the illicit medicine market in the United Kingdom and the Netherlands. *Trends in Organised Crime*, 1-20; Valverde, J. L. (2017). Illegal medicines as threats to public health. *Pharmaceuticals Policy and Law*, 19(1-2), 1-16; See more in AIFA case files. AIFA.(Update 14 August 2014). *Drugs involved in illegal trafficking*. Inspections & Human Medicines Pharmacovigilance Division Batches of *Herceptin*, *Alimta* and *Remicade* concerned by on-going investigation into stolen vials of medicine in Italy, (2014; A few examples from the AIFA communication

3.5.1. Infiltration of the legal supply chain

The legal supply chain was infiltrated in all three Operations by using the guise of parallel import, fake authorisation and use of fake invoices, which were not detected. In Operation Volcano, the German parallel distributor discovered the counterfeit and falsified medicine by detecting the visible signs of tampering of the medicinal products.⁴⁰⁰ Operation Singapore revealed counterfeit and falsified medicine disguised as French parallel imported products, with elaborate French vignettes affixed on the packages.⁴⁰¹ In addition to using the guise of parallel importing, fake invoices were also used. The legal supply chain was infiltrated by selling to authorised dealers through unauthorised dealers in order to ‘whitewash’ the medicinal products. In contrast to Operation Volcano and Operation Singapore, a trend which is widespread in the EU as well as in other parts of the world was evident in Operation Robin, where the legal supply chain was infiltrated by offering the steroids, narcotics and medicinal products for sale over the internet through three websites.⁴⁰²

From these cases, it is apparent that some wholesalers were not following the regulations.⁴⁰³ As is evident from Operation Volcano, non-compliance with the regulatory framework resulted in a lot of wastage of time, money and other resources. As stated in the investigations, the operators who bought the products from “non-authorised wholesalers” underwent sanctions from the competent local authorities because it was a violation of Article 80 of the Medicines Directive

issued are *Alimta* (Germany, Czech Republic, The Netherlands); *Avastin* (The United Kingdom, Switzerland, Germany, The Netherlands), *Avonex* (Germany, Sweden, Hungary). EMA/329302/2014. (2014).

⁴⁰⁰ See Chapter 3, Section 3.2.

⁴⁰¹ See Chapter 3, Section 3.3.

⁴⁰² Hall, A., & Antonopoulos, G. A. (2016). Introduction. In *Fake Meds Online*. Palgrave Macmillan UK. 1-17.

⁴⁰³ License of three operators were suspended as a result of the investigations by the competent local authority in Regione Campania and two of the operators withdrew and were no longer active. *Source*: Di Giorgio, D. (Director of Publication). (2015). White Paper on Operation Volcano, The Herceptin Case: story, lesson learned, proposals, AIFA, AEMPS, AGES, ICZ, MHRA. Rome, Agenzia Italiana del Farmaco.

amended by the FMD,⁴⁰⁴ which requires the holder of distribution authorisation to meet certain minimum requirements. Furthermore, the cost of human life and the erosion of trust in the medical system and practice and machinery of law that is meant to safeguard the systems can take years to rebuild.

3.5.2. Well-organised and premeditated crime

In all three operations based in the different EU Member States, the crime of counterfeiting and falsification of medicines was well-organised and designed. In all the three operations, whether they involved multiple countries or multiple continents, there were networks of specialised criminals in place. For instance, in Operation Singapore, there were three key figures that were at the helm of affairs.⁴⁰⁵ In Operation Robin, there was a clear organised structure with compartmentalisation of production, distribution, accounts etc.⁴⁰⁶ There was a coordinating mastermind, who employed and hired locals to execute the plan of theft. Thereafter, a separate set of people were asked to handle the paperwork and another set of people were hired to tamper with the medication. Similarly, in Operation Singapore, the Chinese partner was responsible for manufacturing the counterfeit medicine and transporting it to the U.K. through Belgium. In this way, Operation Singapore further lifted the veil over the local warehouses being set up for the purpose of tampering with the medicine or medicinal products.

Moreover, in Operation Volcano, the local warehouses were located in Naples⁴⁰⁷ and in Operation Singapore, the local warehouses were located in Slough.⁴⁰⁸ The

⁴⁰⁴ Article 80, Directive 2001/83/EC.

⁴⁰⁵ See Chapter 3, Section 3.3.2.

⁴⁰⁶ See Chapter 3, Section 3.4.2.

⁴⁰⁷ Di Giorgio, D. (Director of Publication). (2015). White Paper on Operation Volcano, The Herceptin Case: story, lesson learned, proposals, AIFA, AEMPS, AGES, ICZ, MHRA. Rome, Agenzia Italiana del Farmaco.

⁴⁰⁸ *Regina v. Gillespie and others*. (2010). Crown Court at Croydon. Confidential case notes.

main purpose of the local warehouses was to give the products an appearance of the true likeness of the product that was being copied. In Operation Singapore, it was revealed that the packaging was touched up to appear as if it was being manufactured in France. In Operation Robin, the Swedish authorities were also able to trace two steroid producing factories⁴⁰⁹ that performed the same function.

3.5.3. Small consignments

In the case of Operation Singapore and Operation Robin, the local postal network was used to send and receive falsified medicines. In Operation Singapore, the active substances were imported from China and arrived at Brussels from Singapore in small packets.⁴¹⁰ In Operation Robin, the small packages containing the counterfeit products were also imported from Asia via the UK, Germany, and Denmark into Sweden using mailbox services like Brevia, UPS and DHL.⁴¹¹ These similarities in the method of operation in the three individual cases shed light on the fact that the packages sent through the postal system and packages arriving via airmail do not always get detected.

3.5.4. Presence of cross-border element

The three Operations discussed above highlight that typically, there are more than three countries involved. Operation Volcano shed light on the fact that even though the main activity of theft of medicine and re-introduction of the counterfeit medicine into the legal supply chain took place in Italy, the fake invoices were issued by players based in Malta, Romania, and Latvia. Operation Singapore

⁴⁰⁹ Case No. B 6262 -12, Judgement of Stockholms Tingsrätt of 25 June 2013.

⁴¹⁰ *Regina v. Gillespie and others.* (2010). Crown Court at Croydon. Operation Singapore. Confidential case notes, paragraph 146 (e), 53.

⁴¹¹ Case No. B 6262 -12, Judgement of Stockholms Tingsrätt of 25 June 2013.

established that the counterfeit medicine was being manufactured in China, shipped to Hong Kong and ended up in Belgium. After the counterfeit medicine was collected in Belgium, finally reached the U.K. The cross-border element was already visible in Operation Singapore. Similarly, Operation Robin revealed that the parcels and packages that carried the counterfeit products moved from Asia, Egypt, the U.K., and Denmark and then ended up in Sweden. Therefore, the question of which country should take the lead in multi-jurisdictional cases must also be addressed as regards to such cases within the EU, at the very least.

3.5.4. Type of medicines being falsified

The investigations in Operation Volcano, pertaining to Herceptin case have indicated that the same business model and network was operating for falsification of other medicines like “Pegasys”, “Avastin”⁴¹², “Alimta” and “Remicade”.⁴¹³ In 2013, Omeprazole (for gastroesophageal reflux disease) was detected in Germany.⁴¹⁴ In the same year, 1.2 million doses of fake aspirin were seized in France, consisting of glucose and no active ingredients.⁴¹⁵ The common denominator is that all these medicines are lifesaving medicines. There seems to be a clear expansion in the kind of pharmaceutical products that are being falsified. In the preceding decade, the focus of falsified medicines was more on

⁴¹² See Paul- Ehrlich Institut (PEI), an institution of the Federal Ministry of Health, Federal Republic of Germany. (19 November 2014). Warning issued by PEI on Falsified Avastin of Romanian origin.

⁴¹³ SEE EUROPEAN MEDICINES AGENCY. (JUNE 3 2014). NEWS. UPDATE ON INVESTIGATION BY ITALIAN AUTHORITIES INTO THE SUPPLY OF STOLEN MEDICINES.U.K.; SEE MORE PEI (JUNE 4 2014). ARZNEIMITTELDIEBSTÄHLE IN ITALIEN - WEITERE INFORMATIONEN. GERMANY.

⁴¹⁴ Jack, A. (2013). Teva discovers Sophisticated Fakes of Popular drug. *Financial Times*.

⁴¹⁵ AIFA. (2010). The Handbook. IMPACT - International Medical Products Anti-Counterfeiting Taskforce – Facts, Activities, Documents developed by the Assembly and the Working Groups of IMPACT 2006-2010). AIFA. Italy.

lifestyle drugs.⁴¹⁶ However, it is apparent that recently the life-saving drugs have become the target of falsification. For instance, in Operation Singapore,⁴¹⁷ carried out by MHRA, it was discovered that fake life-saving medicines were being manufactured in China and finding their way into the U.K. through Belgium in 2006-07. The medicines that were falsified were Plavix (*clopidogrel*), a prescription only medication, which acts as an anti-platelet and is used in the treatment of preventing heart attacks; Zyprexa (*olanzapine*) a prescription only medicine used to treat schizophrenia and bipolar disorder; and Casodex (*bicalutamide*) used in the treatment of advanced prostate cancer.

3.5.5. Institutional issue

Operation Volcano, as well as Operation Singapore, and Operation Robin reveal that there is a need for appropriate coordination and clarity regarding the appropriate structure and chain of command to follow when such incidents take place. This problem affects many Member States, especially in the light of the fact that counterfeiting and falsification of medicines usually involve more than one EU Member State. While a few Member States are housing the “bogus operators”, others are bearing the “flood of falsified medicines” in their territories. The institutional coordination at the Member State level and between the Member States does not seem to be optimal. However, each country dealt with the problem in their own way as highlighted by the case studies. In Sweden, it was the Swedish

⁴¹⁶ Bulletin of the World Health Organisation. (April 2010). *Growing threat from counterfeit medicines*. Vol.88.(4). 241-320. “A Pfizer-sponsored study, one of the largest investigations conducted in 14 European countries, estimated that western Europeans spend more than US\$ 14 billion a year on illicitly-sourced drugs, many of them counterfeit. A big share of the market constitutes the so-called “lifestyle” drugs. The study found that almost half the counterfeit drugs sold on the Internet were for weight loss, followed by influenza medicines. Another key market for counterfeits in Europe, as in Asia, is erectile dysfunction, nourished by the growth in online pharmacies that offer access to prescription-only medicines without the embarrassment of consulting a doctor. A Dutch study cited by the *International Journal of Clinical Practice* found that, of 370 seized Viagra samples, only 10 were genuine.”

⁴¹⁷ Operation Singapore is the name given to the case *Regina v. Gillespie and others*. (2010). Crown Court at Croydon. Confidential case notes.

Customs and Law Enforcement Authority that took the lead in solving the case. In the UK and in Italy, the Medicines Authorities led the investigations. A similar structure involving bogus operators existed in Romania.⁴¹⁸ One could raise questions as to why the inspections carried out by the NCAs did not ring alarm bells while routine inspections were being carried out and vials were clearly being manipulated, which was visible to the naked eyes. Also, even when the local authorities discovered manipulation of the Herceptin vials, there was no obligation to send notifications to the relevant authorities within the country and in the other EU Member States.

3.6. Concluding remarks

It is apparent from the case studies that the problem of counterfeit medicine is not restricted to Asia, Africa, America or Europe. In most of the cases pertaining to falsification and counterfeiting of medicines, more than one country is involved.⁴¹⁹ This is a problem of gargantuan proportion and involves people having sophisticated knowledge about the pharmaceutical sector and well-versed in the art of trade and commerce.⁴²⁰ In most cases, they are highly educated people who understand the financial sector, the legal frameworks and are adept at by-passing and side-stepping the current system of protection, which is erected to safeguard the vulnerable sections – people suffering from illnesses that are sometimes, life-

⁴¹⁸ AIFA case files, (8 August 2014). Rapid Alert issued by AIFA; Di Giorgio, D. (Director of Publication). (2015). White Paper on Operation Volcano, The Herceptin Case: story, lesson learned, proposals, AIFA, AEMPS, AGES, ICZ, MHRA. Rome, Agenzia Italiana del Farmaco.

⁴¹⁹ Surveying, Ö. B. I. G. (2006). Assessing and Analyzing the Pharmaceutical Sector in the 25 EU Member States. *Report Commissioned by the DG Competition—European Commission. Brussels: Office for Official Publications of the European Communities*; See more in Attaran, A. (2015). Stopping murder by medicine: introducing the model law on medicine crime. *The American journal of tropical medicine and hygiene*, 92 (6_Suppl), 127-132.

⁴²⁰ R. v Gillespie (Peter Hugh), Court of Appeal (Criminal Division) 29 November [2011] EWCA Crim 3152; [2012] 2 Cr. App. R. (S.) 24. See section 3.3 for more details.

threatening.

From the case studies, it has become apparent that the crime of counterfeiting and falsification of medicines does not occur in isolation.⁴²¹ It is inevitably accompanied by the crimes of money laundering, smuggling, theft, forgery of documents, fraud and IP violations.⁴²² As Operation Robin illustrated, money laundering to Cayman Islands, Marshall Islands and Switzerland was associated with the counterfeiting and falsification of the medicines, steroids and narcotics.⁴²³ In Operation Singapore, IP violations were also recognised, in addition to fraud, money laundering and forgery of documents.

The case studies also indicate that several ways are employed to conduct trade in counterfeit medicine. Some of the common features of this trade include the presence of a complex and specialised machinery of people that are employed to infiltrate the legal supply chain. In all the three operations, the tasks to execute falsification and counterfeiting were specialised and divided into marketing, assembly of the product, sale and manufacture. Another common feature in all the operations was that the postal services were used as means of transportation and web-based chat rooms and telephones were used for communication between one criminal and another. From the three legal case studies, it also emerged that drugs can either be manufactured with false ingredients or can be stolen and tampered with or sometimes stolen and re-introduced in the black market.

⁴²¹ Spink, J., Moyer, D. C., Park, H., & Heinonen, J. A. (2013). Defining the types of counterfeiters, counterfeiting, and offender organisations. *Crime Science*, 2(1), 8.

⁴²² UNODC. (2014). Counterfeit - don't buy into organised crime. In *The illicit Trafficking of Counterfeit Goods and Transnational Organised Crime*. United Nations Office on Drugs and Crime. Vienna, Austria.

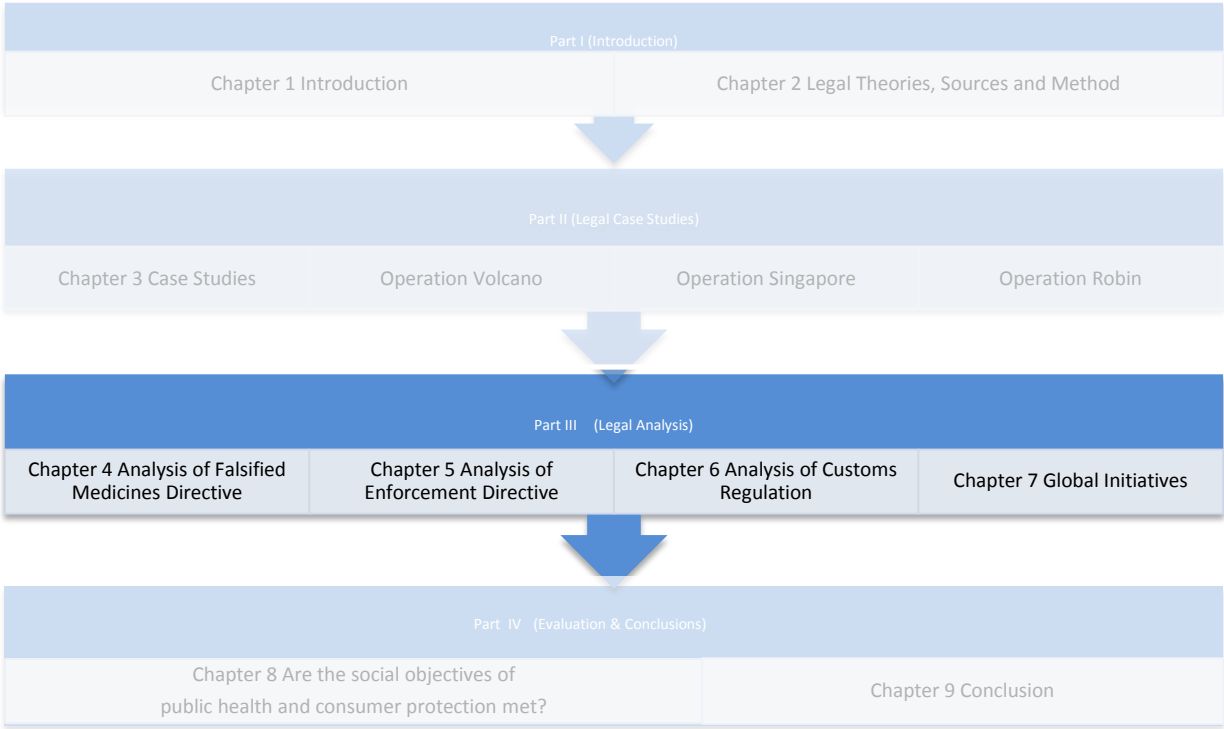
⁴²³ Riccardi, M. (2014). When criminals invest in businesses: Are we looking in the right direction? An exploratory analysis of companies controlled by mafias. In *Organised crime, corruption and crime prevention* (197-206). Springer International Publishing.

In a nutshell, the common issues of concern that have emerged are that the legal supply chain is infiltrated by the illegal supply chain; sale of counterfeit and falsified medicine takes place not only through brick and mortar pharmacies but also through online websites; and the types of medicines being falsified and counterfeited are not restricted to lifestyle drugs but life-saving drugs are also targeted. Furthermore, mostly, the counterfeit and falsified medicinal products are transported in small consignments from one place to the other using courier services or mail box delivery services.

The legal framework does not appear to be geared to deal with the influx of counterfeit medicines as is evident from the increasing number of falsified and counterfeit products being introduced in the market.⁴²⁴ The following segment of the thesis - Part III, it will be analysed how these issues identified in the case studies, are tackled by the legal instruments (the Falsified Medicines Directive, the Enforcement Directive and the Customs Regulation). If there are any gaps in the laws, they will also be pointed out.

⁴²⁴ As also recognised in Recital 2, in the preamble to the Falsified Medicines Directive (Directive 2011/62/EU).

PART III: Legal Analysis



Part III consists of four chapters, wherein using the legal dogmatic method, the legal instruments containing provisions that provide tools to combat falsification and counterfeiting of medicinal products are analysed, in the light of the common issues identified in Part II. In Chapter 4, the Falsified Medicines Directive (Directive 2011/62/EU) is analysed with a focus on the provisions such as introduction of safety features to prevent falsification of medicines; measures to ensure the sanctity of the legal supply chain and provisions to protect the online sale of medicines. This is followed by Chapter 5, wherein the Enforcement Directive (Directive 2004/48/EC) is analysed with emphasis on the provisions that assist the right holders to enforce their rights and the issues with respect to counterfeiting of medicinal products. In Chapter 6, the Customs Regulation (Regulation 608/2013) is analysed with reference to issues raised in Part II and

with special reference to the problems of counterfeit medicinal products entering in small consignments, traveller's luggage and the issues like parallel import, which have not been addressed by the Regulation. This Part ends with Chapter 7 on global initiatives wherein the Medicrime Convention, the ACTA and a few multi-lateral and bilateral agreements are analysed. The primary aim of the analysis of the global initiatives is to ascertain if any of the provisions can be beneficial for the EU legal framework.

Chapter 4: Analysis of the Falsified Medicines

Directive (Directive 2011/62/EU)

4.1. Introduction

The Falsified Medicines Directive (Directive 2011/62/EU), henceforth ‘the FMD’,⁴²⁵ represents the health law perspective.⁴²⁶ The IP law and Criminal law perspective will be dealt with later in the thesis. The chapter will begin by providing a general background to the formation of the FMD, followed by the description of some of the main relevant provisions of the FMD. Subsequently, the focus narrows down on the provisions that are related to the primary issues raised in the previous chapter. The practical challenges that arise in combatting falsification and counterfeiting of medicines in the EU were identified as being the manipulation of the medicinal product itself;⁴²⁷ the infiltration of the legal supply chain by prevalence of fake market authorisation and the use of disguise of parallel importers;⁴²⁸ the sale of counterfeit medicinal products online;⁴²⁹ the presence of cross-border element;⁴³⁰ and the role played by organised crime.

The ‘FMD’ amended the Directive 2001/83/EC⁴³¹ (henceforth, referred to as the ‘Medicines Directive’) in order to update the Medicines Directive for meeting the challenges raised by the infiltration of the legal supply chain by falsified

⁴²⁵ Directive 2011/62/EU.

⁴²⁶ See more in Chapter 2, Section 2.3.4.1.

⁴²⁷ Chapter 3, Section 3.4. Operation Robin, Section 3.2. Operation Volcano, and Section 3.3. Operation Singapore.

⁴²⁸ Chapter 3, Section 3.2. Operation Volcano.

⁴²⁹ Chapter 3, Section 3.4. Operation Robin.

⁴³⁰ Chapter 3, Section 3.3. Operation Singapore, Section 3.2. Operation Volcano.

⁴³¹ Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use.

medicines in the EU. The Medicines Directive, which was developed in 2001, was the first comprehensive directive on medicinal products for human use.⁴³² The broader aim of the Medicines Directive was to establish exhaustive rules to facilitate the functioning of the internal market for medicinal products while ensuring a high level of protection of public health in the EU.⁴³³ Due to the escalation of falsification and counterfeiting of medicines and other related pharmaceutical crimes,⁴³⁴ such as the sale of unregulated and counterfeit medicine through online pharmacies and websites, along with infiltration of the legal supply chain by falsified and counterfeit medicine,⁴³⁵ the need to amend the Directive was recognised. The required changes to the Medicines Directive were articulated in the FMD. The objectives, scope, and relevance of the FMD have been discussed in detail in Chapter 2,⁴³⁶ where it was established that the FMD is in consonance with the provisions of the TFEU (Articles 168, 26 and 114); the TEU (Articles 4, 5 and 9) and Charter of Fundamental Rights of the EU (Articles 2, and 35). The FMD promotes the realisation of the goals of the internal market along with the aims of public health and protection (Article 168, TFEU). It supports access to high-quality medicines to all. The provisions of the FMD should, thus, be viewed

⁴³² Jones, G. (2014). The Falsified Medicines Directive: time to get it right. *The Pharmaceutical Journal*, 293, 7832.

⁴³³ The legal basis springs from Article 114 (3) (ex- Article 95 TEC) of the Treaty on the Functioning of the European Union, 2012, which states:

“The Commission, in its proposals envisaged in paragraph 1 concerning health, safety, environmental protection and consumer protection, will take as a base a high level of protection, taking account in particular of any new development based on scientific facts. Within their respective powers, the European Parliament and the Council will also seek to achieve this objective.”

⁴³⁴ For example, ‘Operation Robin’ conducted in Sweden revealed that fake medicines, steroids, narcotics were being smuggled through small packets from Asia, Egypt, Denmark, and then ended in Sweden. In Sweden, they were being sold through three websites and were delivered by using the postal system. Source:

Source: Europol & OHIM. (June 2013). Reports and Conclusions, *Knowledge Building in IP Enforcement, Combating Pharmacime A knowledge –building Conference on Counterfeit Medicines*. Alicante. Spain

⁴³⁵ Di Giorgio, D. (Director of Publication). (2015). White Paper on Operation Volcano, The Herceptin Case: story, lesson learned, proposals, AIFA, AEMPS, AGES, ICZ, MHRA. Rome, Agenzia Italiana del Farmaco. In Operation Volcano, in Italy, identified that a cancer treatment drug, Herceptin was stolen from an Italian hospital and tampered with and ended up in the legal supply chain; *See also* Newton, N., Amin, A. A., Bird, C., Passmore, Dukes, G., Tomson, G., & White, N. J. (2011). The primacy of public health considerations in defining poor quality medicines. *PLoS Med*, 8(12), e1001139.

⁴³⁶ *See* Chapter 3.

against this backdrop.

As falsified and counterfeit medicine had been identified across the EU, a consensus emerged that the solutions to the problem of falsified and counterfeit medicine would have to be sought at the EU level and not exclusively at the national level alone. This consensus of finding solutions at the EU level was articulated in various EU policies as part of the strategy for safe, innovative, and accessible medicines,⁴³⁷ as well as a general strategy for health in the EU.⁴³⁸ Three main goals were envisioned for the European Union — to strive towards a single and sustainable market in pharmaceuticals; to confront the opportunities and challenges of globalisation; and lastly, to make science deliver for European patients. The long term aim of the collective strategy is to restore the role of the EU as a leader in pharmaceutical innovation.⁴³⁹

The FMD was specifically developed to combat falsified medicinal products in the legal supply chain. In the following sections, the FMD will be evaluated in the context of three main areas that are formulated on the basis of problem areas that came to light and were discussed in Chapter 3 — the manipulation of the medicinal product, the infiltration of the legal supply chain and the sale of medicines online. The FMD contains measures that regulate the medicinal product itself (addressing the problem of manipulation of the medicinal product), which has the aim of safeguarding the product through the introduction of safety features.⁴⁴⁰ The safety features include installation of anti-tampering devices (ATDs), as well as Unique Identifiers (UIs), setting up of a verification system,

⁴³⁷ Safe, Innovative and Accessible Medicines: A renewed Vision for the Pharmaceutical sector, Communication from the Commission to the European Parliament, the Council the European Economic and Social Committee and the Committee of the Regions- Safe, Innovative and Accessible Medicines: a Renewed Vision for the Pharmaceutical Sector, COM (2008) 666 final, 10.

⁴³⁸ White Paper, Together for Health: A Strategic Approach for the EU 2008-2013, COM (2007) 630 final.

⁴³⁹ *ibid.*, 4.

⁴⁴⁰ Article 47a, 54a inserted in Directive 2001/83/EC and Recital 11 and 12 in Directive 2011/62/EU.

and a list of exceptions.

In order to safeguard the legal supply chain, there are provisions that need to be followed while importing and exporting medicinal products for ensuring that counterfeit products do not enter the legal supply chain in the EU.⁴⁴¹ For this purpose, the Good Manufacturing Practices (GMP), which have existed since 2003,⁴⁴² have been expanded and will need to be observed and strictly enforced.⁴⁴³ Also, there are rules regarding Active Pharmaceutical Ingredients (API)⁴⁴⁴ that also concern the distribution system⁴⁴⁵ in the legal supply chain of the medicinal sector, which is regulated to ensure that there is no infiltration of counterfeit medicines through a large number of players in the distribution chain.⁴⁴⁶ Another key feature of the FMD is the introduction of an online logo⁴⁴⁷ that must be displayed on any website that sells pharmaceutical products in the EU in order to safeguard online sale of medicines. Moreover, the FMD has many legal instruments as offshoots, which are relevant for the thesis and assist in combatting falsification of medicines. These are summarised in the following table (*Table 2*):

⁴⁴¹ Clift, C. (2010). *Combating counterfeit, falsified and substandard medicines: defining the way forward?*. London UK: Chatham House.

⁴⁴² GMP laid down in Directive 2001/83/EC under Article 47 provide for a Directive 2003/94/EC of 8 October 2003 laying down the principles and guidelines of good manufacturing practice in respect of medicinal products for human use and investigational medicinal products for human use; *See also* EudraLex – Volume 4 Good Manufacturing Practice (GMP) Guidelines.

⁴⁴³ The manufacturers are obliged to comply with GMP for active substances, including stricter controls and inspections through Commission Delegated Regulation (EU) No 1252/2014 of 28 May 2014 supplementing Directive 2001/83/EC of the European Parliament and of the Council with regard to principles and guidelines of good manufacturing practice for active substances for medicinal products for human use.

⁴⁴⁴ Active Pharmaceutical Ingredient is the core ingredient in the medicinal product that carries the disease fighting power.

⁴⁴⁵ Good Distribution Practices originally laid down under Article 84 and Article 85b(3) of Directive 2001/83/EC are updated regularly; the latest being in Guidelines of 5 November 2013 on Good Distribution Practice of medicinal products for human use, 2013/C 343/01 have also been updated by the FMD, and subsequent introduction of Commission Delegated Regulation (EU) No.1252/2014 of 28 May 2014 and Guidelines of 19 March 2015 on principles of Good Distribution Practice of active substances for medicinal products for human use (2015/C 95/01).

⁴⁴⁶ Besides the traditional players in a distribution chain such as manufacturers, wholesalers, distributors, retailers there are also brokers and parallel importers. Another method of distribution of medicinal products is the online channel.

⁴⁴⁷ Commission Implementing Regulation (EU) No. 699/2014 of 24 June 2014.

Type of Feature	Reference in Directive 62/2011/EU	Type of legal instrument
Safety features in medicinal product	Article 4	Commission Delegated Regulation (EU) 2016/161 of 2 October 2015
Good Manufacturing Practices for active substances	Article 1(5)	Commission Delegated Regulation (EU) No.1252/2014 of 28 May 2014
Principles of Good Distribution practices for active substances	Article 1(5)	Guidelines of 19 March 2015 on principles of Good Distribution Practice of active substances for medicinal products for human use (2015/C 95/01)
Design of the common logo	Article 1(20)	Commission Implementing Regulation (EU) No. 699/2014 of 24 June 2014
Good Manufacturing Practice for excipients	Article 1(7)	Guidelines of 19 March 2015 on the formalised risk assessment for ascertaining the appropriate good manufacturing practices for excipients of medicinal products for human use (2015/C 95/02)
Provisions for brokering in the guidelines on Good Distribution Practices	Article 1(19)	Guidelines of 5 November 2013 on Good Distribution Practices of medicinal products for human use (2013/C 343/01)

Table 2

4.2. The Medicinal product – safety features

The manipulation of the medicinal product is a central issue in counterfeiting and falsification. Therefore, the importance of having safety features in place cannot be emphasised enough for products in general, and for pharmaceutical products, in particular.⁴⁴⁸ The urgency of installing safety features⁴⁴⁹ was prompted by the escalation in the number of counterfeit medicines entering through both the illegal

⁴⁴⁸ Abril, J. L., Holt, D. W., & Wilson, R. R. (2016). Falsified Medicines in the European Union and North America: What are we doing to Protect Public Health? *Journal of Pharmacovigilance*.

⁴⁴⁹ Krähenbühl, C. (2016). The EU-FMD Clock Is Ticking!. *Industrial Pharmacy*, 49(1), 4-6.

and legal supply chain,⁴⁵⁰ as revealed in Chapter 3 through the three case studies – Operation Volcano (the cancer treatment drug which was manipulated and injected with fake products, repackaged, and re-entered the legal supply chain),⁴⁵¹ Operation Singapore (where three prescription only medicines were imported from China, re-packaged, and introduced into the legal supply chain),⁴⁵² and Operation Robin (steroids and medicines manufactured and packaged in Sweden after obtaining raw materials from Asia and sold over the internet). The counterfeit drugs that were injected with fake substances were reintroduced in the market by copying the labels and identifiers that make the counterfeit drugs appear authentic.⁴⁵³ It has been advocated that the packaging of pharmaceutical products should aim at protection, easy identification, and display.⁴⁵⁴ Against this backdrop of an exponential increase in the number of risk profiles,⁴⁵⁵ it was considered imperative to initiate concrete measures to strengthen the safety of the medicinal product itself and impart legal basis to it.⁴⁵⁶ The safety features that are introduced are expected to be fully implemented by 2019 in the EU.

⁴⁵⁰ Chapter 3.

⁴⁵¹ See Chapter 3. For instance in Section 3.2 of the thesis, Operation Volcano revealed that Herceptin drug, which is a drug used for treatment of cancer was stolen from a truck delivering the medicine to an Italian hospital and then was injected with fake pharmaceutical products and re-introduced in the legal supply chain.

⁴⁵² See Chapter 3, Section 3.3.

⁴⁵³ Discussed in detail in Chapter 3, Section 3.4.

⁴⁵⁴ Tiwari, B. (2016). "Current Aspects of pharmaceutical packing materials, importance and its future Trends - A Review. *International Journal of Chemical and Pharmaceutical Analysis*, 3(1).

⁴⁵⁵ Recital 11, Falsified Medicines Directive 2011/62/EU.

⁴⁵⁶ Regulation on Safety Features 2016/161. (2015) Impact Assessment. SWD (2015)189 final.

4.2.1. Main safety features

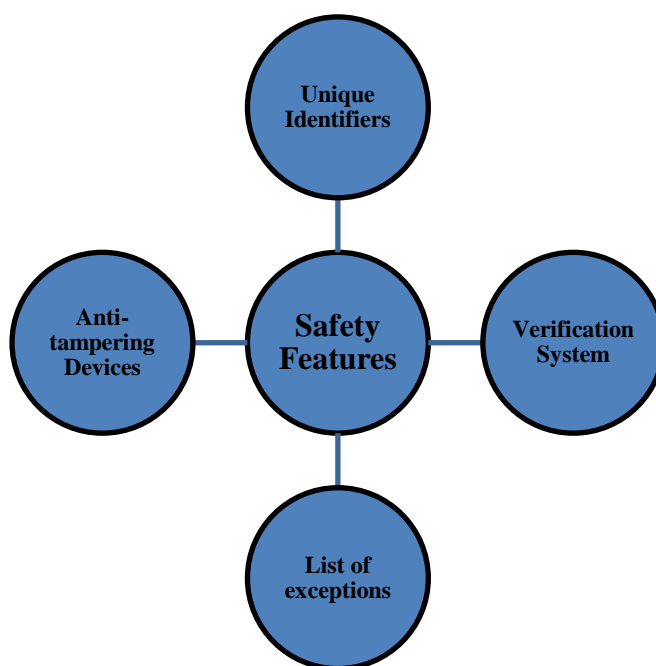


Figure 5

The main safety features that have been introduced by the Regulation⁴⁵⁷ which stems from the FMD (see *Table 2*) include introduction of alphanumerical code enabling the identification and authentication of individual packs bearing Unique Identifiers (UI);⁴⁵⁸ Anti- tampering devices (ATD)⁴⁵⁹ that will allow for ascertaining if tampering has taken place;⁴⁶⁰ the introduction of repositories

⁴⁵⁷ The delegated act entails the characteristics that the safety features should possess; how the authenticity of the medicinal products should be determined and verified; and by which actors. This act came into being in 2016 via Commission Delegated Regulation (EU) 2016/161 of 2 October 2015 supplementing Directive 2001/83/EC of the European Parliament and of the Council by laying down detailed rules for the safety features appearing on the packaging of medicinal products for human use. The Regulation will be applicable with effect from February 9, 2019 in all but three of the Member States in the EU. These three Member States – Italy, Greece and Belgium already have similar systems in place, therefore, they have been given an extended deadline of February 9, 2025 to switch over to the common system.

⁴⁵⁸ Articles 3 and 4 Regulation on Safety Features (EU) 2016/161.

⁴⁵⁹ Article 3 Regulation on Safety Features (EU) 2016/161.

⁴⁶⁰ Article 10 Regulation on Safety Features (EU) 2016/161.

systems⁴⁶¹ for the UI to keep a record across EU, as well as formulation of lists of exceptions for bearing⁴⁶² or not bearing⁴⁶³ the safety features.

The UI and the ATDs are expected to be installed on all medicinal products. The UI can be alphanumeric code enabling identification and authentication of individual packs. The technical characteristics of a UI include a product code, a serial number and national reimbursement or identification number, a batch number, and an expiry date.⁴⁶⁴ The ATDs are meant to verify whether a pack of medicine or product has been opened or tampered with. For example, it could be film wrappers, shrinkable seals, breakable caps, tape seals, blister packs, etc.⁴⁶⁵ The main idea is to have such type of packing that if it is tampered with, it would leave audible or visible traces and the consumer or the authorities will be able to detect the problem.

In addition to having UI and ATDs, an end-to-end verification system is expected to be put in place.⁴⁶⁶ It is not a full track & trace system.⁴⁶⁷ Essentially, an end-to-end verification system entails the manufacturers or the Market Authorisation Holders (MAH) on one end, and the pharmacies or hospitals that receive the medicinal products, on the receiving end. Firstly, the manufacturers or the MAH are responsible for ensuring that the UIs are printed or applied to the packaging of

⁴⁶¹ Article 31-37, Regulation on Safety Features (EU) 2016/161.

⁴⁶² List of medicinal products categories not subject to prescription that shall bear the safety features referred to in Article 45(2), Regulation on Safety Features (EU) 2016/161.

⁴⁶³ List of medicinal product categories subject to prescription that shall not bear the safety features, referred to in Article 45(1), Annex I, Regulation on Safety Features (EU) 2016/161.

⁴⁶⁴ Patrizia, T. (2016). Medicines verification in Europe: What to expect in 2019, DG Sante, *European Commission Stakeholders' Workshop*. 9.

⁴⁶⁵ Gupta, A. K. K. N. V., & Lalasa, P. (2013). A Review on Packaging Materials with Anti-Counterfeit, Tamper-Evident Features For Pharmaceuticals. *International Journal of Drug Development and Research*. 4.

⁴⁶⁶ Recital 4 of Regulation on Safety Features, 2016 /161.

⁴⁶⁷ Patrizia, T. (2016). Medicines verification in Europe: What to expect in 2019, DG SANTE, *European Commission Stakeholders' Workshop*; See also Kelly, S. (2007). Tracking and Tracing Pharmaceutical Products through the Supply Chain. *Supply Chain Europe*, 16(5), 40-42.

the medicines and the information regarding the UIs is uploaded in the secure repository system. Secondly, it is also the responsibility of the manufacturer or the MAH to apply the ATDs on the packaging. At the receiving end, it is the responsibility of pharmacies or hospitals to verify and determine the authenticity of the medicinal products. If it is deemed as a counterfeit, or not original, or is opened or tampered with, it is also the responsibility of the pharmacy or the hospital in question, to decommission the product. Furthermore, it is the responsibility of the pharmacy or the hospital at the receiving end to check the integrity of the ATD attached to the medicinal product. In addition to the aforementioned, a risk-based verification by the wholesalers has to be conducted when the product is returned by another wholesale distributor or a pharmacy - and when the product is not directly provided by a manufacturer or a MAH.

In addition to having UIs and ATDs on the medicinal products, the verification system has also been established to further strengthen the protection of the medicinal products. Furthermore, the Regulation provides for the establishment of a Repositories system.⁴⁶⁸ The primary responsibility of the repositories system is to store information on the legitimate UIs and facilitate the authentication, verification and decommissioning of UIs at any point of the supply chain. In addition, it would also be the central database, where the detection of potential

⁴⁶⁸ This is meant to be established and managed by stakeholders with supervision of the competent authorities, as provided for under Article 32, Regulation on Safety Features 2016/161. The European Medicines Verification Organisation (EMVO) is a non-profit organisation based in Luxembourg and represents the interests of the primary stakeholders and has the primary goal of securing the legal supply chain from illicit medicines. Its members include the European Federation of Pharmaceutical Industries and Associations (EFPIA), the European Generic and Biosimilar Medicines Association (EGA), the Pharmaceutical Group of the European Union (PGEU), GIRP, the European Association of Pharmaceutical Full-line Wholesalers and, the European Association of Euro-Pharmaceutical Companies (EAEPC). The primary task of the EMVO is to implement the repositories system and ensure that the repositories systems are in compliance with the provisions of the Falsified Medicines Directive. The EMVO has designed a blueprint model for National Medicines Verification Organisations (NMVO) to follow. It is the NMVOs that will be responsible for carrying out the management and the establishment of the systems. *Source:* Andreas W., (22 June 2015). *The European Verification Organisation signs framework agreement with service providers to establish blueprint systems*, Press Release. Luxembourg. EFPIA.

falsification of pharmaceutical products will come to light. The Member States will be in charge of supervising the repositories system and enforcing the requirements of the delegated Regulation.

In addition to the above, the Regulation on Safety Features also provides for two lists of exceptions. The general rule governing the principle of application of Safety Features is that if it is a prescription medicine, it has to bear the safety features and if it is a non-prescription medicine, it will not bear the safety features. However, there is a possibility of having an exception to these rules, if an assessment shows that there is a considerable risk of falsification. These exceptions are included in Annex I and II of the Regulation 2016/161. Annex I enumerates the list of medicinal product categories that are subject to prescription but do not bear the safety features, referred to in Article 45(1).⁴⁶⁹ The prescription medicines exempted from the Safety features are, for example, homeopathic, radiopharmaceuticals, ATMPs, medical gases, certain solutions, contrast media, allergy tests and allergen. In addition, Annex II⁴⁷⁰ enumerates the list of product categories that are not subject to prescription and do not bear the safety features, referred to in the Article 45(2).⁴⁷¹

4.2.2. Deficiencies in the provisions on Safety Features

The provision of safety features was introduced due to the rise in the number of counterfeit and falsified medicines in the EU.⁴⁷² Against the backdrop of the case studies, it is evident that protecting the medicinal product itself is a crucial step in

⁴⁶⁹ Annex I, Regulation on Safety Features 2016/161.

⁴⁷⁰ Annex II, Regulation on Safety Features 2016/161.

⁴⁷¹ This includes Omeprazole only, at the moment, since there were reported incidents of falsification of this medicinal product in Annex II, Regulation on Safety Features 2016/161.

⁴⁷² Almuzaini, T., Sammons, H., & Choonara, I. (2013). Substandard and falsified medicines in the UK: a retrospective review of drug alerts (2001–2011). *BMJ open*, 3(7), e002924.

combatting falsification of medicines. The provisions on safety features – UIs; ATDs; verification system; repository system and the introduction of lists will make a significant difference for securing the integrity of the medicinal products.

However, there are certain challenges that can be anticipated by the introduction of the safety features.⁴⁷³ The tracing and tracking system envisaged by the Regulation is an end-to-end system and not a full track and trace system. In a full track and trace system, it is possible to follow the movement of the medicine from the moment it is manufactured, to the end, when it is dispensed or sold to the customer. In contrast, the end-to-end system involves the check at two points only – the starting point and the end point. At the entry point, when the manufacturer introduces the product in the legal supply chain and at the end, by the hospital or the pharmacy when the product is sold to the patient.

It is evident that in a full trace and track system, it is possible to authenticate the product at any time, and thus, chances of manipulation are greatly reduced. However, in an end-to-end system, there is still some scope for manipulation in the middle of the supply chain. This may result in late detection, which makes it challenging to trace exactly where and when the counterfeit drug was introduced. This system, not being a full track and trace system implies that certain gaps can still prevail in the system, leaving the system vulnerable. Hence, a full track and trace system would have been the preferred system, even though it would be more expensive.⁴⁷⁴ Since it would have provided the capability to track the medicine's

⁴⁷³ Bogaert, B. C., & Burton, C. (2015). The mysteries of the Falsified Medicines Directive-where is the logic on safety features. *London: Script Regulatory Affairs*, 1-3; Paxton, M. (2011). Current challenges with supply chain integrity and the threat to the quality of marketed drugs. *Clinical Pharmacology & Therapeutics*, 89(2), 316-319.

⁴⁷⁴ Gostin, L. O., Buckley, G. J., & Kelley, W. (2013). Stemming the global trade in falsified and substandard medicines. *JAMA*, 309(16), 1693-1694; Kang, Y. S., & Lee, Y. H. (2013). Development of generic RFID traceability services. *Computers in industry*, 64(5), 609-623.

present and past location at any point in the supply chain.⁴⁷⁵

The system of risk-based verification places an obligation on not only the manufacturers, but also on the distributors, and wholesalers. The down side of the imposition of these obligations is that the various players in the legal supply chain are at the risk of non-compliance with these risks based verifications. As was evident in Operation Volcano and Operation Singapore,⁴⁷⁶ the different MAH were lax in carrying out these risks based verifications. In Operation Volcano, it was discovered that the illegitimate wholesalers sold the medicine that was tampered with to the legitimate wholesalers. That is how the falsified medicine entered the legal supply chain, as the legitimate wholesalers did not check the authorisation of the previous link in the legal supply chain. Therefore, placing the onus on the manufacturers, distributors and wholesalers through excessive regulation may increase the danger of non-compliance.

4.3. The supply chain

Besides manipulation of medicinal products, the case studies also revealed that the legal supply chain can be infiltrated by the illegal supply chain at various points.⁴⁷⁷ Therefore, besides securing the integrity of the medicinal product, the FMD also contains provisions that aim at strengthening the legal supply chain.⁴⁷⁸ Essentially, a supply chain is composed of many market players, both upstream

⁴⁷⁵ Rotunno, R., Cesarotti, V., Bellman, A., Introna, V., & Benedetti, M. (2014). Impact of Track and Trace Integration on Pharmaceutical Production Systems. *International Journal of Engineering Business Management*, 6, 25; Castro, L., & Fosso Wamba, S. (2007). An inside look at RFID technology. *Journal of Technology Management & Innovation*, 2(1).

⁴⁷⁶ See Chapter 3, Sections 3.2. and 3.3.

⁴⁷⁷ Chapter 3, Section 3.2. Operation Volcano, the medicines were stolen and then re-introduced in the supply chain.

⁴⁷⁸ Smith, G., Smith, J. A., & Brindley, D. A. (2014). The Falsified Medicines Directive: How to secure your supply chain.

(i.e. supply) and downstream (i.e. distribution), including the last link in the chain, the consumer.⁴⁷⁹ By using fake authorisation and posing as legitimate wholesalers or parallel importers, falsified and counterfeit medicines were introduced in the legal supply chain. The problems highlighted in the three case studies are not stand alone instances but an illustration of the typical trend in the falsification of medicines in the EU.⁴⁸⁰ In the light of the general trend also recognised in the preceding legal instruments in the field of medicine in the EU and combined in EudraLex Volume 1,⁴⁸¹ the FMD contains provisions specifically related to proliferation in the number of market players in the legal supply chain;⁴⁸² rules governing authorisations (market as well as manufacturing authorisation); and provisions regulating import and export of APIs.

4.3.1. Proliferation in the number of market players

A few decades ago, the supply chain included just three main actors: the manufacturer supplied the goods to the wholesaler, who, in-turn, supplied it to the pharmacy or the hospital. There were no middlemen (*Figure 6*). However, the rapid pace of technological and economic development has led to an increase in the number of intermediaries.⁴⁸³ Therefore, every movement – from one market player to the other, is an opportunity for counterfeit medicines to infiltrate the market (*Figure 7*).⁴⁸⁴ The pharmaceutical supply chain is not only threatened by

⁴⁷⁹ Mentzer, J. T., DeWitt, W., Keebler, J. S., Min, S., Nix, N. W., Smith, C. D., & Zacharia, Z. G. (2001). Defining supply chain management. *Journal of Business logistics*, 22(2), 1-25; Christopher, Martin L. (1992), *Logistics and Supply Chain Management*, London: Pitman Publishing.

⁴⁸⁰ Almuzaini, T., Sammons, H., & Choonara, I. (2013). Substandard and falsified medicines in the UK: a retrospective review of drug alerts (2001–2011). *BMJ open*, 3(7), e002924.

⁴⁸¹ 'The Rules Governing Medicinal Products in the European Union', EudraLex Volume 1, available at https://ec.europa.eu/health/documents/eudralex/vol-1_en accessed June 29 2017.

⁴⁸² See Recital 6, Directive 2011/62/EU.

⁴⁸³ Tremblay, M. (2013). Medicines counterfeiting is a complex problem: a review of key challenges across the supply chain. *Current drug safety*, 8(1), 43-55.

⁴⁸⁴ Buckley, G. J., & Gostin, L. O. (Eds.). (2013). *Countering the problem of falsified and substandard drugs*. National Academies Press, 197.

the existence of an illegal supply chain, but also by the infiltration of a number of intermediaries that are not accountable or accounted for.⁴⁸⁵ This problem was also evident in the case studies in Chapter 3, wherein the illegal wholesalers based in other countries ‘whitewashed’ the falsified medicinal products by using fake authorisations right before the products were reintroduced in the legal supply chain.⁴⁸⁶

The supply chain has, thus, become increasingly complex⁴⁸⁷ and the vast number of intermediaries has led to a legal necessity of formulation of stricter rules with respect to the distribution system.⁴⁸⁸ The Falsified Medicines Directive addresses the issue of diversity and proliferation in the number of market players in the supply chain.⁴⁸⁹ These market players are mainly categorised as manufacturers, distributors, brokers, wholesalers, and retailers. The Community pharmacies (independent and multiple pharmacies) as well as hospital dispensaries are part of the supply chain and are thus market players.⁴⁹⁰ In addition, parallel importers play an important, though controversial, role in the legal pharmaceutical supply chain. If one were to categorise the different players in the market, at the moment, and their role in the legal supply chain, it would appear in the following manner (*Figure 7*):

⁴⁸⁵ Tremblay, M. (2013). Medicines counterfeiting is a complex problem: a review of key challenges across the supply chain. *Current drug safety*, 8(1), 43-55.

⁴⁸⁶ Chapter 3, Section 3.2. Operation Volcano.

⁴⁸⁷ Tremblay, M. (2006). Finding Common Ground: policy imperatives for Europe. *Coincidence or Crisis: Prescription Medicine Counterfeiting*. London: Stockholm Network.

⁴⁸⁸ Explanatory Memorandum, for a Proposal for a Directive of the European Parliament and of the Council amending Directive 2001/83/EC as regards the prevention of the entry into the legal supply chain of medicinal products which are falsified in relation to their identity, history or source, COM (2008) 668 final.

⁴⁸⁹ Recital 6, Falsified Medicines Directive 2011/62/EU.

⁴⁹⁰ Attaran, A., Barry, D., Basheer, S., Bate, R., Benton, D., Chauvin, J., & Newton, N. (2012). How to achieve international action on falsified and substandard medicines. *Bmj*, 345, e7381.

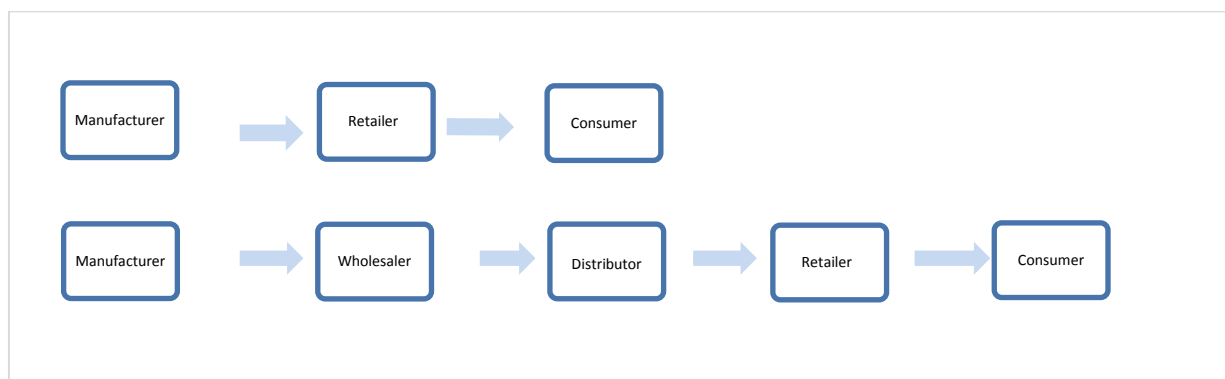


Figure 6

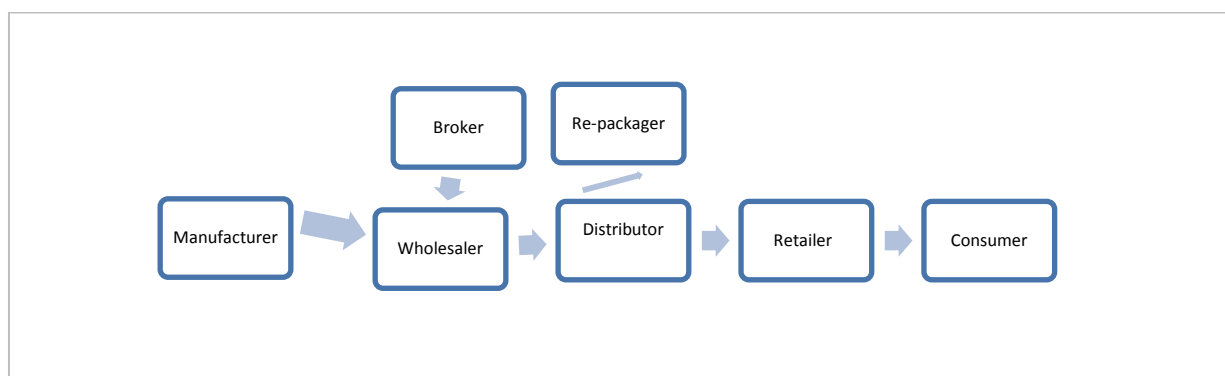


Figure 7

Within the EU, all actors (be it manufacturers, wholesalers, distributors, retailers, brokers or re-packagers of a medicinal product or importers of a medicinal product from a third country) are subject to the provisions of Title IV of Directive 2001/83/EU – Articles 40-53, which have been amended and updated by the FMD. These provisions deal with requirements of obtaining a manufacturing authorisation;⁴⁹¹ the obligations of a manufacturing authorisation holder;⁴⁹² compliance with GMP and GDP;⁴⁹³ requirement of upholding safety features;⁴⁹⁴

⁴⁹¹ Article 1(5), Directive 2011/62/EU.

⁴⁹² *ibid.*

⁴⁹³ Articles 1(5) and 1(7) Directive 2011/62/EU.

and personal qualifications of a manufacturing authorisation holder.⁴⁹⁵ The term ‘manufacturer’ covers distributors, exporters, sellers etc. Each activity requires an authorisation – manufacturing or distribution and associated activities also need an authorisation. All these authorisations spring from the Articles 40-53 in the Directive but validate different activities. Thus, a manufacturer is any person, who manufactures or just packages the medicinal product, is part of the supply chain, and holds a Manufacturing Authorisation (MA).⁴⁹⁶

It is incumbent upon the authorisation holder to be responsible for packaging the manufactured product⁴⁹⁷ and for taking into account the safety features⁴⁹⁸ that are applicable to the medicinal product. Also, there can be actors who are categorised as manufacturers, but who have not actually manufactured the medicinal product but have just purchased it from another wholesaler. Essentially, they hold a MA that makes them responsible for ensuring that if they deal in a product and if they need to repackage, remove, or replace the packaging of the product, the safety features that they attach to the medicinal product, are equally effective and meet the quality standards of the original safety features. All manufacturers of medicinal products are required to be registered by the NCA of the Member State that they are located in.⁴⁹⁹

The authorisation holders, which include all market players now, such as wholesaler, distributors, repackagers, and parallel importers, also have the responsibility of informing the NCA and manufacturing authorisation holder, in case they

⁴⁹⁴ Article 4, Directive 2011/62/EU.

⁴⁹⁵ Title IV Manufacture and Importation, Articles 40 -55, Directive 2001/83/EC.

⁴⁹⁶ De Weerd, E., Simoens, S., Hombroeckx, L., Casteels, M., & Huys, I. (2015). Causes of drug shortages in the legal pharmaceutical framework. *Regulatory toxicology and pharmacology*, 71(2), 251-258.

⁴⁹⁷ Recital 12, Falsified Medicines Directive 2011/62/EU.

⁴⁹⁸ See discussion on safety features discussed in Section 4.2.1.

⁴⁹⁹ Article 52a of Medicines Directive 2001/83/EC inserted by Falsified Medicines Directive 2011/62/EU.

detect that the products entering the legal or illegal supply chain are counterfeit.⁵⁰⁰ The manufacturers of active substances, in addition to the other responsibilities meant for all authorisation holders, are also subject to inspection⁵⁰¹ on the basis of risk-analysis and on the grounds of non-compliance.⁵⁰² Further, it is also the duty of the authorisation holders to abide by the GMP⁵⁰³ and Good Distributing Practices⁵⁰⁴ (GDP), when assessing the viability of excipients to be used in the process of manufacturing the medicines.⁵⁰⁵ An authorisation holder is also responsible for conducting audits⁵⁰⁶ of the manufacturing and distribution sites that manufacture and distribute the active substance, in order to confirm that the

⁵⁰⁰ Article 1 (5) (g), Directive 2011/62/EU.

⁵⁰¹ Recital 18, Directive 2011/62/EU; Article 111 (1a) of Directive 2001/83/EC.

⁵⁰² Recital 7, Directive 2011/62/EU.

⁵⁰³ Article 8 (3) inserted in the Directive 2001/83/EC by Article 1 of the Directive 2011/62/EU. GMP guidelines are not a new phenomenon. GMP are a collection of rules that are systematised, which are in the form of guidelines, and lay down certain standards for necessary adherence. The manufacturing and importation of all types of medicinal products for human use are subject to authorisation. The holder of market authorisation has to adhere to GDP and GMP. The GMP are provided for in the Medicines Directive under Article 47, wherein the Commission is obliged to adopt principles and guidelines of GMP for medicinal products for human use in the form of a Directive. In 2014, the Directive 2003/94/EC was repealed and replaced by a Delegated Act on principles and guidelines of GMP for investigational medicinal products with its legal basis as Article 63(1) of Regulation (EU) No. 536/2014 and a new Implementing Directive on principles and guidelines of good manufacturing practice for medicinal products for human use with the Article 47 of the Medicines Directive as its legal basis. The main purpose of these guidelines is to ensure that the medical products being produced or imported, including import of active substances, are consistent in quality and are being produced under controlled conditions that adhere to the common standards. Safety of medicines is ensured by replicating the initial design of the medicine in exactly the same manner as approved by the approving agency, for instance FDA in the US or the National Competent Authority of the Member States. Each of the market players are expected to follow and adhere to the GMP and GDP.

⁵⁰⁴ (GDP) play a pivotal role in the legal supply chain. The GDP in the EU visualises greater safety of the legal supply chain in the pharmaceutical industry, which is also recognised by the WHO Guidelines. Firstly, by defining the role of the Distributors, the GDP. The Commission published the guidelines in 2013 – Guidelines on Good Distribution Practice of medicinal products for human use. The Guidelines are based on Article 84 and 85 b (3) of Directive 2001/83/EC. The GDP make certain that the quality ensured by the GMP is upheld by the distributors. The principles of the GDP are enshrined in the Directive 92/25/EEC, wherein it is provided for that the medicinal products are distributed in accordance with the EU legislation. The quality as well as the integrity of the legal supply chain can be affected if the GDP are not adhered to. This was evident in the Operations discussed in Chapter 3. For example, Operation Volcano revealed that the integrity of the legal supply chain was compromised, wherein the illegal wholesaler sold the medicines to the legal wholesaler, who sold them to another legal wholesaler based in Germany, who actually detected the flaw and mismatch in the packaging and batch numbers. Even the names of the distributors that were not adhering to the GMP and GDP were listed on the website of the National competent authority. This was a clear example of how counterfeit medicine enters the legal supply chain if the integrity of the legal supply chain is compromised. Had the rules regarding inspections, and audits been in place, at least the legal wholesalers would have been able to detect the mismatch between the batch numbers and bring it to the attention of the competent authorities at the national, as well as the EU level.

⁵⁰⁵ Recital 8, Falsified Medicines Directive 2011/62/EU.

⁵⁰⁶ Article 46 (f) Medicines Directive 2001/83/EC.

GMP and GDP have been complied with.

Another step forward in the EU legal framework in securing the pharmaceutical supply chain is the identification and definition of ‘brokers’ for the first time in the FMD. It recognises ‘brokers’⁵⁰⁷ as a part of the legal supply chain for medicinal products. A definition of ‘brokering’ has been inserted in the Medicines Directive,⁵⁰⁸ which includes all the actors, who do not physically handle the medicinal product but are involved in the sale or purchase of the medicinal products without directly being involved in the sale or purchase themselves or physically owning the products.

The historical reason for the introduction of the market players like ‘brokers’ in the FMD, has been because of the problems that have been caused by them in the past. The brokers that existed in the past in the legal supply chain were not accountable for their actions. Therefore, they were playing a key role in the market but did not have any accountability. Now that the ‘brokers’ are officially added as market players, they are also subject to rules and obligations.

The brokers are expected to abide by the requirements of the Directive, as the other actors in the Directive with respect to upholding the integrity of the legal supply chain. In addition, they are also expected to ensure that the products they are involved in brokering are covered by market authorisation,⁵⁰⁹ which is granted by the competent authorities of the Member State that they are located in, in accordance with the Directive. The Market Authorisation also needs to be in

⁵⁰⁷ Recital 6, Falsified Medicines Directive 2011/62/EU.

⁵⁰⁸ Article 1 (b) of the Falsified Medicines Directive 2011/62/EU introduces 17a in Article 1 of the Medicines Directive 2001/83/EC.

⁵⁰⁹ Article 85b of the Medicines Directive 2001/83/EC.

consonance with the provisions of the Regulation (EC) No. 726/2004.⁵¹⁰

In its bid to tighten the noose around vulnerable parts of the legal supply chain, which includes the ‘brokers’, it was a step in the right direction to discuss penalties that can come about for non-compliance. Even though the Member States have the powers to introduce penalties that need to be dissuasive, proportionate and equitable, the Directive clearly states one such provision. At the moment, the only penalty that appears in the Directive is that the broker will be removed from the register if the provisions of the Directive (Directive 2011/62/EU) are not upheld.⁵¹¹ However, this is inadequate, because if one ‘broker’ is removed on the grounds of non-compliance from the list, another one can appear swiftly. The system stands to be defeated and can get embroiled in handling the new versions of the same broker reappearing time and time again. Therefore, it is important to emphasise that the penalties that are imposed should have teeth to bite and the system that is erected promotes compliance.

In order to strengthen the integrity of the legal supply chain against infiltration by falsified products, regular inspection of the manufacturers and wholesale distributors should also be carried out.⁵¹² In addition, it is also the responsibility of the wholesale distributors to verify the authenticity of the medicinal product and the identity of the individual packs, as well as whether the products have been

⁵¹⁰ Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004, lays down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency. A broker is also subject to requirements such as have a permanent address, contact details in the Union so as to ensure identification, location communication and supervision of their activities by competent authorities. All brokers are also required to be registered with the Competent Authority of the Member State that they are located in. Non-compliance with the requirements can lead to removal from the register.

⁵¹¹ Article 85b (4), Medicines Directive 2001/83/EC.

⁵¹² Recital 18, Falsified Medicines Directive 2011/62/EU.

tampered with.⁵¹³ The possessor of a wholesale distributions authorisation, if purchasing the products from another wholesale distributor, is obliged to check the wholesale distribution authorisation of the distributor he is purchasing from, in addition to verifying whether GDP is being complied with.

The case studies revealed that these requirements were not strictly enforced, as it came to light in Operation Singapore,⁵¹⁴ and Operation Volcano.⁵¹⁵ In Operation Singapore, the wholesale distributors did not check the authorisation of the manufacturer of the product. Since the compliance is slack, the counterfeiters actually took advantage of non-compliance and introduced counterfeit medicines by employing fake authorisation certificates.⁵¹⁶ In Operation Volcano, it was illustrated that there was an organised body of illegitimate manufacturing authorisation holders, who dealt with introducing counterfeit medicinal products into the legal supply chain by introducing the medicinal products to legitimate authorisation holders.⁵¹⁷ The FMD has definitely tried to clarify the role of wholesale distributors. However, the number of responsibilities that the wholesale distributor has been saddled with in the Directive may lead to non-compliance in practice, as was evident in Operation Singapore and Operation Volcano. Inspections, verification of authenticity of individual packs of medicinal products as well as ensuring that all activities are in compliance with GDP and GMP require an increased investment of resources and manpower for distributors and manufacturers.

Retailers are yet another layer of actors in the legal supply chain of selling

⁵¹³ Article 54, Medicines Directive 2001/83/EC.

⁵¹⁴ Discussed in detail in Chapter 3, Section 3.3.

⁵¹⁵ Discussed in detail in Chapter 3, Section 3.2.

⁵¹⁶ See Chapter 3, Sections 3.2.

⁵¹⁷ See Chapter 3, Sections 3.2. and 3.3.

medicinal products. Retailers, as generally understood supply the medicine directly to the public, such as the pharmacies and hospitals. The companies selling medicines online to members of the public also fall under this category and must possess the required authorisation from the Member State, wherein they are located. All companies having an authorisation to sell prescription and non-prescription medicines fall under the umbrella of the term retailers. These retailers are required to display the logo⁵¹⁸ if they are selling the medicinal products online. The Member States are allowed discretion in the restrictions that they impose on such retailers in the interest of protecting the general public and in the interest of public health.⁵¹⁹ It is also possible for the Member States to restrict the sale of medicines through physical pharmacists only and forbid the online sale of medicines if they deem fit.⁵²⁰ In 2009, the Court of Justice reached the same conclusion that the Member States may impose conditions provided that the conditions can be justified as measures to protect public health and do not restrict the functioning of the internal market.⁵²¹

The retailers are obliged to determine that the safety features on the medicinal products are intact and that the medicinal products have not been tampered with. Further, it is the retailers that will also bear the responsibility of carrying information relating to counterfeit medicines and advising on such information to the patients, if they are questioned on counterfeit medicines. As for the hospitals, which are also the final point of the dispensation of medicines, it is required that they also comply with the requirements of the Directive. However, hospitals are

⁵¹⁸ Discussed in Section 4.4 in detail.

⁵¹⁹ By virtue of Principle of subsidiarity, Article 4 and 5 TFEU, discussed in Chapter 2, Section 2.3.3.2.

⁵²⁰ Recital 23 of Falsified Medicines Directive 2011/62/EU.

⁵²¹ Joined cases C-171/07 and C-172/07, *Apothekerkammer des Saarlandes and Others V Saarland* ECR [2009] I-4171, paragraph 34 and 35.

also given certain dispensations with regard to compliance with the FMD.⁵²²

Whether the retailers are able to live up to the expectations of the FMD concerning the obligations of checking the safety features will only be evident once the safety features are fully implemented in 2019. So far, non-adherence to GMP⁵²³ and GDP was a major cause of infiltration of the legal supply chain as revealed in Chapter 3, wherein the wholesalers did not follow on checking the authorisations of the manufacturers. Therefore, in the absence of stringent penalties in the FMD, it is hard to be optimistic about compliance.

In addition to manufacturers, brokers, wholesalers, and retailers, parallel importers also play a significant role in the legal supply chain of medicinal products in the EU.⁵²⁴ Parallel trade has an impact on innovation, pricing, and availability of medicinal products, as voiced from within the CJEU.⁵²⁵ For obvious reasons of making a profit, the parallel traders purchase medicines in the EU in countries where the medicine prices are low and sell them in the countries where the prices of the same products are higher.⁵²⁶ On the other hand, a study concluded in 2005 indicated that the savings by parallel trade for health insurers are approximately 100 million Euros in the six prominent importing countries.⁵²⁷ In the EU, the TFEU and TEU, and the CFREU lay down the fundamental principles of free movement of goods, but at the same time, the Union laws on anti-competition and

⁵²² Smith, J. A., Naughton, B., Kramm, A., Smith, G., Ohanjanyan, A., De Simone, M. & Brindley, D. A. EU Falsified Medicines Directive: Requirements and Implications for Multi-Stakeholder Healthcare Delivery. Regulatory Affairs Professionals Society. Chapter 8, 76.

⁵²³ Bate, R. (2012). *Phake: the deadly world of falsified and substandard medicines*. AEI Press, 36.

⁵²⁴ Orizio, G., Schulz, J., Domenighini, S., Caimi, L., Rosati, C., Rubinelli, S., & Gelatti, U. (2009). Cyberdrugs: a cross-sectional study of online pharmacies characteristics. *The European Journal of Public Health*, 19(4), 375-377.

⁵²⁵ CF. conclusions of AGD. Ruiz- Jarabo Colomer of 1 April 2008 in case C-468/06 and in C 53/03.

⁵²⁶ Kanavos, & Costa-Font, J. (2005). Pharmaceutical parallel trade in Europe: stakeholder and competition effects. *Economic policy*, 20(44), 758-798; Ganslandt, M., & Maskus, K. E. (2004). Parallel imports and the pricing of pharmaceutical products: evidence from the European Union. *Journal of health economics*, 23(5), 1035-1057.

⁵²⁷ Kanavos, & Costa-Font, J. (2005). Pharmaceutical parallel trade in Europe: stakeholder and competition effects. *Economic policy*, 20(44), 758-798.

the legal situation concerning parallel pharmaceutical trader (PPT) are controversial. The PPT are required to hold a pharmaceutical wholesale authorisation, which is issued (in accordance with Article 77 of Directive 2001/83/EC) by the NCA in the Member States in which they are located. Essentially, as a manufacturing operation, all repackaging/re-labelling require a pharmaceutical manufacturing authorisation issued by a competent authority of the Member State where the parallel importer is located.

However, there are shortcomings in terms of the adequacy of legal interpretation, regulatory provisions and their effective implementation with regard to management, especially when it comes to parallel importers.⁵²⁸ The supply chain complexity in the EU has also been identified in the EC 2003 Communication.⁵²⁹ An analysis of this report clearly indicates examples highlighting the uncertainty stemming from the ambiguities of interpretation of EU rules, which spurs different interpretation in Member States. For instance, the potential problem with respect to regulation is the use of the term ‘sufficiently similar’, regarding import of excipients by parallel traders. When it is articulated in this manner that the importer may import a product that is sufficiently similar – it is an invitation for counterfeiters to introduce counterfeit products into the legal supply chain.

4.3.2. Import of APIs

Counterfeit medicines find their way into the EU borders in many forms. As discussed in the preceding chapter on case studies, it came to light that at times, counterfeit medicines enter the legal supply chain through actions of parallel

⁵²⁸ Dégardin, K., Roggo, Y., & Margot, (2014). Understanding and fighting the medicine counterfeit market. *Journal of pharmaceutical and biomedical analysis*, 87, 167-175.

⁵²⁹ Communication from the Commission on Regulation (EC) No. 141/2000 of the European Parliament and of the Council on orphan medicinal products. (2003). OJ C 178, 29.7.2003, 2 – 8.

importers (Operation Robin)⁵³⁰ and at other times, the API is imported from other countries (Operation Singapore⁵³¹ and Operation Robin).⁵³² Subsequently, the counterfeit medicinal product is assembled in the country that sells the product and the sale of the counterfeit medicinal product also occurs online (Operation Robin).⁵³³

The API,⁵³⁴ commonly known as ‘bulk pharmaceuticals’, form the “backbone” of a medicine. Each medicinal drug is composed of two parts – the API or the active substance,⁵³⁵ which is the healing ingredient of a medicinal product, and an excipient,⁵³⁶ which is any constituent of a medicinal product other than the active substance and the packaging material. Therefore, it is important to ensure the quality and safe manufacturing standards of APIs. This is particularly significant for APIs manufactured outside the EU as increasing number of medicines being manufactured are composed of active substances that are imported from a third country. If the active substance, which is imported in the EU is counterfeit, the medicine will obviously be counterfeit.⁵³⁷

In the case study – Operation Robin, the import of active substances transpired,

⁵³⁰ Chapter 3, Section 3.4.

⁵³¹ Chapter 3, Section 3.3.

⁵³² Chapter 3, Section 3.4.

⁵³³ Chapter 3, Section 3.4.

⁵³⁴ “An active pharmaceutical ingredient is defined in ICH Q7 as “any substance or mixture of substances intended to be used in the manufacture of a drug product and that, when used in the production of a drug, becomes an active ingredient in the drug product. Source: International Council of Harmonisation. (2015). *ICH Q7 Guideline: Good Manufacturing Practice Guide for Active Pharmaceutical Ingredients*. Geneva. ICH Secretariat.

⁵³⁵ Article 1 (3a) of the Medicines Directive 2001/83/EC inserted by Article 1 of the Falsified Medicines Directive 2011/62/EU.

⁵³⁶ Article 1 (3b) of the Medicines Directive 2001/83/EC inserted by Article 1 of the Falsified Medicines Directive 2011/62/EU.

⁵³⁷ Bera, A., & Mukherjee, A. (2013). Counterfeit and Spurious drugs: Big Challenges to the Health Care system worldwide. *Pharma Science Monitor*, 3(3); See also De Weerd, E., Simoens, S., Hombroeckx, L., Casteels, M., & Huys, I. (2015). Causes of drug shortages in the legal pharmaceutical framework. *Regulatory toxicology and pharmacology*, 71(2), 251-258.

which resulted in manufacturing of fake medicines in a factory in Sweden.⁵³⁸

Furthermore, another complicating factor is that, at times, an API can be used in different permutations and combinations for multiple products. For instance, the same API can be used for non-medicinal purpose, as well as medicinal purpose, just as medicines can be used for medical or non-medicinal purposes.⁵³⁹ Once the API has been imported into the EU under the guise of being used for a non-medical purpose, there is no way to ensure that the API will not be used for a medicinal purpose, as there are limited ways to precisely ascertain it. Therefore, the EU reformed the rules for importing API.⁵⁴⁰ It is a requirement that all imported APIs must have been manufactured in compliance with standards of GMP, at least equivalent to the GMP of the EU,⁵⁴¹ which introduced an EU wide rule for the importation of active substances. In addition, the European Commission issued further guidelines on principles of Good Distribution Practice of active substances for medicinal products for human use in 2015, which also need to be complied with.⁵⁴²

As evident from the legal case studies, counterfeit APIs are often imported in small packages and escape undetected because they arrive at mailboxes in parcels

⁵³⁸ See Chapter 3, Section 3.4.

⁵³⁹ Abadinsky, H. (2010). *Drug use and abuse: A comprehensive introduction*. Cengage Learning.

⁵⁴⁰ European Commission. (2013). New Rules on importing active pharmaceutical ingredients into the European Union. Press Release. Brussels.

⁵⁴¹ Article 46 b (2) Medicines Directive 2001/83/EC states that active substances can only be imported if, inter alia, the active substances are accompanied by a written confirmation from the competent authority of the exporting third country, which, as regards the plant manufacturing the exported active substance, confirms that the standards of good manufacturing practice and control of the plant are equivalent to those in the Union.

⁵⁴² Guidelines on principles of Good Distribution Practice of active substances for medicinal products for human use, of 19 March 2015, 2015/95/01; See also The manufacturing standards recognised in the EU for APIs are those of the 'International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH). (2015). The ICH Quality Guidelines, Q7 relate to Good Manufacturing Practices. It is part of tripartite guidelines, developed by an expert working group, for adoption and sent to the regulatory bodies of the European Union, Japan and USA. Geneva. ICH.

and couriers.⁵⁴³ Furthermore, at times, the APIs imported for non-medicinal purpose penetrate the legal supply chain. This issue is especially convoluted, because these APIs are not imported as APIs, and therefore, these substances cannot be apprehended at the EU borders. After these substances enter the EU borders, under the guise of ‘fertilisers’ or vitamins or such, they are assembled in factories, as occurred in Operation Robin,⁵⁴⁴ and thereafter, are sold as medicinal products. In the regulation of chemical substances, which can be hazardous,⁵⁴⁵ there is a provision of reverse burden of proof. In that provision, a substance that can be used as a chemical substance is considered a hazardous chemical substance unless otherwise proven. Even though APIs, if used in manufacture of falsified medicines can be equally hazardous to public health and safety, such a ‘reverse burden of proof’ does not exist in the sphere of Medicine law, as yet.

4.3.3 Deficiencies

4.3.3.1 Illegal supply chain feeds the legal supply chain

In the EU, the legal supply chain for pharmaceutical products involves a series of market players.⁵⁴⁶ The typical flow of the supply chain is like this: the manufacturer sends over the pharmaceutical products to the distributor, who delivers to the wholesaler and the wholesaler delivers to the retailers, which can be the pharmacy, the hospital, or any other authorised retailer, like Boots in the UK or Matas in Denmark. At times, the retailers can also be online pharmacies or

⁵⁴³ Chapter 3, Case No. B 6262 -12, Judgement of Stockholms Tingsrätt of 25 June 2013 discussed in Section 3.4. Operation Robin.

⁵⁴⁴ Chapter 3, Section 3.4., Operation Robin.

⁵⁴⁵ Hansson, S. O. (1997). Can we reverse the burden of proof? *Toxicology Letters*, 90(2-3), 223-228.

⁵⁴⁶ Tremblay, M. (2013). Medicines counterfeiting is a complex problem: a review of key challenges across the supply chain. *Current drug safety*, 8(1), 43-55.

other authorised sellers who hold a market authorisation. The retailers finally sell the medicinal product to the patients. In the legal supply chain in the EU, the complexity of the supply chain is amplified by the presence of parallel importers, brokers, and re-packagers as well. In addition, to these additional actors in the legal supply chain, there can also be secondary wholesalers or multiple wholesalers in the legal supply chain, as illustrated in (Figure 8). It is presumed that, in the legal supply chain, the end product is purchased by the patient, who believes that he is paying for the original/non-counterfeit medicinal product.

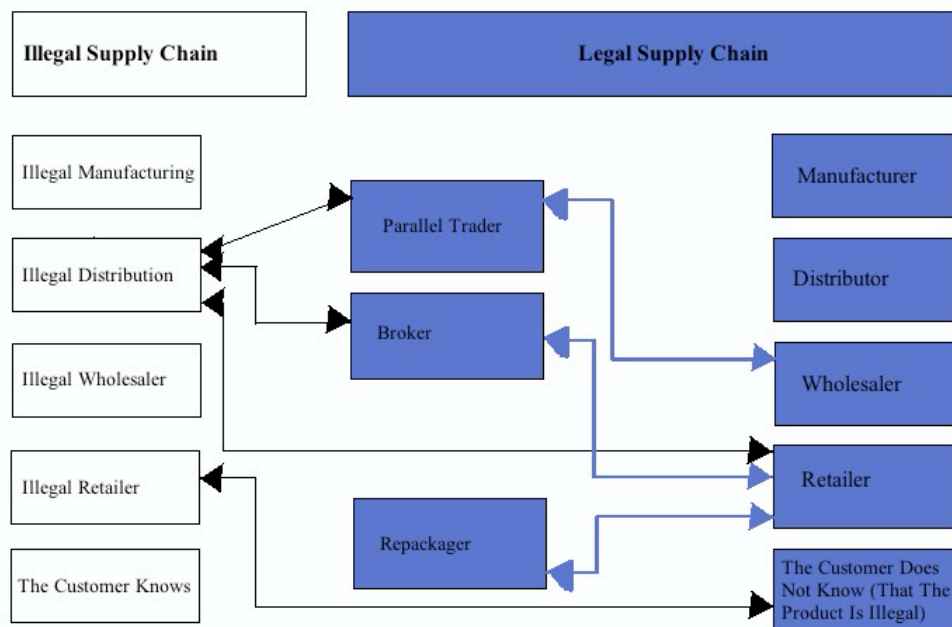


Figure 8: Adapted from 2015 Situation Report on Counterfeiting in the European Union – A joint project of Europol and OHIM⁵⁴⁷

It is important to recognise that parallel to the legal supply chain, there is also an illegal supply chain, which has a similar structure (see Figure 8), as was revealed

⁵⁴⁷ Adapted from Office of Harmonisation in the Internal Market & Europol. (2015). Situation Report on Counterfeiting in the European Union – A joint project between Europol and the Office for Harmonization in the Internal Market. 20.

in Operation Singapore, Operation Volcano⁵⁴⁸ and Operation Robin, as discussed in Chapter 3.⁵⁴⁹ In the documentary evidence for Operation Robin, the entire management structure carrying out the counterfeit operation network was pieced together and revealed.⁵⁵⁰ It can be deduced, as was also presented in the Situation Report 2015⁵⁵¹ that parallel to the legal supply chain, there exists an illegal supply chain comprises of illegal manufacturer, distributor, wholesaler, and retailers, who sell to patients, who are sometimes aware of what they are getting themselves into. In other words, sometimes, the patients willingly buy illegal products.⁵⁵²

However, the complexity of the supply chains that compounds the problems for the legal framework is the fact that the illegal supply chain feeds the legal supply chain. For instance, as illustrated in *Figure 8*, a parallel importer can unwittingly purchase products from the illegal distributor and supply the products to a legitimate wholesaler. At times, a legitimate retailer may also purchase medicinal products from an illegal wholesaler. There have also been instances, where a patient has unknowing purchased medicines from an illegal website, assuming that the products being sold are legitimate.⁵⁵³

⁵⁴⁸ The medicines, after being stolen from the truck carrying the authentic medicines, were sent to an illegal wholesaler, who manipulated the drugs and re-introduced them in the legal supply chain by delivering them to a legitimate wholesaler. *See more in* Chapter 3, Section 3.2.

⁵⁴⁹ Chapter 3, Section 3.4.

⁵⁵⁰ Case No. B 6262 -12, Judgement of Stockholms Tingsrätt of 25 June 2013.

⁵⁵¹ Office of Harmonisation in the Internal Market & Europol. (2015) Situation Report on Counterfeiting in the European Union – A joint project between Europol and the Office for Harmonization in the Internal Market.

⁵⁵² Pál, S., Laszlo, K., Andras, F., Gabriel, H., Hajnal, F., Adriana, C. I. U. R. B. A., & Lajos, B. (2015). Attitude of patients and customers regarding purchasing drugs online. *Farmacia*, 63(1), 93-98; Fittler, A., Lankó, E., Brachmann, B., & Botz, L. (2013). Behaviour analysis of patients who purchase medicines on the internet: can hospital pharmacists facilitate online medication safety? *European Journal of Hospital Pharmacy: Science and Practice*, 20(1), 8-12.

⁵⁵³ Lavorgna, A. (2015). The online trade in counterfeit pharmaceuticals: new criminal opportunities, trends and challenges. *European Journal of Criminology*, 12(2), 226-241; *See also* Hoofnagle, C. J., Altaweel, I., Cabrera, J., Choi, H. S., Ho, K., & Good, N. (2017). Online pharmacies and technology crime. *The Routledge Handbook of Technology, Crime and Justice*, 146.

4.3.3.2. Lack of clear regulation

A closer assessment of the three Operations, as well as the exploration of other cases,⁵⁵⁴ reveal that the reason for late detection of counterfeit medicine is not lack of regulation, as much as lack of clear regulation. The overlap in the responsibilities of a Market Authorisation Holder, as a distributor, or wholesaler has an inbuilt scope for ignoring responsibilities or relying on the previous member of the supply chain for having complied with the requirements. Hence, there is a clear possibility that no action or checking actually takes place. For instance, in Operation Volcano,⁵⁵⁵ the investigations⁵⁵⁶ were commenced when a wholesaler filed a complaint for incongruence between batch numbers discovered in some packages of Herceptin purchased from an Italian wholesaler, Farmaceutica Internazionale S.r.l., which were on their way to Germany. Up until that point, the counterfeit medicine had travelled from Italy to the UK, bound for Germany, without suspicion.

In order to encourage compliance, it is imperative to strike the right balance.⁵⁵⁷ For instance, loading too much responsibility on the wholesalers as regards to compliance with GDP and GMP, and expecting them to cross check manufacturing authorisation of all the previous holders of medicinal products, or expecting hospitals, pharmacies and retailers to check the safety features without

⁵⁵⁴ Jack, A. (15 February 2017). *Teva Discovers Sophisticated Fake Drugs*. Financial Times. Omeprazole (for gastroesophageal reflux disease), fake drugs were supplied to wholesale drug distributors and reached patients discovered in Germany in 2013.

⁵⁵⁵ See more in Chapter 3, Section 3.2. Herceptin (for breast cancer) was discovered in Finland, Germany, Austria, and Sweden in 2014 where vials labelled as Herceptin were thought to have labels and packaging tampered with, following theft of Herceptin in Italy. The product was suspected to be in possession of many wholesalers in several countries.

⁵⁵⁶ AIFA case files. (16 April 2014). *Theft and laundering of medicines: early results of the AIFA project: The Herceptin Case* Press Release n. 355. Rome. Agenzia Italiana del Farmace (AIFA).

⁵⁵⁷ Hamilton, W. L., Doyle, C., Halliwell-Ewen, M., & Lambert, G. (2016). Public health interventions to protect against falsified medicines: a systematic review of international, national and local policies. *Health policy and planning*, 31(10), 1448-1466.

having effective means to check compliance, may actually lead to non-compliance, as recognised in the previous chapter. And non-compliance with the requirements opens up the legal supply chain to infiltration by falsified and counterfeit products.

One major hurdle in dealing with an inflow of falsified and counterfeit medicines in the EU is controlling entry of counterfeit APIs into the EU. This typically occurs when the APIs arrive in small consignments.⁵⁵⁸ Although it is recognised that the solution to this problem may lie in Customs Regulation, it is nevertheless vital to recognise this deficiency in the system. Secondly, the APIs are sometimes imported under the disguise of non-medical ingredients like vitamins, antioxidants and minerals when there are very strict guidelines in place in the EU with regard to dealing with import of APIs.⁵⁵⁹

As was discovered in Operation Volcano, as well as Operation Singapore – a common problem has been the use of falsified documents to facilitate infiltration of the falsified and counterfeit medicines in the legal supply chain. In Operation Volcano, fake authorisations and forged receipts were issued by fake wholesalers and distributors based in other countries.⁵⁶⁰ Unlike the paper currency, which has an authenticating watermark which makes it difficult to forge currency, the authorisation certificates used in the trade of medicinal products lack such security features required by law. Thus, there is a lack of concrete methodology for ensuring the authenticity of the official certification documents in the trade of medicinal products.

⁵⁵⁸ Chapter 3, Section 3.3.

⁵⁵⁹ European Commission, New Rules on importing active pharmaceutical ingredients into the European Union, Press Release, October 2013.

⁵⁶⁰ Chapter 3, Section 3.2.

Further, in the light of the fact that a cross- border element is always involved in cases of counterfeiting and falsification of medicines, having clarity as to which Member State should take the lead and on what basis, in the Directive is imperative. In certain matters, clarification of the role and responsibilities of the Member States is also provided. For example, under Article 85c 1(c)⁵⁶¹ wherein it is stated that the Member State (where the natural or legal person offering the medicinal products for sale at a distance is based) shall ensure that the medicinal products comply with the national legislation of the Member State of destination. However, this degree of clarity does not exist in the context of initiation of inquiries and investigations. Therefore, it continues to be challenging to assess which particular Member State should lead the investigations. It could potentially be the Member State that received the falsified substances to be used in the manufacturing process of a falsified medicine. But it could also be the Member State where the counterfeit medicines were put together. This unresolved dilemma that confronts the authorities, in practice, results in loss of crucial time and has an impact on the detection of cases of counterfeiting and falsification medicines.

4.4. Online sale of medicinal products

Besides the traditional means of distributing medicines through brick and mortar pharmacies, there is a marked global increase in the number of medicines (both prescription as well as non-prescription) being sold online.⁵⁶² In fact, a lot has changed since Soma.com⁵⁶³ came into existence in January 1999, as the first

⁵⁶¹ Article 85c (1) (c) of Medicines Directive (Directive 2001/83/EC) was inserted by Article 1(20) of Falsified Medicines Directive (Directive 2011/62/EU).

⁵⁶⁴ Clark, F. (2015). Rise in online pharmacies sees counterfeit drugs go global. *The Lancet*, 386(10001), 1327-1328; Eban, K. (2006). *Dangerous doses: A true story of cops, counterfeiters, and the contamination of America's drug supply*. Houghton Mifflin Harcourt.

⁵⁶³ Gallagher, J. C., & Colaizzi, J. L. (2000). Issues in Internet pharmacy practice. *Annals of Pharmacotherapy*, 34(12), 1483-1485.

pharmacy to operate via the internet for selling medicines. Currently, it is estimated that there are around 35,000 internet pharmacies operating worldwide.⁵⁶⁴ This trend of selling and buying medicines online has led to an increase in the number of cases of sale of counterfeit medicinal products in general.⁵⁶⁵

In the EU, Operation Robin⁵⁶⁶ revealed the role of online pharmacies in the sale of counterfeit medicines as a game changer. As discussed in depth in Chapter 3,⁵⁶⁷ three different websites were used to sell counterfeit medicinal products,⁵⁶⁸ – www.steriodakuten.org, www.vikingstore.org and www.anabolic.cc.⁵⁶⁹ In this case, the crucial point of contact between the customers and the sale of illegal products was through the websites. This practice of sale of counterfeit medicine through online pharmacies is not exclusively occurring in the EU, and is, in fact, a worldwide phenomenon since the sale and purchase of pharmaceutical products is possible through the internet, and is accessible in all parts of the world.

In the light of increasing number of such incidents and reports of fake pharmaceutical websites in the EU, the 2001 Medicines Directive was amended to address the online sale of medicines by the FMD. As acknowledged in the Preamble of the FMD,⁵⁷⁰ the illegal sale of medicines to the public through the internet is perceived as an important threat to public health. Due to the recognition of the seriousness of the risk, the Member States have been given the power to

⁵⁶⁴ CSIP, LegitScript, (January 2016) *The Internet Pharmacy Market in 2016: Trends, Challenges, and Opportunities*. Center for Safe Internet Pharmacies. USA..

⁵⁶⁵ Seeberg-Elverfeldt, N. J. (2009). Mail-Order Trade in Medicines in Europe—A Guide for Legislators to Protect Consumers. *European journal of health law*, 16(4), 351-366.

⁵⁶⁶ See Chapter 3, Section 3.4.

⁵⁶⁷ Chapter 3.

⁵⁶⁸ Case No. B 6262 -12, Judgement of Stockholms Tingsrätt of 25 June 2013.

⁵⁶⁹ Case No. B 6262 -12, Judgement of Stockholms Tingsrätt of 25 June 2013, 47.

⁵⁷⁰ Recitals 21 and 24 Falsified Medicines Directive 2011/62/EU.

restrict the sale of pharmaceutical products through online pharmacies.⁵⁷¹

Recognising the importance of assisting the general public in sifting the legitimate websites selling medicines from the illegitimate websites,⁵⁷² the FMD introduced a provision enlisting the requirements to be fulfilled by all legitimate websites selling medicinal products. They are required to bear a common EU logo, which must be prominently displayed, as introduced by the Medicines Directive 2001/83/EC amended by the FMD.⁵⁷³

The exact provisions pertaining to the features of the logo for online pharmacies are contained in the Regulation (EU) no. 699/2014.⁵⁷⁴ The logo is expected to identify persons offering medicinal products for sale at a distance to the public and the technical, electronic, and cryptographic requirements for verification of its authenticity for online retailers and the establishment of registers of legitimate online retailers.

The primary goal of the EU logo for online pharmacies in the EU is to serve as a mark of authentication⁵⁷⁵ and aid in identifying legitimate online pharmacy in the EU.⁵⁷⁶ Each online pharmacy is required to be linked to the national competent authority's website, i.e. the National Medicines Agency of a Member State. By

⁵⁷¹ Judgment of the Court of 19 May 2009 in Joined Cases C 171/07 and C 172/07 *Apothekerkammer des Saarlandes and Others v Saarland* ECR [2009] I-4171, paragraph 34 and 35.

⁵⁷² Recital 25, Falsified Medicines Directive, 2011/62/EU.

⁵⁷³ Article 85 (c) inserted in Directive 2001/83/EC by Directive 2011/62/EU of the European Parliament and of the Council of 8 June 2011 amending Directive 2001/83/EC on the Community code relating to medicinal products for human use, as regards the prevention of the entry into the legal supply chain of falsified medicinal products

⁵⁷⁴ Commission Implementing Regulation (EU) No 699/2014 of 24 June 2014 on the design of the common logo to identify persons offering medicinal products for sale at a distance to the public and the technical, electronic and cryptographic requirements for verification of its authenticity.

⁵⁷⁵ Concept Paper, Implementing Act on a Common Logo for legally operating online pharmacies/retailers offering medicinal products for human use for sale at a distance to the public, Sanco.ddgl.d. 6 (2012) 1117232.

⁵⁷⁶ Consultation paper October 17, 2012, Implementing Act on a Common Logo for Legally Operating Online Pharmacies/Retailers Offering Medicinal Products for Human Use for Sale at a Distance to the Public.

clicking on the link, the consumer should be led to the national competent authority's website and this would imply that the online pharmacy is a legitimate website and is registered in the Member State. A list of all legitimate online pharmacies is maintained by the NCAs for assisting the patients in determining the legitimacy of the online pharmacies/websites selling medicines. For instance, in Denmark, each legitimate online pharmacy⁵⁷⁷ would have a logo prominently displayed on its website, in fact, on each of its webpages. When a consumer clicks on the logo, the consumer is led to the Danish Medicines Authority's webpage, where the name, address, and website of the online pharmacy is clearly stated.⁵⁷⁸

The foremost advantage⁵⁷⁹ of the EU logo is that it is user-friendly because all that is required is to click on a logo, which leads to the verification of the website. Thus, in a relatively easy manner, it is easy for an average person to determine the legitimacy of the website.

4.4.1. Deficiencies

Firstly, although there is a mechanism set in place to determine the authenticity of the website,⁵⁸⁰ there are no concrete measures to determine whether the website in question is leading to the national website or a fake one. Unlike the preferred strategy in the US, where the top level domain (TLD) '.Pharmacy' (dot Pharmacy) is encouraged to be used by legitimate pharmacies and retailers selling medicines

⁵⁷⁷ As an example <http://www.apoteket.dk/Webshop.aspx> last accessed on January 23 2017.

⁵⁷⁸ Danish Medicines Agency. (September 2015). Pharmacies selling medicines legally online. In *Pharmacies and sale of medicines*. Copenhagen. Danish Medicines Agency.

⁵⁷⁹ Kohli, V. P. (2015). New EU Logo for Online Pharmacies: Is it geared to serve its Purpose? In *Erhvervsretlige Emner*. Copenhagen. Djøf/Jurist-og Økonomforbundet. 101-114.

⁵⁸⁰ Jack, A. (2016). Can anyone stop the illegal sale of medicines online? *BMJ: British Medical Journal (Online)*, 352.

as it allows the patients to identify authentic and legitimate websites easily,⁵⁸¹ in the EU the system is more complex. Therefore, it is difficult to assess if the website connecting to the online pharmacies is an authentic national website.

Secondly, there is a marked proliferation of the methods in which the medicines are finding their way online.⁵⁸² For instance, the social media such as Facebook⁵⁸³ and Twitter are also being used, at times, as a legitimate source of advertising,⁵⁸⁴ but also for *malvertising*⁵⁸⁵ to sell medicines online. For instance, when unsolicited bulk email messages or spam are sent to compromised computers. Recently, in case studies conducted,⁵⁸⁶ it was revealed that sometimes the perpetrators are hired to spam. Another form of malvertising is when peer-to-peer advertising is done on online forums, mainly dealing with dangerous substances, for example, hazardous slimming treatment or anabolic steroids that have not undergone the required clinical tests and thus, have a potentially harmful effect.⁵⁸⁷

Currently, there are a number of websites, one for each NCA, which is linked to the online pharmacies. Therefore, there are at least 28 Member State websites that need to be maintained and protected from fraud and need to have exactly the same

⁵⁸¹ In the US, the National Association of Boards of Pharmacies (NABP) is the mastermind behind the initiative to handle the challenges of sale of counterfeit and falsified medicines online. ⁵⁸¹NABP owns the 'Pharmacy' (top level domain) TLD. This TLD is devoted to patient safety and health. The 'Pharmacy' TLD can only be obtained for the legitimate purpose of selling authentic medicines and they have to adhere to ten core safety standards. It is a significant method used to pre-validate online pharmacies. This venture is supported by FIP (the global federation of 126 national associations of pharmaceutical scientists and federations).

⁵⁸² Hall, A., Koenraadt, R., & Antonopoulos, G. A. (2017). Illicit pharmaceutical networks in Europe: organising the illicit medicine market in the United Kingdom and the Netherlands. *Trends in Organised Crime*.

⁵⁸³ Zabyelina, Y.G. (2017). United States v. Eric L. Crocker, 'The United States District Court' in Can criminals create opportunities for crime? Malvertising and illegal online medicine trade., *Global Crime Vol. 18*, (1)

⁵⁸⁴ The legitimate advertising method of sale would be in consonance with the FMD and the Regulation as long as the logo is clearly visible.

⁵⁸⁵ A term which denotes malicious advertising and is used while referring to legitimate online advertising, which is maliciously embedded with malware to latch on to legitimate advertising. The malvertising phenomenon is hard to trace and the victims are often unfamiliar with the process.

⁵⁸⁶ Zabyelina, Y.G. (2017). Can criminals create opportunities for crime? Malvertising and illegal online medicine trade. *Global Crime Vol. 18*, (1)

⁵⁸⁷ *ibid*.

authentication function. It would have been simpler to have one common link to one EU wide authentication website, as also recommended by the EFPIA in the response to the Public Consultations.⁵⁸⁸ Thereby, a consumer based in the Netherlands buying from a legitimate Italian website could still get the required authentication data. The requirement for national websites has given a broader area for illegal operators to play with.

The problem with the current approach is that not only is the onus shifting from the authorities to the general public – especially when it comes to managing the problem - it is also going to give rise to the problem of enforcement. In the current context of online pharmacies and counterfeit medicines in general, the patients have to be aware of the problem of illegitimate websites, as it is the consumers that are required to check if the websites are linked to the competent authority's website. The authorities will only intervene if illegitimate websites are brought to their attention. A questionable practice that seems to emerge here is that the FMD, being part of the public law, is swerving towards placing the onus on private citizens to take action just like it was enforcement of a private right such as an IPR.

Furthermore, the use of the online logo is a symptom of this trend. There is also no effective way, provided by law, of technically withdrawing the logo after it is granted to an online pharmacy, if that pharmacy turns rogue. The only action that can be taken is the removal of the name of the pharmacy from the Member States link to list of valid online pharmacies. If the potential consumer only looks at the

⁵⁸⁸ EFPIA. (17 January 2013). Implementing Act on a common logo for legally-operating online pharmacies/retailers offering medicinal products for human use for sale at a distance to the public - Concept Paper submitted for Public Consultation EFPIA Response.2.

logo and buys from the online pharmacy without checking if the name of the website appears on the list of valid online pharmacies maintained by the Member State, the goal of controlling counterfeit medicines in the EU stands to be defeated.

4.5. Concluding remarks

The FMD only addresses the legal supply chain; the trade in counterfeit and falsified medicines is illegal in nature and when this trade occurs with the knowledge and consent of the consumer in the illegal supply chain, it is more difficult to detect. However, the problem becomes even more convoluted when the illegal supply chain permeates the legal supply chain, as illustrated in Figure 8.⁵⁸⁹ Therefore, while addressing the general problem of counterfeiting in the pharmaceutical sector in the EU, it is pertinent to take into consideration all channels that allow entry of counterfeit medicines in the EU.

In efforts to control counterfeiting of medicines in the EU, the legal framework has to be cautious about zealously pursuing regulation. Lack of clear regulation can lead to non-compliance, as has been evidenced in the case of the supply chain, where manufacturing authorisation holders did not check the authorisation of the previous holders of the medicinal products and did not verify if GDP and GMP were being complied with. The legal supply chain has been made clearer by defining the roles of the various players. By explicitly requiring specific authorisations for all the market players, including the brokers as introduced by the FMD attempts to impart greater clarity to the individual role of each actor in the legal supply chain. If the authorisation certificates were secured with

⁵⁸⁹ See Figure 8 in Section 4.3.3.1.

watermarks, as employed in the currency or with other security mechanisms, which would be difficult to imitate and copy, it would assist in eliminating the problem of fake authorisations. By doing so, one common avenue of the introduction of falsified medicines into the legal supply chain can be blocked.

Furthermore, the importation of APIs is also a critical matter in which products that aid in the production of falsified medicines, enter the EU, as was witnessed in Operation Robin. Therefore, it is important to have a strong dissuasive measure in order to be more effective such as ‘reverse burden of proof’ used in import of chemical substances because falsified medicines can be just as hazardous as chemical substances.

Another important contribution of the FMD is the rules pertaining to the online sale of medicines in the EU. The introduction of the online logo will go a long way in protecting the patients in the long run. However, there are still certain gaps that need to be bridged in this area. For instance, determining the authenticity of the website itself and a mechanism for dealing with pharmacies that turn rogue.

The other issues that remain to be tackled are, firstly, the question of which Member State should take the lead in initiating investigations of the act of counterfeiting. It could be beneficial to the case to require the Member State where the raw materials (for example, the counterfeit APIs) are found to head the investigations but the Member State where the counterfeit product is manufactured or assembled is equally relevant and crucial to resolving such cases. However, as a result of lack of clarity on this matter, potential cases run the risk of not getting addressed. It would be prudent to involve the Member State in which the counterfeit material is received, as well as the State where the manufacturing of the counterfeit product actually takes place. These are, in fact, two steps of the

larger process of counterfeiting and falsification of the medicinal product. Hence, there needs to be clarity regarding the role of the Member States involved.

Moreover, being a cross-border activity where there are at least two different Member States involved, sharing of information and coordination of resources is crucial. As the case studies revealed, Operation Singapore and Operation Robin were two distinct operations involving an investment of the huge amount of resources. There have been similar cases across the EU, but common coordinated efforts have been few.

In the Medicines Directive, there is a provision for coordinated action requiring issuing of Rapid Alerts under 117a (3),⁵⁹⁰ which as introduced by the FMD, Article 1(24), whereby all the relevant authorities across the Member States must be informed if falsified medicines having life threatening consequences are discovered. Further, if the medicinal product in question has reached the patients, then urgent recalls⁵⁹¹ must be issued, making public announcements incorporating information on the suspected quality defect and the possible risks. However, a similar provision pertaining to this problem, where more than two Member States are involved is lacking.

In the light of the fact that it is asserted in the thesis that counterfeiting and falsification of medicines lies at the intersection of IP Law, Medicine Law, and Criminal Law,⁵⁹² it is of utmost importance to have lines of communication and information sharing open between the authorities representing the three spheres of law in order to effectively combat the problem of counterfeiting and falsification

⁵⁹⁰ Article 117a (3), Directive 2001/83/EC inserted by Article 1(24) of Directive 2011/62/EU.

⁵⁹¹ A drug recall means removal of a prescription or over-the-counter drug from the market by the national competent authority, usually a medicines agency.

⁵⁹² See Chapter 1, Section 1.2.

of medicinal products in the EU. Therefore, a similar provision for building synergies between the three streams of law – Medicine law, IP law and Criminal law, between the different relevant authorities within and across the Member States in connection with general coordination strategy could be extremely relevant for resolving matters revolving around counterfeiting and falsification of medicinal products. However, in the current laws, such a provision is absent.

Chapter 5: Analysis of Enforcement Directive (Directive 2004/48/EC)

5.1. Introduction

Since the issue of counterfeiting and falsification of medicinal products lies at the intersection of IP law, Medicine law and Criminal law,⁵⁹³ it is imperative to consider all the relevant spheres of laws to obtain a complete understanding. In the previous chapter, the perspective of Medicine law was presented by analysing the FMD, specifically with reference to areas pertaining to manipulation of the product, infiltration of the legal supply chain and online sale of medicines.⁵⁹⁴ It was also explained in the preceding chapter that the FMD does not address the IP law violations.⁵⁹⁵

Therefore, in this chapter, the Directive 2004/48/EC⁵⁹⁶ (henceforth, referred to as ‘the Enforcement Directive’) is analysed, representing the IP Law perspective.⁵⁹⁷ The general background to the formation of the Enforcement Directive serves as the starting point of the discussion, followed by a broad legal analysis with respect to the fundamental difference between the nature of Enforcement Directive and Customs Regulation, on the one hand, and the FMD, on the other hand. Thereafter, the repercussions of this crucial difference on combatting counterfeiting and falsification of medicinal products will be analysed. Thereafter,

⁵⁹³ Chapter 1, Section 1.2.

⁵⁹⁴ Chapter 4, Sections 4.2, 4.3, and 4.4.

⁵⁹⁵ Recitals 5 and 29, Directive 2011/62/EU.

⁵⁹⁶ Directive 2004/48/EC of the European Parliament and of the Council of 29 April 2004 on the enforcement of intellectual property rights.

⁵⁹⁷ See more in Chapter 1, Section 1.2. and Chapter 2, Section 2.3.4.2.

the focus of the chapter narrows down to analysing the challenges that arise while combatting counterfeit medicines in the EU, as highlighted in Chapter 3.⁵⁹⁸ The main challenges recognised in Chapter 3 included the manipulation of medicinal products; infiltration of the legal supply chain due to prevalence of fake market authorisations and use of disguise of parallel imports; sale of counterfeit medicinal products online; involvement of more than one Member State and the role played by organised crime.⁵⁹⁹ In other words, an analysis of the challenges that arise due to cross-border applicability of the provisions while enforcing IP rights will be considered. After that, the role of intermediaries in cases of online sale of medicines will be evaluated. Finally, the lack of harmonisation of criminal measures with respect to violation of IP rights will be taken into consideration.

While examining with the problem of counterfeiting of medicines in the sphere of IP law, primarily the area of trademarks is most relevant for the purposes of this thesis. In the EU, the Directive 2015/2536⁶⁰⁰ (henceforth, referred to as ‘the Trademarks Directive’), contains provisions that approximate the laws of the Member States relating to trade marks. The Trademarks Regulation⁶⁰¹ provide the legal basis of protection of EU trade marks (EUTM) and contains other measures to streamline the entire system to grant more legal certainty and foster a well-functioning internal market. The most common issues that arise with respect to counterfeit medicines usually pertain to false representation due to products not being in original packaging⁶⁰² as illustrated in C – 102/77 Hoffmann-LaRoche v.

⁵⁹⁸ Chapter 3, Section 3.5.

⁵⁹⁹ *ibid.*

⁶⁰⁰ Directive (EU) 2015/2436 of the European Parliament and of the Council of 16 December 2015 to approximate the laws of the Member States relating to trade marks.

⁶⁰¹ See Articles 9 and 10, of Regulation (EU) 2017/1001 of the European Parliament and of the Council of 14 June 2017 on the European Union trademark, applicable from October 1, 2017.

⁶⁰² Most of the case law available on counterfeit medicine in the EU, revolves around the question of re-packaging and conditions which were not upheld, thus infringing the rights in the trademarks. See Case 102/77 Hoffmann-La Roche v Centrafarm [1978] ECR 1139 paragraph 7, Case 1/81 Pfizer v Eurim-Pharm [1981] ECR 2913,

Centrafarm, C 1/81 Pfizer v. Eurum –Pharm. The false products can also appear in false packaging,⁶⁰³ which cause loss of reputation and goodwill of the original producer and the proprietor of the trademark in violation of Article 10(2) and (3) and Article 11 of Directive 2015/2536. This was very well illustrated in Operation Singapore, wherein the primary accused P. Gillespie was sentenced for three years of imprisonment on the counts of selling counterfeiting medicines.⁶⁰⁴ Therefore, it is relevant to consider the Enforcement Directive, which encompasses rules pertaining to the enforcement of IPRs, including protection of trademarks in the EU.

The Enforcement Directive came about in accordance with the provisions of the internal market of the Treaty of Rome.⁶⁰⁵ The main aim of the Enforcement Directive is the protection and enforcement of IPRs and it further contributes to the realisation of freedom of movement; elimination of distortions of competition, and promotion of innovation and investment in the EU.⁶⁰⁶ The goals of the Enforcement Directive are in consonance with the right to property as well as the right to IP as envisaged respectively, in the Charter of Fundamental Rights of the European Union⁶⁰⁷ and the TFEU.⁶⁰⁸

paragraph 7; *See more examples in* C 71/94 Judgment of the Court of 11 July 1996. Eurim-Pharm Arzneimittel GmbH v Beiersdorf AG (C-71/94), Boehringer Ingelheim KG (C-72/94) and Farmitalia Carlo Erba GmbH (C-73/94). Reference for a preliminary ruling: Bundesgerichtshof - Germany. Repackaging of trade-marked products - Article 36 of the EC Treaty. Joined cases C-71/94, C-72/94 and C-73/94. European Court Reports 1996 page I-03603. *See also* Chapter 3, Section 3.2. Operation Volcano, where *Herceptin*, the cancer treatment drug was stolen from a delivery truck on its way, to deliver authentic medicines, to a hospital. Thereafter, the drug was manipulated and re-introduced in the original packaging of its manufacturer, Roche, and re-introduced in the legal supply chain.

⁶⁰³ *See more in* Chapter 5, Section 3.3., R v. Peter Hugh Gillespie and others, Crown Court at Croydon in R v. Peter Hugh Gillespie (2012) 2 Cr. App. R. (S) 24. Peter Gillespie was convicted and sentenced Trade Mark offence for selling counterfeit goods (*Casodex, Plavix and Zyprexa*).

⁶⁰⁴ *ibid.*

⁶⁰⁵ Treaty establishing the European Economic Community, 25 March 1957, 294 U.N.T.S. 3 (entry into force 1 January 1958).

⁶⁰⁶ See Article 26, TFEU, and Recital 32, Directive 2004/48/EC.

⁶⁰⁷ See Article 17(2), CFREU.

⁶⁰⁸ See Article 118, TFEU.

The need for a legal framework in the EU as regards enforcement of IP was recognised much before,⁶⁰⁹ but only later in the 1980s with regulation regarding counterfeit goods (see *Table 3* below), it began to be formalised with respect to combatting counterfeit goods. Subsequently, in the 1990s, as an aftermath of the TRIPS Agreement⁶¹⁰ and especially through the Green Paper on Combatting Counterfeiting and Piracy in the Single Market,⁶¹¹ the differences in the legislations of the Member States were brought to light. The Green Paper also underlined the negative impact of these disparities on realisation of the goals of the internal market. These deliberations culminated in establishment of the Enforcement Directive⁶¹² Although it was the first endeavour at the EU level to introduce harmony in laws of the Member States in civil law legislations, the Enforcement Directive was a target of extreme criticism.⁶¹³ As is evident from the table (*Table 3* below), continuous efforts have been made over the year through specific strategies designed particularly, in 2008, 2010, and 2014 to address the pertinent issues of counterfeiting and piracy.

⁶⁰⁹ See Chapter 2, Section 2.3.4.2.

⁶¹⁰ TRIPS: Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 1869 U.N.T.S. 299, 33 I.L.M. 1197 (1994).

⁶¹¹ Green Paper of 15 October 1998 'Combating Counterfeiting and Piracy in the Single Market', COM (98) 569 final.

⁶¹² Vrins, O., & Schneider, M. (2014). Cross-border enforcement of intellectual property: The European Union. Torremans, P. (Ed.) (2014). *Research handbook on cross-border enforcement of intellectual property*. 166-328.

⁶¹³ The Directive was passed just days before ten East and Central European countries were going to accede to the EU. The Accession Treaty entered into force on 1 May 2004 and the European Union's biggest expansion. Cyprus, the Czech Republic, Estonia, Hungary, Latvia, Lithuania, Malta, Poland, the Slovak Republic, and Slovenia joined Europe. See more in Gateva, E. (2016). *European Union enlargement conditionality*. Springer. Therefore, the Directive was labelled as 'fear-driven' to protect IPRs and have the new Member States regulate their legislation on the same level as in the rest of the EU; See also Torremans, P., (Ed.). (2014). *Research Handbook on Cross-border Enforcement of Intellectual Property*. Edward Elgar Publishing.

Year	Regulation
1986	Council Regulation (EEC) No. 3842/86 of 1 December 1986 laying down measures to prohibit the release for free circulation of counterfeit goods (1986) OJ L347/1.
1994	Council Regulation (EC) No. 3295/94 laying down measures to prohibit the release for free circulation, export, re-export or entry for a suspensive procedure of counterfeit and pirated goods (1994) OJ L341/8. (This was extended in 1999, 2003, and 2013).
1998	Green Paper of 15 October 1998 'Combating Counterfeiting and Piracy in the Single Market', COM (98) 569 final.
2000	Communication from the Commission to the Council, the European Parliament and the European Economic and Social Committee, 'Follow-Up' to the Green Paper on Combating Counterfeiting and Piracy in the Single Market', COM(2000) 789 final.
2004	Directive 2004/48/EC of the European Parliament and the Council of 29 April 2004 on the enforcement of intellectual property rights (2004) OJ L157/45.
2005	Strategy for the Enforcement of Intellectual Property Rights in Third Countries (2005) OJ C129/3.
2008	Communication on a New Industrial Property Rights Strategy for Europe, COM (2008) 465 final.
2008	Council Resolution on Comprehensive European Anti-Counterfeiting and Anti-Piracy Plan.
2009	Council Resolution of 16 March 2009 on the EU Customs Action Plan to combat IPR infringements for the years 2009 to 2012 (2009) OJ C71/1.
2010	Council Resolution of March 1 2010 on the enforcement of intellectual property rights in the internal market, (2010) OJ C56/1.
2012	New Customs Action Plan to combat IPR infringements for the years 2013-17. European Commission, 'Enforcement of Intellectual Property Rights MEMO/14/449.
2014	Communication from the Commission to the European Parliament, the Council and the European economic and Social Committee 'Towards a renewed consensus on the enforcement of Intellectual Property Rights: An EU Action Plan', COM (2014) 392 final.

Table 3

The scope of application of Enforcement Directive encompasses protection of IPRs such as trademark rights, copyrights, patent rights, utility models, design rights, plant variety rights, trade names, etc.⁶¹⁴ The Enforcement Directive does not only deal with the issue of counterfeit medicine, but it also entails the enforcement of all types of IP rights irrespective of the sector the IP rights may be associated with.⁶¹⁵

Even though the Enforcement Directive is a broad directive, it is of relevance in combatting counterfeiting of medicinal products in the EU. The term counterfeit medicine refers to those medicines, which violate an IP right (be it trademark right that is violated, or design right, or patent right).⁶¹⁶ This is different from the term falsified medicine as defined in the FMD.⁶¹⁷ Typically, when a falsified medicinal product, defined as any product that has false representation pertaining to its origin, history, or source,⁶¹⁸ is discovered, it almost always presents a component of violation of an IP right. Usually, it is violation of a trademark right with respect to false packaging.⁶¹⁹ While the FMD deals with the violation of the FMD, the Enforcement Directive specifically provides for the provisions of enforcing the private rights of the right holder in case of violation of IP rights.⁶²⁰ For example, in Operation Volcano, the cancer treatment medicine Herceptin was stolen from the delivery truck on its way to deliver the medicines to the hospital.⁶²¹ This stolen medicine was manipulated and re-introduced in the legal supply chain. It not only

⁶¹⁴ Statement by the Commission concerning Article 2 of Directive 2004/48/EC of the European Parliament and of the Council on the enforcement of intellectual property rights (2009/295/EC).

⁶¹⁵ Kur, A., Planck, M., & Dreier, T. (2013). *European intellectual property law: text, cases and materials*. Edward Elgar Publishing.

⁶¹⁶ See, Chapter 1, Section 1.6. on Terminology.

⁶¹⁷ Article 1, Directive 2011/62/EU.

⁶¹⁸ *ibid.*

⁶¹⁹ See Articles 10 and 11, Directive (EU) 2015/2436 of the European Parliament and of the Council of 16 December 2015 to approximate the laws of the Member States relating to trade marks.

⁶²⁰ Torremans, P. (2016). *Holyoak and Torremans intellectual property law*. Oxford University Press.

⁶²¹ Chapter 3, Section 3.2.

was ‘false representation’ with respect to its origin and source, and thus a violation of FMD, it also violated the trademark rights of the right owner ‘Roche’, who owns the trademark rights, because it affected their goodwill and reputation.

5.2. Private rights vis-à-vis public rights

The protection of IPRs is protection of private rights of the right holder.⁶²² The IP rights bestow upon the owner: the right to sell, transfer, assign, subdivide, or invoke the power of the State to assert their rights in case of violation of the same.⁶²³

The Enforcement Directive and the Customs Regulation fall under the umbrella of private law, as opposed to the FMD that lies under the purview of public law. The private law governs the relationship between subjects, and public law governs the relationship between institutions of the State, or between the State and the subjects.⁶²⁴ Traditionally, private law is believed to be the law that revolves around serving private interests, and not public interests. In that sense, IP rights form a part of private law, since they are concerned with protection of personal interests.⁶²⁵ Secondly, the aim of private law is to deal corrective justice in contrast with public law, where the main goal is to impart distributive justice,⁶²⁶ as

⁶²² Merges, R. (2017). What Kind of Rights Are Intellectual Property Rights? (Forthcoming in Rochelle C Dreyfuss & Justine Pila (eds), *The Oxford Handbook of Intellectual Property Law* © RP Merges 2017; Michaels, R., & Jansen, N. (2006). Private law beyond the state? Europeanisation, globalisation, privatisation. *The American Journal of Comparative Law*, 54(4), 843-890.

⁶²³ Geiger, C. (2006). Constitutionalising intellectual property law? The influence of fundamental rights on intellectual property in the European Union. *International Review of Intellectual Property and Competition Law*, 37(4).

⁶²⁴ Loughlin, M., & Tschorne, S. (2016). *Public law* (pp. 324-337). Routledge.

⁶²⁵ Michaels, R., & Jansen, N. (2006). Private law beyond the state? Europeanization, globalization, privatization. *The American Journal of Comparative Law*, 54(4), 843-890.

⁶²⁶ Weinrib, E. J., (2012). *The idea of private law*. Oxford University Press.19.

in the case of the FMD, which is a public law. Thirdly, the IP law, as with other laws in the realm of private law, governs the relationship between private parties (it may include the State as a party in its role as a market participant). In comparison, the sphere of public law involves the State, as the sovereign, as one of the parties.⁶²⁷

The Enforcement Directive aims to enforce the IP rights in the EU, belongs to the realm of private law. On the contrary, the FMD strives to realise the goals of safeguarding public health and safety, and thus, falls under the area of public law. This distinction between the two streams of law is of crucial importance. The significance lies in diversity of the fundamental aims of the two types of law – IP law and Medicine law. The IP law aims to protect the rights of the individual or select few as it lies in the realm of private law, while the Medicine law aims at protecting the rights of the public health and safety, belonging to the fold of public law.

The distinction between the two spheres of law does not end here. Procedurally and in terms of enforcement mechanisms the two streams of law are different. In the case of infringement of trademarks due to counterfeiting of a medicinal product, the proprietor of the trademark is responsible for taking the initiative to seek redressal because it is a violation of a private right. However, in case of detection of a falsified medicine, the State or an agency of the State is responsible for taking the initiative to protect the citizens.

The paths of the two types of law intersect, while addressing the problem of falsification and counterfeiting of medicines. However, both types of laws govern

⁶²⁷ Weinrib, E. J., (2012). *The idea of private law*. Oxford University Press.19.

separate and distinct aspects of the same problem – counterfeiting and falsification of medicinal products. Even though it would be more expedient to concurrently address the problem, it is not the current practice.

5.3. Lack of cross-border applicability of the Enforcement

Directive

In the EU, the cross-border concept of enforcement has attributes of confusion,⁶²⁸ because on one hand, the internal market implies free movement of goods, services, people, and capital implemented through Directives, Regulations, and other legal instruments and supranational institutions. While, on the other hand, the Member States enjoy full control over other matters such as criminal matters and judicial systems. The Enforcement Directive delimits⁶²⁹ itself from dealing with rules pertaining to judicial cooperation, jurisdiction, the recognition and enforcement of decisions in civil and commercial matters.

However, counterfeiting and falsification of medicinal products is, typically, a cross-border element is present in the counterfeiting and falsification of medicines.⁶³⁰ The case studies, as discussed in Chapter 3, highlighted the act of falsification and counterfeiting of medicines usually involves two or more countries. For instance, Operation Robin revealed that the raw materials were sent from China to Belgium and delivered in Sweden via Denmark and other

⁶²⁸ Vrins, O., & Schneider, M. (2014). Cross-border enforcement of intellectual property: The European Union. Torremans, P. (Ed.) (2014). *Research handbook on cross-border enforcement of intellectual property*. 166-328.

⁶²⁹ Recital 11, Directive 2004/48/EC.

⁶³⁰ See European Commission. (2014). The EU explained: Borders and security. Building an open and secure Europe. Brussels. European Commission.

countries.⁶³¹ The counterfeit APIs were delivered in Belgium, which arrived in small packages in Denmark alongside other Member States, before they finally were received in Sweden.⁶³² Thereafter, the manufacturing of the counterfeit and falsified medicine was conducted in a factory in Sweden.⁶³³ Similarly, within Europe, other cases have revealed identical pattern involving more than two Member States.⁶³⁴

In the context of counterfeiting of medicinal products in the EU there are certain provisions in the Enforcement Directive that present potential for contributing to speedier resolution of cases, subject to room for cross-border applicability. These include, particularly, the Right of Information (Article 8);⁶³⁵ application of provisional and precautionary measures (Article 9)⁶³⁶ and injunctions (Article 11)⁶³⁷ because these provisions contain the tools needed to hinder the act of counterfeiting, with almost an immediate effect.

The Right of Information under Article 8 of the Enforcement Directive aims to increase transparency and grant access to information in order to ensure effective governance. Thus, Article 8 of the Enforcement Directive extends the right to obtain information about the involvement of the third parties. As recognised in Recital 21 of the Enforcement Directive, the primary motive of introducing right of information is to allow for precise information access with respect to origin of the infringing goods or services, the distribution channels, and the identity of any

⁶³¹ See Chapter 3, Section 3.4.

⁶³² *ibid.*

⁶³³ *ibid.*

⁶³⁴ Bate, R. (2012). *Phake: the deadly world of falsified and substandard medicines*. AEI Press.50.

⁶³⁵ Article 8, Directive 2004/48/EC.

⁶³⁶ Article 9, Directive 2004/48/EC.

⁶³⁷ Article 11, Directive 2004/48/EC.

third parties involved in the infringement.⁶³⁸ As a result of this provision, the IPR holder can request for information such as: names, addresses of producers, manufacturers, distributors, suppliers, intended wholesalers, previous holders of goods or services, quantities of goods produced, manufactured, delivered, received or ordered, as well as prices obtained for the goods or services in question. The extended right to information had been attempted previously in Directive on the Legal Protection of Industrial designs (OJ L 289/28), and existed in Germany⁶³⁹ and some Benelux countries.⁶⁴⁰

The practical application of this provision over the past decade has revealed that, there are certain challenges associated with pursuing offenders in different countries, where national procedures are applied in their unique way.⁶⁴¹ Since each Member State has its own judicial system and set of procedures, crucial time is expended to obtain the required orders to pursue the accused in cases of counterfeiting in different Member States, as also acknowledged in Operation Robin.⁶⁴²

In cases involving counterfeiting and falsification of medicines, time is an important factor. As evident from the case studies, the counterfeit material arrives in small consignments and travels from one Member State to another, as specifically witnessed in Operation Robin.⁶⁴³ Further, procedural delays can result

⁶³⁸ Recital 21, Enforcement Directive 2004/48/EC.

⁶³⁹ Right to third party information was introduced in Germany in 1990 by the Product Piracy Act (Produkthaftungsgesetz).1990.

⁶⁴⁰ Confined to trade mark infringements, see Article 13^{bis} of the Benelux Trademark Act (Uniform Benelux Law on Marks (amended by the Protocol of November 10, 1983, amending the Uniform Benelux Law on Trademarks and by the Protocol of December 2, 1992, amending the Uniform Benelux Law on Marks).

⁶⁴¹ Vrins, O., & Schneider, M. (2014). Cross-border enforcement of intellectual property: The European Union. Torremans, P. (Ed.) (2014). *Research handbook on cross-border enforcement of intellectual property*. 166-328.

⁶⁴² Chapter 3, Section 3.4.

⁶⁴³ See Chapter 3, Section 3.4.

in potential cases not being detected within reasonable timeframe. Therefore, having limited relevant automatic procedures, to assist in controlling counterfeiting and falsification of medicines can result in better IPRs enforcement. For instance, as recommended in the Public Consultation Report,⁶⁴⁴ a provision to institute a near automatic procedure, whereby courts in Member States could enforce the production of documents, which have been ordered by courts in other Member States, could be beneficial.

The precautionary and preventive measures arm the legal machinery to prevent damage before it is done, rather than relying on the law to compensate afterwards. In the Enforcement Directive, Article 9⁶⁴⁵ provides for provisional and precautionary measures. It specifically means that the judicial bodies are authorised to issue interlocutory injunctions, which aim to prevent a possible infringement of an IPR. In addition, it is provided that the judicial authority may also order a seizure of goods suspected of infringing an IPR before the said goods enter the channels of commerce.⁶⁴⁶ In those cases, where infringement of an IPR occurs on a commercial scale, after taking into consideration the existing circumstances, the judiciary can subsequently provide for precautionary seizures. It can only happen in cases where it is demonstrated that recovery would be endangered.⁶⁴⁷ These seizures, as part of the precautionary measures, can include a seizure of movable as well as immovable property, blocking of bank accounts, communications relating to ban, financial or commercial documents, and other relevant information.

⁶⁴⁴ European Commission. (14 September 2016). Summary of responses to the public consultation on the evaluation and modernisation of the legal framework for the enforcement of intellectual property rights. Ref. Ares (2016) 5286091-14/9/2016. Brussels. European Commission. 23.

⁶⁴⁵ Article 9(1) (a), Enforcement Directive 2004/48/EU.

⁶⁴⁶ Article 9 (1) (b), Enforcement Directive 2004/48/EU.

⁶⁴⁷ Article 9(2), Enforcement Directive 2004/48/EU.

The main goal of the introduction of provisional measures was to provide for instant termination of infringements, without waiting for a decision on the substance of the case *inaudita altera parte*.⁶⁴⁸ This provision is a reflection of the Mareva injunctions developed in the UK.⁶⁴⁹ The Mareva injunctions are also known as freezing orders against the movement of assets, pending decision of the courts.⁶⁵⁰ The introduction of provisional measures was considered justifiable particularly in those situations, where it is believed that these would not cause irreparable harm.⁶⁵¹

This provision is especially relevant in cases of violations concerning medicinal products. For instance, when the law enforcement agency becomes aware of a particular business engaging in an illegal activity i.e. printing labels for a counterfeit medicine and that business is packaging counterfeit medicine to be introduced in the legal supply chain, as was the case in Operation Singapore,⁶⁵² such a provision would have prevented loss of significant evidence. A similar problem was also witnessed in Operation Robin carried out by the Swedish Law Enforcement Authorities. In their bid to capture evidence, the Swedish Customs and Law Enforcement authorities had to keep track of the investigations carried out between January 1 2009 and May 8 2012, with the help of surveillance teams, hidden cameras, historical deliveries of parcels, etc.⁶⁵³ In the light of these circumstances, the importance of the precautionary and preventive measures

⁶⁴⁸ Recital 22, Enforcement Directive 2004/48/EU; Article 9 (2) and 9 (4), Directive 2004/48/EC.

⁶⁴⁹ Vrins, O., & Schneider, M. (2014). Cross-border enforcement of intellectual property: The European Union. Torremans, P. (Ed.) (2014). *Research handbook on cross-border enforcement of intellectual property*. 166-328.

⁶⁵⁰ See more in *Mareva Compania Naviera S.A. v. International Bulk-carriers S.A.* [1975] 2 Lloyd's Rep. 509; [1980] 1 All E.R. 213, C.A. Pending the final result of the law suit, this order of the court prevents a defendant from transferring assets.

⁶⁵¹ Devonshire, P. (1999). Mareva Injunctions and Third Parties: Exposing the Subtext. *The Modern Law Review*, 62(4), 539-563.

⁶⁵² See Chapter 3, Section 3.3.

⁶⁵³ Case No. B 6262 -12, Judgement of Stockholms Tingsrätt of 25 June 2013.

cannot be underestimated because the counterfeiting and falsification of medicines, by nature, are illegal activities that transpire behind closed doors.

The practical application of this provision in the past decade has shown that right holders face some specific problems in the application of this provision, especially in cross-border contexts. In addition, the issue of legal uncertainty in cross-border situations causes a lot of IPR holders to refrain from availing these measures.⁶⁵⁴ And those who do resort to the first step of obtaining provisional or precautionary measures, the additional costs, such as for translations in cross border situations, add another burden to the already cumbersome process.⁶⁵⁵ Further, variable time span for procedures in different Member States and differences in procedures itself, also fail to persuade the right holders to go forward with the legal redress channel, as the first priority. Another factor that has emerged and contributed towards complaints on part of the right holders towards the current system is the domestic geographical limitation, with specific reference to scope of injunctions and no recognition of judgments or evidence in different Member States.⁶⁵⁶ This issue is particularly relevant to the counterfeiting in the pharmaceutical sector, which is notoriously a cross-border activity within the EU as denoted by Operation Volcano, where the wholesalers were located in Italy, and parallel importers were located in the UK, and another wholesaler was located in Germany.⁶⁵⁷

⁶⁵⁴ European Commission. (July 2013). Synthesis of the Responses: Civil Enforcement of Intellectual Property Rights: Public Consultation on the Efficiency of Proceedings and Accessibility of Measures. Directorate General Internal Market and Services. Intellectual Property, Fight against counterfeiting and piracy. Brussels. European Commission.

⁶⁵⁵ *ibid.*

⁶⁵⁶ European Commission. (14 September 2016). Summary of responses to the public consultation on the on the evaluation and modernisation of the legal framework for the enforcement of intellectual property rights. Ref. Ares (2016)5286091-14/9/2016. Brussels. European Commission. 31.

⁶⁵⁷ See Chapter 3, Section 3.2., 3.3, and 3.4.

Therefore, it is important to point out that the lack of case law and empirical data on the application of the provisions of the Enforcement Directive need to be viewed against the exponential increase of statistical data indicating increase in counterfeiting and falsification of medicinal products in the EU.⁶⁵⁸ This juxtaposition reveals the lack of effectiveness of these provisions, especially in context of counterfeit medicines, which is essentially a cross-border crime.

Injunctions

Article 11 of the Enforcement Directive provides for injunctions applied by the national courts⁶⁵⁹ and Article 12 lays down the provisions for alternative measures that may be employed to resolve IPR conflicts. The central goal of these provisions is to allow the Member States to prohibit the continuation of infringement. For example, an injunction would usually be sought for blocking access to infringing content online or by stopping the manufacturing of the infringing products, or to prevent infringing content from appearing. Article 11 and 12 should ideally work together in the sense that the phrasing of Article 11 (using the word ‘may’) and the existence of Article 12 in the Directive, indicate that there is an alternative to injunctive relief. It further imparts the idea that the Courts in Europe would have discretion in determining the final injunctions, which should be granted or an alternative should be the appropriate course of action,⁶⁶⁰ as is now the method employed in the US.⁶⁶¹ The past decade shows that, in the EU, courts usually grant injunctive relief when the merits of the case

⁶⁵⁸ Recital 2, Directive 2011/62/EU.

⁶⁵⁹ The Information Society Directive (Directive 2001/29/EC of the European Parliament and of the Council of 22 May 2001 on the harmonisation of certain aspects of copyrights and related rights in the information society, OJ L 167 22 June 2001, 10-19) Article 8 (3) also stands in relation to Article 11 of the Enforcement Directive (2004/48/EC).

⁶⁶⁰ Cook, T. (2015). Enforcement Directive & Harmonisation of the Remedies for IP Infringement in the EU, *Journal of Intellectual Property Rights*, Vol 20., 264-269.

⁶⁶¹ eBay v. Merc Exchange 546 US 1029; 126 S Cr. 1837; 78USPQ 2D 1577 (Supreme Court).

allow for it. However, there have been no references made to the Court of Justice for seeking clarification on this practice up until this date for any type of IP matter that can challenge this practice.⁶⁶²

Over the past decade, the practice has revealed the use of this provision by the majority of right holders who have taken the course of litigation.⁶⁶³ While in domestic scenarios, where the injunction was sought in the Member State of the right holder, the procedure went more smoothly compared to cross-border situations. Right holders were confronted with a number of problems in cross-border situations, such as costs (translations), length of procedures, test purchase in all jurisdictions, notarisation of evidence, diverging substantive scope of injunctions, rules on jurisdictions and the lack of adequate legal basis.⁶⁶⁴

Further, the discrepancy in the application of the Enforcement Directive between Member States⁶⁶⁵ can also have consequences for the pharmaceutical sector with reference to counterfeiting and falsification of medicines, while also affecting other sectors. The lack of a uniform action in the Member States can make certain countries the target of counterfeiting, and other nations within the EU will be

⁶⁶² The decision of the Court of Justice while considering whether permanent injunction should be granted in a case where a standard essential patent is found valid and infringed because to sticking to the standard, Case C-170/13 Huawei Technologies Co., Ltd., v ZTE Corp., ZTE Deutschland GmbH (Court of Justice, 16 July 2015) hinged upon Article 102 Treaty on the Functioning of the European Union, which forbids abuse of dominant position in the relevant market and not Article 11 of the Enforcement Directive.

⁶⁶³ European Commission. (July 2013). Synthesis of the Responses: Civil Enforcement of Intellectual Property Rights: Public Consultation on the Efficiency of Proceedings and Accessibility of Measures. Directorate General Internal Market and Services. Intellectual Property, Fight against counterfeiting and piracy. Brussels. European Commission.

⁶⁶⁴ Vrins, O., & Schneider, M. (2014). Cross-border enforcement of intellectual property: The European Union. Torremans, P. (Ed.) (2014). *Research handbook on cross-border enforcement of intellectual property*. 166-328.

⁶⁶⁵ *ibid.*; European Commission. (July 2013). Synthesis of the Responses: Civil Enforcement of Intellectual Property Rights: Public Consultation on the Efficiency of Proceedings and Accessibility of Measures. Directorate General Internal Market and Services. Intellectual Property, Fight against counterfeiting and piracy. Brussels. European Commission.

vulnerable to the housing the counterfeiters.⁶⁶⁶ This trend was already apparent in Operation Volcano, which revealed that Latvia, Romania, Malta, and Cyprus primarily were those countries, which had fake authorisation holders, while Germany was one of the target countries receiving the falsified medicines.⁶⁶⁷

5.4. The role of Intermediaries

The online sale of counterfeit and falsified medicines is a recognised threat in the EU.⁶⁶⁸ Consequently, a specific provision to regulate the online sale of medicines was introduced in the FMD,⁶⁶⁹ whereby all websites based in the EU selling medicinal products are required to display the common EU logo on each page of their respective websites.⁶⁷⁰ In addition to the FMD, which deals only with falsification of medicines, the Enforcement Directive is important and relevant as regards the enforcement on IPRs. In addition to the FMD, the Enforcement Directive, the E-Commerce Directive,⁶⁷¹ and the Info-Society Directive⁶⁷² also contain specific rules regarding the role of intermediaries in the digital environment, which have an impact upon the sale of medicinal products online. However, for the purposes of this chapter, only the Enforcement Directive is being assessed.

There are no special provisions with regard to online sale or digital infringements

⁶⁶⁶ Ekwall, D., Bröls, H., & Wyer, D. (2016). Theft of pharmaceuticals during transport in Europe. *Journal of Transportation Security*, 9(1-2), 1.

⁶⁶⁷ See Chapter 3, Section 3.2.; *See also* Theft of medicines, Trends over the years, (2017), AIFA.

⁶⁶⁸ Hall, A., & Antonopoulos, G. A. (2016). Introduction. In *Fake Meds Online* (1-17). Palgrave Macmillan UK.

⁶⁶⁹ Article 85c in Directive 2001/83/EC was introduced by Article 1(20) of Directive 2011/62/EU.

⁶⁷⁰ Commission Implementing Regulation, 699/2014/EU, of 24 June 2014 on the design of the common logo to identify persons offering medicinal products for sale at a distance to the public and the technical, electronic and cryptographic requirements for verification of its authenticity. OJ L184, 25.6.2014, 5-7.

⁶⁷¹ Directive 2000/31/EC of the European Parliament and of the Council of 8 June 2000 on certain legal aspects of information society services, in particular electronic commerce, in the Internal Market. OJ L178, 17.7.2000, 1-16.

⁶⁷² Recital 59, Directive 2001/29/EC.

of IPRs in the Enforcement Directive, it applies equally to online and offline cases.⁶⁷³ Article 9(1) (a) provides for interlocutory injunctions⁶⁷⁴ and Article 11 provides for permanent injunctions.⁶⁷⁵ Both types of injunctions can be used against infringers and intermediaries (whose services are used by the infringers). The CJEU has ruled that the national courts should rule in favour of ending an infringement, and prevent such acts of infringement from occurring in the future. Such injunctions must be effective, proportionate and dissuasive, and should not create hurdles in legitimate trade.⁶⁷⁶ The CJEU reached a similar conclusion with respect to Internet Service Providers (ISPs) and hosting service providers in cases C-7-70/10 *Scarlet Extended v. SABAM*⁶⁷⁷ and C-360/10 *Netlog v. SABAM*.⁶⁷⁸

The sale of counterfeit and falsified medicines online is difficult to trace.⁶⁷⁹ The requirement for an online logo on all legitimate websites is a progressive step in the right direction in equipping the customers with the ability to detect legitimate websites in the EU.⁶⁸⁰ The Enforcement Directive, through the provisions in Articles 9 and 11, presents the potential to assist in the fight against counterfeiting - also of medicinal products. While considering the online sale of products, it is often easier to identify the intermediaries rather than the infringers.⁶⁸¹ Moreover, the intermediaries can be instrumental in curtailing the infringement. Therefore,

⁶⁷³ Vrins, O., & Schneider, M. (2014). Cross-border enforcement of intellectual property: The European Union. Torremans, P. (Ed.) (2014). *Research handbook on cross-border enforcement of intellectual property*. 166-328.

⁶⁷⁴ Interlocutory injunctions are issued to prevent an imminent infringement or forbid the continuation of an alleged infringement. *See more* in Section 5.3.

⁶⁷⁵ A court order prohibiting someone from doing some specific act or commanding someone to undo some wrong or injury. This type of injunction is intended to be in force until the end of the specific law suit. *See more in* Black, H.C., Nolan, J.R., & Nolan-Haley, J.M. (1990). *Black's Law Dictionary*. (Sixth Edition). St. Paul, Minn. West Publishing Co.784.

⁶⁷⁶ Case C-324/09 *L'Oreal v. eBay* (2011) ECR I-06011.

⁶⁷⁷ C-70/10 *Scarlet v. SABAM*, (2011) ECR I-11959, para.31.

⁶⁷⁸ Case C-360/10 *Netlog v. SABAM*, 16 February 2012, para 29.

⁶⁷⁹ Lee, K. S., Yee, S. M., Zaidi, S. T. R., Patel, R., Yang, Q., Al-Worafi, Y. M., & Ming, L. C. (2017). Combating Sale of Counterfeit and Falsified Medicines Online: A Losing Battle. *Frontiers in pharmacology*, 8.

⁶⁸⁰ *See more in* Chapter 4, Section 4.4.

⁶⁸¹ Vrins, O., & Schneider, M. (2014). Cross-border enforcement of intellectual property: The European Union. Torremans.. (red.)(2014). *Research handbook on cross-border enforcement of intellectual property*. 166-328.

both offline⁶⁸² and online intermediaries are targeted by the IP right holders for enforcement of their rights.⁶⁸³ The Enforcement Directive extends to the national courts in the Member States the right to issue injunctions on intermediaries, even though the intermediaries have acted in good faith.⁶⁸⁴

Currently, some jurisdictions only allow for issuing injunctions on proven active involvement of the intermediaries, while in other jurisdictions, for issuance of an injunction, the proof of intermediary's prior knowledge of the act is sufficient. Similarly, while in some jurisdictions general monitoring obligations cannot be imposed, it is possible in others. These disparities also necessitate uniformity in rules.⁶⁸⁵

The provisions for injunctions in the Enforcement Directive have been effective in putting a stop to the act of infringement when pursued, as illustrated by case law discussed above with regard to cases, *C-7-70/10 Scarlet Extended v. SABAM*⁶⁸⁶ and *C-360/10 Netlog v. SABAM*.⁶⁸⁷ However, it is not adequate, because the Enforcement Directive is not suitably equipped to trace the infringer. The sellers of counterfeit products operate anonymously, as was observed in Operation Robin,⁶⁸⁸ and use shell companies as was evident in Operation Singapore.⁶⁸⁹ The

⁶⁸² O'Byrne, P., & Burstall, R. (2011). Liability of landlords for infringing activities. *Journal of Intellectual Property Law & Practice*, 6(10), 738-742.

⁶⁸³ European Commission. (July 2013). Synthesis of the Responses: Civil Enforcement of Intellectual Property Rights: Public Consultation on the Efficiency of Proceedings and Accessibility of Measures. Directorate General Internal Market and Services. Intellectual Property, Fight against counterfeiting and piracy. Brussels. European Commission.

⁶⁸⁴ See Recital 23, Directive 2004/48/EC; Case C-324/09 *L'Oreal v. eBay*. (2011). para 128. ECR I-06011; *See also* Husovec, M. (2013). Injunctions against innocent third parties: Case of website blocking. *Journal of Intellectual Property, Information Technology and E-Commerce Law: JIPITEC*, 4(2), 116-129.

⁶⁸⁵ European Commission. (14 September 2016). Summary of responses to the public consultation on the evaluation and modernisation of the legal framework for the enforcement of intellectual property rights. Ref. Ares (2016)5286091-14/9/2016. Brussels. European Commission, 35.

⁶⁸⁶ *C-70/10 Scarlet v. SABAM*, (2011) ECR I-11959, para.31.

⁶⁸⁷ Case C-360/10 *Netlog v. SABAM*, 16 February 2012, para 29.

⁶⁸⁸ *See* Chapter 3, Section 3.4.

goal, especially in context of counterfeiting and falsification of medicines, is to prevent further counterfeiting and falsification of medicinal products. Therefore, it is important to trace the perpetrators of the crime, and hence, location of the person (or persons) selling the counterfeit medicines online. Currently, the Enforcement Directive provides for shutting down the access points - the websites - with the help of the intermediary, but that does not weed out the problem, as another website can easily replace the website that has been shut down.

While addressing the problem of counterfeit and falsified medicines, it is apparent that only one sphere of law is not adequate to resolve the problem of counterfeit and falsified medicines. The Medicine law primarily governs from the public health and safety perspective and targets online sale of medicine by provision of a logo for identification by the consumers. This is one part of the solution. The second part of the solution is provided by the provision of injunctions in the Enforcement Directive, whereby the online sellers can be blocked with the help of ISP. However, the problem that remains to be solved is tracing the online sellers. In certain cases, the ISPs may be forced to reveal their identity,⁶⁸⁹ but in other cases, the infringers are not traceable, because they cease to work under one identity and create a new identity in relatively short time span. Therefore, this is one problem that needs a solution.

⁶⁸⁹ See more in Chapter 3, Section 3.3., in Operation Singapore Gillepsie worked through a shell company based in Luxembourg.

⁶⁹⁰ Jakobsen, S. S. (2010). Mobile Commerce and ISP Liability in the EU. *International Journal of Law and Information Technology*, 19(1), 29-52.

5.5. Lack of criminal measures

The need for harmonisation of criminal measures with respect to enforcement of IPR has been raised and acknowledged at both, EU level⁶⁹¹ and at the International level.⁶⁹² In Articles 82 and 83(2) of the TFEU, the importance of approximation criminal measures is explicitly articulated.⁶⁹³ The Enforcement Directive contains only civil measures that may be applied in case of infringement of IPRs in its current form. The original proposal for the Enforcement Directive contained criminal measures for enforcement of IPRs as well, which was not taken forward in the final draft.⁶⁹⁴ However, the preamble⁶⁹⁵ of the Enforcement Directive, states the importance of incorporating criminal measures in the legal framework at the Member State level. The European Commission published an amended proposal for a Directive containing criminal measures, which would have enforced IPRs (2005/0127 COD) popularly known as IPRED II,⁶⁹⁶ which was later withdrawn⁶⁹⁷ due to widespread disagreement.⁶⁹⁸

The need for having harmonisation of provisions of criminal measures in the enforcement of IPRs at EU level has been emphasised due to the increase in trade

⁶⁹¹ The proposal for a directive on criminal measures (2005/0127 COD) aimed at ensuring the enforcement of intellectual property rights was a proposal to supplement Directive 2004/48/EC.

⁶⁹² The ACTA contained concrete provisions and some bilateral and multilateral trade agreements carry forward some of the provisions.

⁶⁹³ Articles 82 and 83 of TFEU.

⁶⁹⁴ Hilty, R. M., Kur, A., & Peukert, A. (2006). Opinion-Statement of the Max Planck Institute for Intellectual Property, Competition and Tax Law on the Proposal for a Directive of the European Parliament and of the Council on Criminal Measures Aimed at Ensuring the Enforcement of Intellectual Property Rights. *IIC. International review of industrial property and copyright law*, 37(8), 970.

⁶⁹⁵ Recital 28, Directive 2004/48/EC.

⁶⁹⁶ Proposal for a European Parliament and Council Directive on criminal measures aimed at ensuring the enforcement of intellectual property rights. OJ C/2006/49/37. The proposal for a directive on criminal measures aimed at ensuring the enforcement of intellectual property rights was a proposal to supplement Directive 2004/48/EC.

⁶⁹⁷ The withdrawal was announced in the 'Withdrawal of obsolete Commission proposals in the Official journal of the European Union. (18 September 2010), 2010/C 252/9.

⁶⁹⁸ Geiger, C. (Ed.). (2012). *Criminal Enforcement of Intellectual Property: A Handbook of Contemporary Research*. Edward Elgar Publishing.

in counterfeit goods. The recent OECD estimates indicate that the trade in counterfeit and pirated products amounted to up to 5 percent of imports in 2013 in the European Union.⁶⁹⁹ In monetary terms, the trade amounted to 85 billion Euros (USD 116 million).

Even though national laws have provisions of criminal measures against infringement of IPRs in the Member States, in accordance with Article 61 of the TRIPS agreement, the level of enforcement and penalties are variable. The harmonisation envisaged by the TRIPS agreement has failed to produce the anticipated results.⁷⁰⁰ The risk of having variations in penalties as well as enforcement is that some Member States with comparatively weaker penalties and enforcement can become ‘havens’ or focus areas for counterfeiters to camp and base their activities out of those Member States. However, more importantly, the entire EU would remain vulnerable to counterfeit products, because of the fluid borders and free movement of goods in the EU.⁷⁰¹ At the moment, countries such as Italy, Latvia, and Romania⁷⁰² have been known to house the counterfeiters of medicinal products, because of the weaker enforcement in these countries.⁷⁰³ As also indicated in Operation Volcano, the fake authorisation holders were based in these countries.⁷⁰⁴

In the EU, the violation of IPRs ranges from copying music to the sales of counterfeit medicines. In the industries such as the medicinal sector, the toy manufacturing sector, the automobile industry, and the food & beverages industry - the threat of counterfeiting in regard to public health and safety is more

⁶⁹⁹ Trade in Counterfeit and Pirated Goods, Mapping the Economic Impact, OECD- EUIPO Report, 2016.

⁷⁰⁰ Geiger, C. (2016). Towards a Balanced International Legal Framework for Criminal Enforcement of Intellectual Property Rights. In *TRIPS plus 20*. Springer Berlin Heidelberg. 645-679

⁷⁰¹ See Article 26, TFEU.

⁷⁰² See Chapter 3, Section 3.2.

⁷⁰³ *ibid.*

⁷⁰⁴ *ibid.*

pronounced, which can have serious consequences, including causing loss of lives.⁷⁰⁵ In the context of counterfeiting in the medicinal sector,⁷⁰⁶ as indicated by the case studies in Chapter 3, one of the reasons contributing to trade in counterfeit medicines is the high profit margins and the low penalties.⁷⁰⁷ Penalties act as a strong deterrent to the commission of crime.

Therefore, due to the potentially serious impact of counterfeiting and falsification of medicinal products on public health and safety, and also in order to uphold the goals of public health and consumer protection, as envisaged in the TFEU, it is important to seriously consider criminal enforcement.

5.6. Concluding remarks

The Enforcement Directive complements the Customs Regulation⁷⁰⁸ in combatting counterfeiting of medicinal products in the EU, in the sphere of IP law.⁷⁰⁹ The Enforcement Directive came about in an unprecedented swift manner in the wake of ten European nations joining the EU. The Enforcement Directive has achieved a degree of success in the harmonisation of civil measures in regard to the enforcement of IPRs in the EU with respect to provisions such as provisional and precautionary measures enshrined in Article 9, and injunctions stated under Article 11 that may be issued to ensure enforcement of IPRs. But for the precise purpose of combatting counterfeiting of medicinal products, it hasn't proved to be very useful. This is primarily because counterfeiting is usually a cross-border activity

⁷⁰⁵ *ibid.*

⁷⁰⁶ Attaran, A. (2015). Stopping murder by medicine: introducing the model law on medicine crime. *The American journal of tropical medicine and hygiene*, 92(6_Suppl), 127-132.

⁷⁰⁷ Blackstone, E. A., Fuhr Jr, J., & Pociask, S. (2014). The health and economic effects of counterfeit drugs. *American health & drug benefits*, 7(4), 216.

⁷⁰⁸ Discussed in Chapter 6.

⁷⁰⁹ Discussed in Chapter 2, Section 2.3.4.3.

involving more than one Member State and the Enforcement Directive categorically delimits itself from cross-border applicability.⁷¹⁰ Consequently, in the usual cross-border scenario, the right holders have to pursue cases in each jurisdiction where the violations have been known to occur, which is not practical for the right holders, as indicated in the public consultation reports.⁷¹¹ Therefore, using the enforcement route through courts is seldom adopted by the right holders as indicated by the almost negligible case law in the area and also put forward in the public consultation reports of the European Commission. Most of the case law relates to repackaging of medicinal products and conditions, which need to be upheld while doing so in the EU.⁷¹²

Furthermore, as highlighted in Section 5.2, the Enforcement Directive falls under the broad category of private law contrary to the FMD, which is a public law. The basic differences in the types of law that the two major Directives fall under, is also significant. It is recognised that goals of the two types of laws, and the procedures for enforcement of the two spheres of law are different. While enforcing public law such as the FMD, the State takes initiative for enforcement. On the contrary, the enforcement of private law, such as the Enforcement Directive, it is the private right holder, who has to take the initiative. The differences in the aims of the two types of law, also underline the differences in

⁷¹⁰ Recital 11, Directive 2004/48/EC.

⁷¹¹ European Commission. (July 2013). Synthesis of the Responses: Civil Enforcement of Intellectual Property Rights: Public Consultation on the Efficiency of Proceedings and Accessibility of Measures. Directorate General Internal Market and Services. Intellectual Property, Fight against counterfeiting and piracy. Brussels. European Commission.

⁷¹² See Case 102/77 Hoffmann-La Roche [1978] ECR 1139, Case 1/81 Pfizer [1981] ECR 2913, Joined Cases C-427/93, C-429/93 and C-436/93 Bristol-Myers Squibb and Others [1996] ECR I3457, and Case C-232/94 MPA Pharma [1996] ECR I3671. See also Case C-400/09 - Orifarm A/S ('Orifarm'), Orifarm Supply A/S ('Orifarm Supply'), Handelsselskabet af 5. januar 2002 A/S, in liquidation, ('Handelsselskabet') and Ompakningsselskabet af 1. november 2005 A/S ('Ompakningsselskabet') and - in Case C-207/10 - Paranova Danmark A/S ('Paranova Danmark') and Paranova Pack A/S ('Paranova Pack') and Merck Sharp & Dohme Corp., formerly Merck & Co. Inc., Merck Sharp & Dohme BV and Merck Sharp & Dohme.

the approaches. The Enforcement Directive is entirely focused on protection of the rights of the right holder and the FMD concentrates on the social objective of protection of public health and safety. The two legal instruments are not opposed to each other but there is no synergy between the two either.

It was noted that the Enforcement Directive provides for injunctions, which have been effective in putting a stop to an online infringing activity. But the provisions of the Directive have not always been able to facilitate reaching the perpetrators of the infringement. In cases of counterfeiting and falsification of medicinal products, it is one challenge that still needs to be tackled.

The pharmaceutical industry rarely resorts to the legal redress mechanism. Even though there is widespread disagreement regarding the need for criminal means of enforcement of IPR in the EU, for the purpose of combatting counterfeiting of medicinal products, it is important to have strong criminal measures because it can have serious consequences.⁷¹³ The importance of having criminal enforcement measures with respect to counterfeit medicine has been recognised by the Council of Europe, which is the creator of the Medicrime Convention that has been ratified by four EU Member States. It is believed that the ratification of the Medicrime Convention by the EU has the potential to resolve a large part of the issue pertaining to criminal enforcement in context of counterfeit medicinal products.

⁷¹³ Attaran, A. (2015). Stopping murder by medicine: introducing the model law on medicine crime. *The American journal of tropical medicine and hygiene*, 92 (6 Suppl), 127-132.

Chapter 6: Analysis of the Customs Regulation (Regulation 608/2013)

6.1. Introduction

In the thesis, the legal instruments that govern the counterfeiting and falsification of medicinal products in the EU are analysed. It was established in Chapter 1 that the issue of counterfeit and falsified medicines lies at the intersection of Medicine law, IP law and Criminal Law.⁷¹⁴ The area of Medicine law has been dealt with in Chapter 4, in which the FMD was analysed. The sphere of IP law entails two legal instruments– the Enforcement Directive and the Customs Regulation; detailing rules that are applied to combat counterfeiting of medicines. The former instrument has been dealt with in the previous chapter and this chapter analyses the second major legal instrument⁷¹⁵ under IP law regime that governs counterfeit medicines - the EU Regulation 608/2013.

The legal analyses in Part III of the thesis is being done in the light of the case studies discussed in Chapter 3 (Part II). The case studies brought to light the five key issues that have emerged in context of counterfeiting and falsification of medicines in the EU – manipulation of the medicinal products; infiltration of the legal supply chain; sale of counterfeit and falsified medicinal products online; involvement of more than one Member State; and the role played by organised crime. Some of these issues have been addressed in Chapter 4 and 5, such as the manipulation of the medicinal product, the infiltration of the legal supply chain,

⁷¹⁴ See Chapter 1, Section 1.2.

⁷¹⁵ The first legal instrument being the Enforcement Directive 2004/48/EC discussed in Chapter 6.

and online sale of medicinal products.⁷¹⁶

Usually, the probable means through which the counterfeit and falsified products can enter the EU are by air, express, post, rail, road, sea or through personal baggage of the travellers.⁷¹⁷ The EU Regulation 608/2013, henceforth referred to as the ‘Customs Regulation’,⁷¹⁸ is important for the thesis because it empowers the customs authorities to stop the entry of the counterfeit and falsified medicine, at the point of arrival into the EU borders. The Customs Regulation was adopted in context of the EU’s Customs Action Plan to fight infringement of IPRs.⁷¹⁹ The main aim of the Customs Regulation is articulated in Recital 4 of the preamble to the Regulation, which is to enforce the IPRs at the border in order to effectively provide legal protection to the right holder, the users as well as the producers.⁷²⁰

In this chapter the focus will be on provisions that specifically concern small consignments, parallel imports and the entry of counterfeit medicinal products through luggage of travellers – the diverse ways in which the legal supply chain has been known to be infiltrated by the illegal supply chain with counterfeit and falsified medicines.

Before delving into the analysis of the Customs Regulation and its relevant provisions, it is imperative to outline the background and set the context of the customs union in the EU. The European Union Customs Union (EUCU) is a customs union composed of all the Member States of the EU, Monaco and some territories of the UK, which are not part of the EU and some countries are part of

⁷¹⁶ See Chapter 4, Sections 4.2., 4.3, and 4.4., and Chapter 5, Section 5.4.

⁷¹⁷ See European Commission. (2015). Report on EU customs enforcement of intellectual property rights. Results at the EU border 2015. Luxembourg. Publications office of the European Union.

⁷¹⁸ Regulation, 608/2013/EU of 12 June 2013 concerning customs enforcement of intellectual property rights and repealing Council Regulation (EC) No 1383/2003. OJ L 181, 29.6.2013, 15–34.

⁷¹⁹ Council Resolution on the EU Customs Action Plan to combat IPR infringement for the years 2013-2017. (2013). OJ C 80, 19.3.2013, 1-7. Henceforth, ‘EU Customs Action Plan (2013-2017)’.

⁷²⁰ Recital 4, Regulation 608/2013.

the customs union through separate agreements such as Andorra, and San Marino. It was in 1958 that the European Economic Community was formed with the customs union as its key component. Some of the main features of the customs union include: there are no customs duties levied within the customs union; the customs union levies a common tariff on all the goods entering the EU; and the European Commission is responsible for negotiating all international trade agreements on behalf of the customs union.

Recently, as part of the process of modernisation of the Customs Union, the new Union Customs Code (UCC) came into force⁷²¹ and is expected to be fully implemented by the end of 2020⁷²² with the main goal of modernising the customs procedures by streamlining the customs processes, legislations and procedures; increasing legal certainty and clarity for customs officials in the EU; transform the customs authorities into a paperless, fully electronic and interoperable environment. The main goal is to enhance competitiveness in the EU and concurrently ensure safety and security with a contribution to the economic growth.⁷²³

In this broad framework of the Customs Union, the Customs Regulation deals with the civil enforcement of IPRs with respect to border measures that can be initiated by the customs authorities. The first Customs Regulation came into being in 1986 (Regulation 3842/86)⁷²⁴ that lay down measures to prohibit the release for free

⁷²¹ The Union Customs Code (UCC) was adopted on 9 October 2013 as Regulation (EU) No. 952/2013 of the European Parliament and of the Council. It came into force on 30.10.2013 but most of its substantive provisions will be applicable from 1 May 2016; *See also* Aigner, S. (2017). The Union Customs Code. *Global Trade and Customs Journal*, 12(2), 49-53.

⁷²² European Commission. (August 2017). *UCC – Introduction*. In Taxation and customs union. European Commission.

⁷²³ Aigner, S. (2017). The Union Customs Code. *Global Trade and Customs Journal*, 12(2), 49-53.

⁷²⁴ Council Regulation (EEC) No. 3842/86 of 1 December 1986 laying down measures to prohibit the release for free circulation of counterfeit goods. OJ L 357, 18.12.1986, 1- 4.

circulation of counterfeit goods. The first Customs Regulation addressed only counterfeiting of registered trademarks. In 1994, the second Customs Regulation (Regulation 3295/94)⁷²⁵ emerged, which lay down measures to prohibit the release for free circulation, export, re-export or entry for a suspensive procedure of counterfeit and pirated goods. Thus, the scope of the Customs Regulation expanded in 1994 to include design and copyrights. In addition, the powers of the customs authorities were enlarged – the customs authorities could act ex-officio in certain cases. In 1999, the Customs Regulation was amended (Regulation 241/1999)⁷²⁶ to include patents in its scope of IPRs as well. The powers of the customs authorities were further expanded in 2003 (Regulation 1383/2003)⁷²⁷ wherein the link between organized crime and counterfeit trade was recognised and the scope of IPRs to be addressed by the Regulation was further expanded to include plant variety, geographical indications as well. In 2013, the current Customs Regulation (Regulation 608/2013)⁷²⁸ came into being, repealing the 2003 Regulation.

The current Customs Regulation is concerned with customs enforcement of IPRs and it strengthens and consolidates customs procedures pertaining to the enforcement of IP rights in Europe. The Customs Regulation is a result of a review of the Council Regulation No. 1383/2003, which was requested by the Council's resolution of 25th September 2008 via a comprehensive European anti-

⁷²⁵ Council Regulation (EC) No. 3295/94 of 22 December 1994 laying down measures to prohibit the release for free circulation, export, re-export or entry for a suspensive procedure of counterfeit and pirated goods. OJ L341, 30.12.1994, 8-13.

⁷²⁶ Council Regulation (EC) No. 241/1999 of 25 January 1999 amending Regulation (EC) No. 3295/94 laying down measures to prohibit the release for free circulation, export, re-export or entry for a suspensive procedure of counterfeit and pirated goods. OJ L 27, 02.02.1999, 1-5.

⁷²⁷ Council Regulation (EC) N. 1383/2003 of 22 July 2003 concerning customs action against goods suspected of infringing certain intellectual property rights and the measures to be taken against found to have infringed such rights. OJ L 196, 2.8.2003, 7-14.

⁷²⁸ Regulation (EU) No. 608/2013 of the European Parliament and of the Council of 12 June 2013 concerning customs enforcement of intellectual property rights and repealing Council Regulation (EC) No. 1383/2003. OJ L 181, 29.6.2013, 15-34.

counterfeiting and anti-piracy plan (2009-2012).⁷²⁹

This Council Resolution of 2008 was followed by another Council Resolution on the EU Customs Action Plan to combat IPR infringement for the years 2013 to 2017.⁷³⁰ This action plan is in consonance with the Europe 2020 strategy on smart, sustainable and inclusive growth;⁷³¹ the Commission Communication on a comprehensive EU strategy concerning intellectual property rights;⁷³² and Council Resolution of 16 March 2009 on the EU Customs Action Plan to combat IPR infringements for the years 2009 to 2012.⁷³³ The current EU action plan emphasises that the IPR legal framework must be backed by effective enforcement⁷³⁴ and should contain specific objectives for effective implementation and monitoring of the new regulation; tackling major trends in trade of IPR infringing goods; tackling trade of IPR infringing goods throughout the international supply chain; and strengthening cooperation with the European Observatory on infringement of IPRs and law enforcement authorities.⁷³⁵

⁷²⁹ Recital 1, Regulation (EU) No 608/2013; *See also* The comprehensive European anti-counterfeiting and anti-piracy plan came into being parallel to the Commissions strategic report and the new cycle of the renewed Lisbon strategy for growth and jobs (2008-2010). The need to fight counterfeiting and piracy and show respect towards basic freedoms of the internal market that promote competitiveness, unleash creative forces and innovation were recognised in the action plan. It contained communication regarding customs initiatives to combat counterfeiting and piracy at the borders and outside the European Union; setting up of a European counterfeiting and piracy observatory which came into being and is now known as the EUIPO; called for rapid exchange of information on counterfeit products and proposals for encouraging public/private partnerships for combating counterfeiting and to address online sale of counterfeit products.

⁷³⁰ Council Resolution on the EU Customs Action Plan to combat IPR infringement for the years 2013-2017.(2013). OJ C 80, 19.3.2013, 1-7.

⁷³¹ Communication from the Commission, Europe 2020 – A strategy for smart, sustainable and inclusive growth, COM (2010) 2020 final.

⁷³² European Commission. (2011). Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Region- A Single Market for Intellectual Property Rights Boosting creativity and innovation to provide economic growth, high quality jobs and first class products and services in Europe. Brussels. European Commission. COM (2011) 287 final.

⁷³³ Council Resolution of 16 March 2009 on the EU Customs Action Plan to combat IPR infringements for the years 2009 to 2012. (2009). OJ C 71, 25.3.2009, 1-7.

⁷³⁴ Council Resolution on the EU Customs Action Plan to combat IPR infringement for the years 2013-2017. (2013). OJ C 80, 19.3.2013, 1-7.

⁷³⁵ Council Resolution on the EU Customs Action Plan to combat IPR infringement for the years 2013-2017. (2013). OJ C 80, 19.3.2013, 1-7.

The current Customs Regulation (608/2013) has further expanded the scope of the type of IPRs to include topography and utility models, trade names and instruments used to circumvent technology. The Customs Regulation is divided into six chapters dealing with the subject matter, scope and definitions of key terms (Articles 1 and 2); formalities with regard to application procedures (Articles 3 to 16); the actions that can be taken by the Customs authorities with regard to goods (Articles 17 to 26); the provisions dealing with liability, costs and penalties (Articles 27 to 30); the provisions relating to exchange of information between Member States (Articles 31 to 33); and the final provisions regarding implementation and follow up (Articles 34 to 40), respectively. In this chapter, the focus will be on the issues, which are most relevant for the thesis, particularly the specific areas of measures addressing small consignments, goods in transit, goods carried in travellers luggage and parallel imports in context of the Customs Regulation.

6.2. Small Consignments

The trade of counterfeit goods involves use of small consignments for transportation purposes, as illustrated by the legal case studies and supported by recent statistics. This was observed in Operation Volcano, Operation Robin and Operation Singapore, wherein small packages were used to transport, sell as well as deliver counterfeit and falsified medicines.⁷³⁶ The Report 2013 revealed that the cases related to postal and courier traffic for counterfeit goods amounted to 72 percent of detentions.⁷³⁷ It was observed that the medicinal products were the

⁷³⁶ See Chapter 3, Sections 3.2, 3.3, and 3.4.

⁷³⁷ European Commission. (2014). Report on EU customs enforcement of intellectual property rights: Results at the EU border 2013. Luxembourg. Publication Office of the European Union.

category of products that were detained the most.⁷³⁸ The report states that even though the volume of medicinal products that are detained has decreased over the years from 69 % in 2010 to 19% in 2013, the medicinal products still constitute the majority of products that are seized in the postal and courier traffic. The reason that the counterfeit operations involving medicinal products make use of the postal and courier services is to avoid detection by the authorities. In addition, the online sale of counterfeit and falsified medicines has further encouraged the use of postal and courier services as channels of distribution.⁷³⁹

An important and relevant provision in this context is Article 26⁷⁴⁰ of the Customs Regulation that empowers the customs authorities to destroy small consignments of counterfeit and pirated goods, at the request of the right holder.⁷⁴¹ This provision explicitly states that if the goods are suspects to be counterfeit; the goods are not perishable; the goods are covered by a decision granting an application; the holder of the decision has requested the use of the procedure as enumerated in this Article; and the goods are transported in small consignments, then this provision is applicable. This is further stated that the customs authorities are obligated to inform the holder of the goods, once they detain the goods, within one working day. The holder of the goods has ten working days to express his agreement or disagreement (‘right to be heard’) and the absence of a response is interpreted as consent to destruction of the goods.⁷⁴²

The value of this provision in blocking the entrance of counterfeit and falsified

⁷³⁸ *ibid.*

⁷³⁹ Acquah, D. (2015). Trends on the implementation of the EU Customs Regulation: for better or for worse? *Journal of Intellectual Property Law & Practice*, 10(10), 775-784.

⁷⁴⁰ Article 26, Regulation 608/2013.

⁷⁴¹ See Article 2(19), Regulation 608/2013, which defines a small consignment as ‘a postal or express courier consignment, which contains three units or less or has a gross weight less than two kilograms’.

⁷⁴² Article 26(4), Regulation 608/2013.

medicines in the EU cannot be underestimated. However, this measure finds application, on the request of the right holder only and the customs authorities do not have the authority to take *ex-officio* action against small consignments of goods that infringe IPRs. In practice, the provision is still effective because in the majority of cases, the right holders make a prior application, as required by the Customs Regulation.⁷⁴³

The latest Report on EU customs enforcement of IPR⁷⁴⁴ revealed that the postal and courier traffic amounts to 77 % of all detentions despite the more than 20% decrease in postal traffic detention. It is significant to point out that when considering the numbers of articles detained in postal traffic, medicinal products figure at second place, constituting 16 % of all the products detained, just after electronic equipment, which constitutes 32 % of all products detained. In 22 % of all the cases, the small consignments were destroyed, applying the new provisions. In the light of Operation Robin,⁷⁴⁵ wherein the APIs were delivered in small packs arriving from overseas through Belgium and then delivered by making use of Brevia and UPS services, such interception of small consignments would have been invaluable. In Operation Robin, the Swedish Customs Authorities had pointed out that the well-organised body of criminals⁷⁴⁶ was making use of the postal services to deliver their products from one point to another, so as to dodge the keen eyes of the legal machinery. The packs containing counterfeit products

⁷⁴³ See Articles 3-16, Regulation 608/2013.

⁷⁴⁴ European Commission. (2015). Report on EU customs enforcement of intellectual property rights. Results at the EU border 2015. Luxembourg. Publications office of the European Union.7.

⁷⁴⁵ Discussed in Chapter 3, Section 3.4., where in Sweden the Customs Authorities traced the transportation of counterfeit medicinal products overseas, land and air were able to trace that counterfeit products were being delivered by employing postal services of Brevia and UPS.

⁷⁴⁶ Case No. B 6262 -12, Judgement of Stockholms Tingsrätt of 25 June 2013; See also (5.10.2016) 'Operation Robin' Presentation by Swedish Customs Authority. In Supplementary confidential case notes. Stockholm. Swedish Customs and Law Enforcement Authority.3.

were shipped from Belgium to Denmark to Sweden.⁷⁴⁷ And upon arrival in Sweden they arrived at the destination where they were assembled and offered for sale through three websites.⁷⁴⁸ The deliveries were made through postal system. It is still reported that the registered cases by means of transport clearly indicate that 70.51 % of such cases make use of the postal system.⁷⁴⁹

The years following the implementation of the Customs Regulation indicate that this procedure has led to the lowering of administrative burden for customs authorities and right holders, and more efficient and timely treatment of counterfeit goods that were transported by couriers or through post. It was reported that 30 % of the applications for action consisted of applicants requesting this procedure by the Customs authorities, for destroying small consignments.⁷⁵⁰

6.3. Goods in transit

Goods in transit have been a bone of contention for a decade or even longer,⁷⁵¹ especially with regard to medicinal products.⁷⁵² It has been observed that in context of medicinal products, specifically in respect of generic medicines,⁷⁵³ the peculiar feature of goods in transit is that there is no infringement in the country of origin and destination, however there is an IPR infringement in the country where the goods are in transit. According to the CJEU in Diesel/ Montex case (C-

⁷⁴⁷ Europol & OHIM. (June 2013). Reports and Conclusions, *Knowledge Building in IP Enforcement, Combating Pharmacrime A knowledge –building Conference on Counterfeit Medicines*. Alicante. Spain.

⁷⁴⁸ Case No. B 6262 -12, Judgement of Stockholms Tingsrätt of 25 June 2013: www.steriodakuten.org, www.vikingstore.org and www.anabolic.cc.

⁷⁴⁹ European Commission. (2015). Report on EU customs enforcement of intellectual property rights. Results of the EU border 2015. Luxembourg. Publications office of the European Union.40.

⁷⁵⁰ *ibid.*, 14.

⁷⁵¹ Mercurio, B. (2012). ‘Seizing’ pharmaceuticals in Transit: analysing the WTO dispute that wasn’t. *International and Comparative Law Quarterly*, 61(2), 389-462.

⁷⁵² *ibid.*

⁷⁵³ See Glossary for definition of generic medicines.

281/05), Nokia (C-495/09) and Phillips (C-446/09)⁷⁵⁴ if the goods were not meant to be put on the market in the EU, then the European Customs Regulation would not detain them. However, in context of medicinal products, Recital 11 of the Customs Regulation places an obligation on the customs authorities to assess the risk of IPR infringement to take account of any substantial likelihood of diversion of such medicines onto the market of the Union, while making their assessment. In addition to Recital 11 of the Customs Regulation, there are also other rules regulating medicines in transit, which underline the importance of the trade in medicinal products and supplement and strengthen the legal framework concerning medicinal products in transit in the EU.⁷⁵⁵ The Trademark Regulation,⁷⁵⁶ the Trademarks Directive,⁷⁵⁷ and the Commissions notice on the customs enforcement of IPRs concerning goods brought into the customs territory⁷⁵⁸ recognise the need to facilitate the smooth transit of legitimate medicines across the EU.

These provisions should also be read in conjunction with Article 52b of the Medicines Directive inserted by Article 1(10)(8) of the FMD,⁷⁵⁹ which empowers the Member States to initiate necessary measures for prevention of falsified products from entering the EU market, if there are sufficient grounds for suspecting that those goods may be falsified. This provision is also valid in those situations where the goods are not intended to be placed on the market in the EU. Therefore, evidently while greater attention has been extended to infringement of

⁷⁵⁴ Case C-281/05 Diesel/Montex ECLI:EU:C:2006:709; and Joined Cases C-446/09 Phillips and C-495/09 Nokia ECLI:EU:C:2011:796.

⁷⁵⁵ Also see Recital 11, Regulation 608/2013.

⁷⁵⁶ Recital 19, Regulation (EU) 2015/2424.

⁷⁵⁷ Recital 25, Directive (EU) 2015/2436.

⁷⁵⁸ Commission notice on the customs enforcement of Intellectual Property Rights concerning goods brought into the customs territory of the Union without being released for free circulation including goods in transit. (2016). OJ C 244, 5.7.2016, 4-9.

⁷⁵⁹ Article 52b of the Medicines Directive (Directive 2001/83/EC) inserted by Article 1(10) (8) of the Falsified Medicines Directive (Directive 2011/62/EU).

medicinal products, with respect to the other products, ‘reasonable indications’⁷⁶⁰ of possible infringement are construed as being enough.

It is vital to distinguish between the trade in generic medicines and trade in counterfeit medicinal products. The generic medicines are legitimate medicines in the manufacturing country of those medicines and the country, which is the final destination of the product. The legitimacy of trade in generic medicines has been recognised in the Doha Declaration⁷⁶¹ under the TRIPS regime and by the EU in its representations at the WTO.⁷⁶² When these generic medicines are the goods in transit, they cannot be equated to counterfeit medicinal products.⁷⁶³ This issue was contested and discussed in academic circles⁷⁶⁴ in great detail especially in context of what transpired at the Dutch borders in 2008, when in EU several shipments of generic medicines in transit were returned or delayed because they were suspected of patent infringements.⁷⁶⁵ These shipments originated in India and the destination countries were developing countries such as Brazil, Venezuela, Columbia, Peru and Nigeria. The medicines in transit were protected in the EU and thus, the Customs Regulation of 2003 was applicable. The Customs Regulation has since been amended to accommodate medicinal products in transit as incorporated in Recital 11 of the current Customs Regulation.

In order to cover the risk of counterfeit goods camouflaged as goods in transit

⁷⁶⁰ Article 2 (7) Regulation 608/2013.

⁷⁶¹ World Trade Organisation. (20 November 2001). Doha WTO Ministerial Declaration. WT/MIN(01)/DEC/1; 41 ILM 746 (2002).

⁷⁶² See WTO. (2009). Minutes of the Meeting. WTO TRIPS Council (June 8-9 2009). IP/C/M/60 2009.

⁷⁶³ Kumar, S. P. (2010). Border enforcement of IP rights against in transit generic pharmaceuticals: an analysis of character and consistency. *European Intellectual Property Review*.

⁷⁶⁴ Heath, C., & Seizures, C. Transit and Trade—In Honour of Dieter Stauder’s 70th Birthday’ (2010). *IIC*, 8, 881.

⁷⁶⁵ Grosse Ruse-Khan, H., & Jaeger, T. (2009). Policing patents worldwide? EC border measures against transiting generic drugs under EC and WTO intellectual property regimes. *IIC-international review of intellectual property and competition law*, 40(5), 502-538.

entering the EU market, the Customs Regulation empowers the customs authorities to initiate action in likelihood of the goods in transit entering the supply chain in the EU. This assessment is carried out by the relevant Member States' customs authority on a case by case basis. However, so far, the guise of goods in transit is not the chosen medium of infiltration of counterfeiting medicinal products in the EU, as indicated by the EU Customs Report 2015.⁷⁶⁶ The counterfeit medicinal products enter through small consignments through parcels and couriers.⁷⁶⁷ However, this does not completely rule out the use of this medium in the future for supplying counterfeit medicinal products in the EU. However, a balance needs to be maintained as attempted in the new Customs Regulation, between enforcement of IPRs in the EU and maintaining the international obligations with respect to goods in transit, specifically with reference to flow of generic medicines through the EU.⁷⁶⁸

6.4. Travellers' Luggage

Counterfeit and falsified medicines enter the EU borders through various means such as by air, express, post, rail, road and by sea.⁷⁶⁹ The Report on EU customs enforcement of IPR 2015 indicates the postal, air and express means of transport to be the most often used means of transport in the majority of cases that were detained. In contrast to 2014, there is a decrease in the use of postal traffic but that is not only in small consignments but also at times, in the personal luggage of the

⁷⁶⁶ European Commission. (2015). Report on EU customs enforcement of intellectual property rights. Results at the EU border 2015. Luxembourg. Publications office of the European Union.

⁷⁶⁷ *ibid.*

⁷⁶⁸ Rosina, M. S. G. and Shaver, L. (2012), Why Are Generic Drugs Being Held Up in Transit? Intellectual Property Rights, International Trade, and the Right to Health in Brazil and Beyond. *The Journal of Law, Medicine & Ethics*, 40: 197–205.

⁷⁶⁹ European Commission. (2015). Report on EU customs enforcement of intellectual property rights. Results at the EU border 2015. Luxembourg. Publications office of the European Union.

passengers.⁷⁷⁰ In the Report on EU Customs enforcement of IPR 2015, the statistics of the goods intercepted at the borders indicate that a large number of labels and packaging material that has been intercepted was being carried in personal luggage of the travellers.⁷⁷¹ As was revealed by the EU Customs Report from the previous years, the quantity of labels and tags was more than 20 percent in 2010 and more than 18.4 percent in 2013,⁷⁷² which were purportedly on the way to the EU to be used on infringing goods. Since the Customs authorities do not check every passengers' luggage upon arrival, the statistics do not reflect the exact volume of labels and tags that enter the EU borders through personal luggage of the passengers.⁷⁷³

Under Article 1(4) of the Customs Regulation⁷⁷⁴ it is clearly stated that the goods being carried by the passengers for non-commercial purposes are outside the scope of the Customs Regulation. The preamble of the Customs Regulation also elaborates on the exclusion of travellers' personal luggage if the products are of non-commercial nature.⁷⁷⁵ Since the personal luggage of travellers carrying goods for non-commercial purposes are exempt from application of the Customs Regulation⁷⁷⁶ and the luggage of travellers are not checked as a matter of routine, it is difficult to intercept the counterfeit goods if those are slipped in the personal luggage disguised as goods for non-commercial personal use. This traditional

⁷⁷⁰ European Commission. (2015). Report on EU customs enforcement of intellectual property rights. Results at the EU border 2015. Luxembourg. Publications office of the European Union. Annex 8, 38.

⁷⁷¹ *ibid.*

⁷⁷² European Commission. (2014). Report on EU customs enforcement of intellectual property rights: Results at the EU border 2013. Luxembourg. Publication Office of the European Union.

⁷⁷³ Schneider, M., & Maillefer, C. (2015). How Europe deals with private imports of counterfeit and pirated goods. *Journal of Intellectual Property Law & Practice*, 10(4), 262-268.

⁷⁷⁴ See Article 1(4), Regulation 608/2013.

⁷⁷⁵ See Recital 4, Regulation 608/2013.

⁷⁷⁶ Recital 4 and Article 1(4), Regulation 608/2013.

practice has encouraged ‘ant traffic’⁷⁷⁷ and it transmits a signal that ‘a little bit of counterfeiting is ok.’⁷⁷⁸ The Customs Regulation also implies that a counterfeit good may be purchased for private use without infringing any IPR, since private acts fall outside the ambit of the Customs Regulation and the IP law would be invoked only in case showing ‘commercial use’.⁷⁷⁹

A landmark case that illustrated that the acquisition of counterfeit and pirated goods falls under the scope of Regulation 608/2013 was *Blomqvist v. Rolex*.⁷⁸⁰ Martin Blomqvist purchased a counterfeit Rolex from a Chinese website and this Rolex was seized by the customs authorities in Denmark. When the customs authorities contacted Blomqvist for permission to destroy the fake Rolex, he did not give his consent. The matter was referred to the High Court, who referred the question to CJEU. THE CJEU interpretation explained that the Customs Regulation finds application and holder of an IPR enjoys protection by the Regulation even if the goods were purchased through a website of a non-Member State.⁷⁸¹ Although not related to pharmaceuticals industry, this case illustrated the applicability of the Regulation to goods infringing IPRs that are imported for private use, inclusive of cases when the buyer is aware of the counterfeit nature of the goods that he or she is importing.⁷⁸²

This point is significant and can be kept as a reference while considering import of medicine by individual travellers for ‘personal use’. A large number of people buy

⁷⁷⁷ Schneider, M., & Maillefer, C. (2015). How Europe deals with private imports of counterfeit and pirated goods. *Journal of Intellectual Property Law & Practice*, 10(4), 262-268.

⁷⁷⁸ *ibid.*

⁷⁷⁹ Petersen, C. S., Riis, T., & Schovsbo, J. (2012). Intellectual property enforcement at the EU border: the challenge of private imports. *Journal of Intellectual Property Law & Practice*, 7(10), 747-762.

⁷⁸⁰ Judgment in *Martin Blomqvist v Rolex SA, Manufacture des Montres Rolex SA* (C-98/13, EU: C: 2014:55). The decision of the case relates to Regulation 1383/2003 but is still relevant and valid under Regulation 608/2013.

⁷⁸¹ Case C-98/13 Judgment in *Martin Blomqvist v Rolex SA, Manufacture des Montres Rolex SA*.

ECLI:EU:C:2014:55, para 35.

⁷⁸² *ibid.*

medicines abroad and carry them along when they return to their country. Some people buy medicines and bring them because of cheaper cost of medicines abroad, unavailability without prescription in the EU; or because they are not easily available, as in the case of homeopathic medicines. It also needs to be recognised that transporting medicines for personal use in reasonable quantity and for reasonable time frame should be allowed. This would most likely be cases in which an individual has gone on vacation and needed prescription medicine and that is what he/she is carrying in their luggage.

Therefore, in this context, the avenue of counterfeit goods entering the EU through private travellers also needs to be addressed. The provisions do not need to become draconian and unreasonable but the scope for carrying counterfeit medicines and packaging material that assists in counterfeiting needs to be dealt with. In the present context, it is recognised that it would be a disproportionate administrative burden to suggest that the luggage of all passengers should be screened upon arrival by the customs authorities. Moreover, it would be against the principle of protection of public health, enshrined under Article 168 of the TFEU to suggest that the travellers should not be allowed to bring medicines for personal use. Therefore, in the current circumstances, this provision of the Customs Regulation does not necessarily mandate an amendment but the customs authorities need to remain vigilant and continue to take the problem seriously.

6.5. Parallel Imports

The concept of parallel importation⁷⁸³ allows the importation of products, which are manufactured and marketed by the right holder in a country other than where the right holder intended after the right holder or a person/entity approved by him has sold the product in the domestic market. In the Single Market in the EU, the benefit of parallel importation is that it keeps the market competitive⁷⁸⁴ and also the practice of parallel import of products is widespread in the EU. The parallel import of pharmaceutical products is a vital part of the market. The downside of parallel importing in the pharmaceutical sector is that the system of parallel import is also used to infiltrate counterfeit and falsified medicines⁷⁸⁵ in the legal supply chain as witnessed in the case studies, discussed in Chapter 3.⁷⁸⁶ For instance, in Operation Singapore (*R v. P. Gillespie & others*),⁷⁸⁷ the counterfeit and falsified medicines were portrayed as parallel imported products from France.⁷⁸⁸ Even though the practice of parallel import is good for competition in the Single Market, it creates certain issues that must be addressed.

The Customs Regulations does not address parallel imports and overruns,⁷⁸⁹ as stated in Recital 6 of the Customs Regulation,⁷⁹⁰ because the customs authorities

⁷⁸³ Bartelt, S. (2003). Compulsory licenses pursuant to TRIPS article 31 in the light of the Doha Declaration on the TRIPS Agreement and public health. *The Journal of World Intellectual Property*, 6(2), 283-310.

⁷⁸⁴ Bale Jr, H. E. (1998). The conflicts between parallel trade and product access and innovation: the case of pharmaceuticals. *Journal of International Economic Law*, 1(4), 637-653.

⁷⁸⁵ *ibid.*

⁷⁸⁶ Chapter 3.

⁷⁸⁷ See more in Chapter 3, Section 3.3.

⁷⁸⁸ *ibid.*

⁷⁸⁹ Parallel imports are those products which are genuine and have been manufactured with the consent of the right holders. Parallel trade, based on the principle of free movement of goods and has led to the development of the Internal Market. Parallel imports tend to occur when price of similar products are significantly different, thereby leading to purchase of the products in one Member State and sale of the same product in different Member States to achieve profit.. Overruns, are those products which were also produced with the consent of the right holder but not in the given number, sometimes called 'nightshift production'.

⁷⁹⁰ Recital 6, Regulation 608/2013.

are not concerned with genuine products. As a rule, parallel imported products are genuine products and the trade in parallel imports is usually legitimate since the production of the goods is carried out with the consent of the right holder or with the consent of a person authorised by the right holder. On the other hand, there can also be situations, when an illegal trader pretends to be trading in parallel traded products, which is especially true in the pharmaceutical sector where there is room to make huge profits.⁷⁹¹

Within the EU, it is attractive to indulge in parallel trade in pharmaceutical products simply because of significant differences in the prices of the same medicinal products in different EU Member States. The differences in prices occurs primarily because, each EU Member State is guided by its own health policies, and other individual systems and structure. Therefore, there is space and scope for illegal traders to make profit by leveraging the opportunity of making profit at an even bigger scale, if counterfeit products are substituted for real products though exploitation of this avenue. Thereby, it is possible to pass off a counterfeit medicinal product as a parallel traded product as occurred in Operation Singapore,⁷⁹² wherein the illegal trader attached fake labels and packaging to products to pass off counterfeit products as parallel traded products from France, to be sold in the UK.

Therefore, although the logic behind the Customs Regulation not addressing the parallel trade is valid because parallel traded products are supposed to be legitimate products, the problem arises when counterfeit products use the disguise of parallel traded products. This precise problem needs to be addressed, since it

⁷⁹¹ Office of Harmonisation in the Internal Market & Europol. (2015). Situation Report on Counterfeiting in the European Union – A joint project between Europol and the Office for Harmonization in the Internal Market.11.

⁷⁹² See Chapter 3, Section 3.3.

constitutes a major stumbling block for authorities while weeding out counterfeit medicine from the legal supply channels. This was also highlighted in Operation Volcano,⁷⁹³ where the Italian authorities concluded that the vulnerability of the parallel import channel was a contributory factor to prevalence and proliferation of falsified medicine in the EU.

The importance of parallel import in context of the Single Market is undeniable since it upholds the basic values of the Single Market⁷⁹⁴ of free movement of goods and services and maintaining the market and prices of the products at competitive levels.⁷⁹⁵ The benefits of parallel trade far outweigh the negative impact of parallel import of medicinal products. Therefore, it is not prudent to consider prohibition of parallel import of medicinal product in order to root out trade in counterfeit and falsified medicines. It should, however, also be emphasised that the disguise of parallel traded products is often used in selling counterfeit medicinal products and therefore, it is imperative to address the issue of how to resolve the use of disguise of parallel trade in counterfeiting of medicines.

The solution may not directly lie under the Customs Regulation but it can be found in the area of Medicine law. In the FMD, there is a requirement of authorisation for participating in trade (manufacture, market, sell, broker, packaging, etc.) in medicinal products. If these authorisations carry security features, such as watermarks, as discussed in Chapter 4⁷⁹⁶ the issues arising due to

⁷⁹³ See Chapter 3, Section 3.2.

⁷⁹⁴ See Article 26, TFEU.

⁷⁹⁵ European Commission. (2011). Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Region- A Single Market for Intellectual Property Rights Boosting creativity and innovation to provide economic growth, high quality jobs and first class products and services in Europe. Brussels. European Commission. COM (2011) 287 final.

⁷⁹⁶ See Chapter 4, Section 4.3.3.2.

parallel trade in medicines could be resolved because the authorisations would be able to ensure authentication and the security features such as watermarks, would make forgery of authorisations more difficult.

6.6. Concluding remarks

The new Customs Regulation came into being in the backdrop of the anti-counterfeiting and anti-piracy plan, where the specific issue of counterfeiting being a serious threat to economic growth was recognised in the EU. As a result, a strategy to fight against counterfeiting and piracy was devised at the Union level. In this chapter, the Customs Regulation has been analysed in the light of the five core issues identified in Chapter 3 with regard to counterfeiting and falsification of medicines.⁷⁹⁷ Specifically, the issue of using small consignments for transport of counterfeit and falsified medicines; infiltration of the legal supply chain with regard to goods carried in personal luggage of the travellers as well as infiltration of the supply chain through parallel imports has been discussed in detail in this chapter. In addition, the difference between generic medicines and counterfeit medicines – with respect to goods in transit has been clarified. It has been concluded that the provisions concerning small consignments⁷⁹⁸ and goods in transit⁷⁹⁹ are effective and function better since the institution of the new Customs Regulation in 2013.

Prior to 2013, the situation was different, as was indicated by the legal case

⁷⁹⁷ The five core issues that were identified were manipulation of the medicinal product; infiltration of the legal supply chain; online sale of medicinal products; cross border involvement; and small consignments used as means of transportation. See more in Chapter 3, Section 3.5.

⁷⁹⁸ Article 26, Regulation 608/2013.

⁷⁹⁹ Article 22(2), Regulation 608/2013.

studies⁸⁰⁰ covering the period between 2007 to 2014, wherein counterfeit APIs and counterfeit medicines entered the EU borders in small consignments, using air, land, post and express services. With the changes that have been incorporated in the Customs Regulation, especially with respect to Article 23 and Article 26, the small consignments that are intercepted can be dealt with instantly. As was also indicated in the 2016 EU Customs enforcement Report,⁸⁰¹ there has been a decline in the number of counterfeits entering through small consignments.

As regards, goods being carried in the personal luggage of the travellers, it is apparent that a significant number of labels and packaging material to probably be affixed on infringing goods have been regularly detected.⁸⁰² It is recognised that amending the Regulation to check the personal luggage of all passengers or prohibit all medicines for personal use entering the EU borders seems unviable. As a result, this issue of fake packaging material trickling in the EU through personal luggage of the travellers is left unresolved. Further, the prohibiting the travellers from bringing medicinal products in the EU will be in violation of the principle of proportionality, which is one of the basic tenets of the Union.⁸⁰³ One of the basic principles of the Union is that the laws that are made must be proportionate, pursuing legitimate aims and necessary in the given circumstances. Therefore, the problem of dealing with counterfeiting goods entering the EU in the luggage of travellers is still outstanding.

Further, it came to light that the system of parallel trade has allowed for infiltration of the legal supply chain of pharmaceutical products. But in the

⁸⁰⁰ See Chapter 3.

⁸⁰¹ European Commission. (2017). Report on EU customs enforcement of intellectual property rights. Results of the EU border 2016. Luxembourg. Publications office of the European Union.

⁸⁰² European Commission. (2017). Report on EU customs enforcement of intellectual property rights. Results of the EU border 2016. Luxembourg. Publications office of the European Union.

⁸⁰³ See Article 5, TFEU.

Customs Regulation, there are no provisions that exclusively address parallel imported products because the Regulation categorically delimits itself from addressing the issue of parallel importation since parallel imported products are supposed to be genuine and legitimate products.⁸⁰⁴ Even though for the pharmaceutical sector, it is a significant area that requires attention, the benefits of parallel imports for the Single Market far outweigh the negative impact the disguise of parallel trade has on the pharmaceutical sector. Therefore, use of the disguise of parallel trade to infiltrate the legal supply chain by counterfeit and falsified products still needs to be resolved.

⁸⁰⁴ Recital 6, Regulation 608/2013.

Chapter 7: Global Initiatives

7.1. Introduction

The main purpose of this chapter is to analyse steps being taken in international instruments at the global level towards combatting counterfeiting and falsification of medicines, in order to draw inspiration for strengthening the legal framework in the EU that contains provisions to combat counterfeit and falsified medicinal products. Specifically, the Medicrime Convention,⁸⁰⁵ the Anti-Counterfeiting Trade Agreement (ACTA) and a few multilateral and bilateral agreements have been analysed.

As established in Chapter 1, the issue of counterfeit and falsified medicines lies at the intersection of IP law, Medicine law and Criminal law.⁸⁰⁶ The harmonisation at the EU level in the sphere of Medicines law pertaining to falsified medicines has been addressed in Chapter 4. Further, IP law is also harmonised at EU level. The Enforcement Directive and the Customs Regulation contain provisions to combat counterfeit medicines, which have been dealt with in Chapters 5 and 6. However, there is no harmonisation in the area of Criminal law at the EU level so far, even though attempts have been made to reach some sort of harmonisation in the context of IPR.⁸⁰⁷

The Medicrime Convention, a Council of Europe (COE) initiative, which aims at

⁸⁰⁵ Council of Europe. (2011) Council of Europe convention on counterfeiting of medical products and similar crimes involving threats to public health. Strasbourg. Council of Europe. (Also known as the Medicrime Convention). Council of Europe Treaty Series. No. 211. Henceforth, referred to as 'The Medicrime Convention'.

⁸⁰⁶ See Chapter 1, Section 1.2.

⁸⁰⁷ Amended proposal for a Directive of the European Parliament and of the Council on criminal measures aimed at ensuring the enforcement of intellectual property rights (COM/2006/0168 final - COD 2005/0127).

the criminalisation of counterfeiting, is specifically reviewed. It is imperative to state that even though the Medicrime Convention uses the term ‘counterfeiting’ as used, it actually implies ‘falsified’ as understood in the EU because it is similar to the definition of falsified medicinal products,⁸⁰⁸ as stated in the FMD.

In addition, the Anti-Counterfeiting Trade Agreement (ACTA) is also analysed.⁸⁰⁹ Even though ACTA failed in its current form, the reason for its inclusion is to isolate lessons that can be learnt especially in context of criminal measures that can be instituted for violation of IPRs, including against counterfeit medicines. This is important because the Medicrime Convention does not govern IPR violations but only handles the issue from the perspective of public health and safety. ACTA came about in 2010 having the goal of establishing a framework that would be globally applicable and compatible to curb counterfeiting and enforce IP rights. It was negotiated in a non-transparent manner by a few powerful countries that sparked a public uproar⁸¹⁰ regarding the lack of transparency.⁸¹¹ There were other controversial elements present in the ACTA, which will be discussed in detail in Section 7.3, which led to its ultimate failure.

In the last part of this chapter, the multilateral and bilateral agreements are assessed and how those agreements handle counterfeiting and falsification of medicines is analysed. The bilateral and multilateral agreements – Tran- Pacific

⁸⁰⁸ Article 1(1) (c) Directive 2011/62/EU.

⁸⁰⁹ Anti-Counterfeiting Trade Agreement, 2011. (ACTA). ACTA final text, May 2011, Retrieved from: http://www.mofa.go.jp/policy/economy/i_property/pdfs/acta1105_en.pdf Accessed April 6, 2017. Henceforth, referred to as ‘ACTA, 2011’.

⁸¹⁰ Dür, A., & Mateo, G. (2014). Public opinion and interest group influence: how citizen groups derailed the Anti-Counterfeiting Trade Agreement. *Journal of European Public Policy*, 21(8), 1199-1217.

⁸¹¹ McManis, C. R. (2009). The proposed anti-counterfeiting trade agreement (ACTA): two tales of a treaty. *Hous. L. Rev.*, 46, 1235.

Partnership (TPP),⁸¹² Transatlantic Trade and Investment Partnership (TTIP),⁸¹³ RCEP (Regional Comprehensive Economic Partnership),⁸¹⁴ Comprehensive Economic and Trade Agreement (CETA),⁸¹⁵ stand out as the major global level instruments that contain measures to aid in the fight against counterfeiting of medicines. The challenge that seems to confront the current international and regional agreements is to achieve a balance between the focus on protection of IPRs, as in ACTA, TPP, TTIP, RCEP, CETA, and public health and safety objectives.

Before commencing a detailed analysis of the Medicrime Convention and other global instruments, it would be ideal to provide a background of the different initiatives at the international level. Briefly, the Trans-Pacific Partnership (TPP) is a trade agreement being negotiated between Australia, Brunei, Canada, Chile, Japan, Malaysia, Mexico, New Zealand, Peru, Singapore and the United States (until 23 January 2017) and Vietnam.⁸¹⁶ Being the largest trade agreement negotiated in history, the TPP is purported to enhance innovation, productivity and competitiveness, if ratified. The TTIP is another trade agreement being negotiated between the US and the EU, primarily oriented towards setting new rules for reduction of bureaucratic hurdles in export and import of products and investment,

⁸¹² Trans-Pacific Partnership Agreement- a trade agreement between Australia, Brunei, Canada, Chile, Japan, Malaysia, Mexico, New Zealand, Peru, Singapore, the United States (until January 23, 2017) and Vietnam. It contained both tariff and non-tariff barriers to trade and it set up investor-state dispute settlement (ISDS).

⁸¹³ TTIP is an agreement to scale down the tariffs and regulatory barriers between trade between the US and the Member States in the EU and would include certain specific industries, such as, pharmaceuticals, cars, energy, finance, chemicals, clothing, and food and drink. It has also reached a stalemate. See Section 7.4. for more.

⁸¹⁴ RCEP is a regional free trade agreement being negotiated by the Association of Southeast Asian Nations (ASEAN) (Brunei, Cambodia, Indonesia, Laos, Malaysia, Myanmar, the Philippines, Singapore, Thailand, Vietnam) and six other nations, with which ASEAN has pre-existing free trade agreements. The other nations being Australia, China, India, Japan, South Korea and New Zealand. See Section 7.4 for more details.

⁸¹⁵ CETA is an agreement being negotiated between Canada and the EU to promote trade. It has been approved by the European Parliament but the approval of the EU national parliaments is awaited. European Commission. Press Release. (IP/17/270).

⁸¹⁶ Fergusson, I. F., Cooper, W. H., Jurenas, R., & Williams, B. R. (2013). The Trans-Pacific Partnership negotiations and issues for congress. *Current Politics and Economics of South, Southeastern, and Central Asia*, 22(2), 209.

thereby contributing to economic growth and development.⁸¹⁷ The RCEP is a free trade agreement (FTA) being negotiated between the ten countries that are part of the (Association of Southeast Asian Nations (ASEAN) and the six countries with which the ASEAN has FTAs – Australia, China, India, Japan, South Korea and New Zealand. The RCEP is perceived as the alternative to TTP in Asia, which proposes common principles in the area of trade in goods, services and investments.⁸¹⁸ Lastly, CETA is a FTA between Canada and the EU,⁸¹⁹ which aims at strengthening trade and enhancing economic growth, by lowering customs tariffs and other barriers to trade between Canada and the EU.⁸²⁰

The challenge that seems to confront the current international and regional agreements is striking a balance between the focus on protection of intellectual property rights, as in ACTA, TPP, TTIP, RCEP, CETA, and public health and safety objectives.

The bilateral, multilateral and plurilateral trade agreements are similar to a large extent because they mainly aim at strengthening and enhancing trade, investment and innovation by reducing barriers to trade such as by reducing customs duties and by levelling the playing field for creative industries, and innovators by providing protection to IPRs, amongst other measures. Besides the differences in geographical configurations, the other differences lie in the comprehensive nature of the agreements. For instance, the CETA and the TTP, both are composed of

⁸¹⁷ Pitschas, C. (2016). Transatlantic Trade and Investment Partnership (TTIP): The Devil in Disguise or a Golden Opportunity to Build a Transatlantic Marketplace? *British Journal of American Legal Studies*, 5(2), 315-340.

⁸¹⁸ Lewis, M. K. (2013). The TPP and the RCEP (ASEAN6) as Potential Paths toward Deeper Asian Economic Integration. *Asian J. WTO & Int'l Health L & Pol'y*, 8, 359.

⁸¹⁹ The European Parliament votes in favour of CETA on 15 February 2017. European Commission. Press Release (IP/17/270)

⁸²⁰ Grootendorst, P., & Hollis, A. (2011). The 2011 Canada-European Union Comprehensive Economic and Trade Agreement: an economic impact assessment of the EU's proposed pharmaceutical intellectual property provisions. *Journal of Generic Medicines*, 8(2), 81-103.

thirty chapters each. The common feature of these bilateral and multilateral agreements is their analogous focus on the protection of IPRs under the broad circle of IP law. Even though the goal of public health and safety is recognised, the rules do not focus on provisions to be incorporated in Medicine law. The measures focus on how to make the sectors more competitive, and reduce barriers to trade.

In the following sections, the Medicrime Convention, the ACTA and the multilateral and bilateral agreements will be analysed, in order to identify the unique features and assess if the international instruments can strengthen the legal framework governing the counterfeiting and falsification of medicinal products in the EU.

7.2. Medicrime Convention

The Medicrime Conventions is the first of its kind construct that criminalises counterfeiting⁸²¹ of medicinal products. The purpose of including the Council of Europe's 'Convention on counterfeiting of medical products and similar crimes involving threats to public health' (henceforth 'Medicrime Convention')⁸²² is with a view to analyse if the Medicrime Convention would contribute in combatting counterfeiting and falsification of medicines in the EU. The Medicrime Convention came into force in January 2016 after it was ratified by six countries.⁸²³

⁸²¹ As explained earlier in Section 7.1, the term 'counterfeit' as used in the Medicrime Convention implies 'falsified' as understood in the EU because it is similar to the definition of a falsified medicinal product, as stated in the Article 1(1) (c) of Directive 2011/62/EU.

⁸²² The Medicrime Convention, 2011.

⁸²³ The Medicrime Convention has been ratified by Albania, Armenia, Belgium, France, Hungary, Spain, Moldova, and Ukraine from amongst the Members of the Council of Europe. (Status as of 14.7.2017). For updated status, see <http://www.coe.int/en/web/conventions/full-list/-/conventions/treaty/211/signatures>.

In the EU, the FMD⁸²⁴ provides for concrete measures from the public health perspective such as safety measures to prevent manipulation of the medicines, rules for authorisations to prevent infiltration of the legal supply chain, a unique online logo for all websites selling medicinal products in the EU, and rules for import and export of active substances. The IP law perspective of providing for protection and enforcement of IP rights of the right holders is governed by the Enforcement Directive and the Customs Regulation dealt with in detail in chapters 5 and 6. The Enforcement Directive provides for the civil measures that may be employed to enforce the IP rights that may be affected by counterfeiting and falsification of medicines. So far, criminal measures for enforcement of IPR violations or violations of the FMD have not been harmonised at the EU level and the Medicrime Convention could potentially provide for harmonisation of the missing provisions with regard to criminal measures against falsification and counterfeiting of medicinal products in the EU, if ratified by the EU.

7.2.1. Background

The genesis of having a common treaty on pharmaceutical crime can be traced back to 2005 when the (Council of Europe) COE Ad hoc Group on counterfeit medicines conducted a seminar “Counteract the counterfeiters: Limiting the risks of counterfeit medicines to public health in Europe by adequate means and measures”.⁸²⁵ Thereafter, an international conference organised at Moscow addressed “Europe against Counterfeit Medicines” in 2006 consolidated the

⁸²⁴ See Chapter 4 wherein Directive 2011/62/EU discussed in detail.

⁸²⁵ Hamilton, W. L., Doyle, C., Halliwell-Ewen, M., & Lambert, G. (2016). Public health interventions to protect against falsified medicines: a systematic review of international, national and local policies. *Health policy and planning*, 31(10), 1448-1466.

political will to formulate a Convention in the field of pharmaceutical crime.⁸²⁶ Between the period of 2007-2009, the draft of the Medicrime Convention was written under the auspices of the Council of Europe Committee of Ministers and support of other relevant organs of the COE.⁸²⁷ It is built upon the foundation of the fundamental right of right to life,⁸²⁸ since the most serious consequences of counterfeit medicine can result in death which is a violation of that inalienable right to life. The Medicrime Convention was formally adopted on 8 December 2010 by the Committee of Ministers of COE and opened for signature in 2011. On 1 January 2016, after obtaining the required ratifications the Medicrime Convention came into force.

The Medicrime Convention is the first international convention against the counterfeiting of medical products and other similar offences that threaten public health.⁸²⁹ Its main contribution is to criminalise the counterfeiting of medical products and use of criminal law in combatting all forms of counterfeiting of medical products by integrating rules pertaining to cooperation, prevention, and protection of victims.⁸³⁰ It establishes the manufacturing; supplying; offering to supply; trafficking; the falsification of documents and marketing of medical products and devices as offences.⁸³¹ The Convention empowers the signatory States with tools to introduce common minimum standards on substantive and

⁸²⁶ Council of Europe. (20 April 2007). *The quality of medicines in Europe*. Recommendation 1794, Parliamentary Assembly, Council of Europe. (Doc. 11193, report of the Social, Health and Family Affairs Committee, rapporteur: Mr Marquet). Text adopted by the Assembly on 20 April 2007 (18th Sitting).

⁸²⁷ Schmahl, S., & Breuer, M. (Eds.). (2017). *The Council of Europe: Its Laws and Policies*. Oxford University Press.

⁸²⁸ Article 2, Council of Europe. (1950). *European Convention for the Protection of Human Rights and Fundamental Freedoms, as amended by Protocols Nos. 11 and 14*, 4 November 1950, ETS 5.

⁸²⁹ Council of Europe. (20 April 2007). *The quality of medicines in Europe*. Recommendation 1794, Parliamentary Assembly, Council of Europe. (Doc. 11193, report of the Social, Health and Family Affairs Committee, rapporteur: Mr Marquet). Text adopted by the Assembly on 20 April 2007 (18th Sitting).

⁸³⁰ Keitel, S. (2012). The MEDICRIME convention: criminalising the falsification of medicines and similar crimes. *GBI J, 1*, 138-41.

⁸³¹ Article 8, The Medicrime Convention, 2011.

procedural criminal law, as well as provisions aiming at improving cooperation and information exchange between national and international competent authorities.

7.2.2. Purpose

The main purpose of the Medicrime Convention is to deal with counterfeiting and falsification of medicinal products – an issue of global concern by classifying counterfeiting, manufacture, and supply of medicinal products marketed without authorisation or without complying with safety requirements - as a crime.⁸³²

Likewise, the criminalisation of the trade in counterfeit medicines is important because national or regional responses to this international problem have proved to be inadequate and insufficient.⁸³³ The WHO has articulated a number of reasons, which have led to the proliferation of counterfeit and falsified medicines.⁸³⁴ These reasons encompass insufficient national regulation of drug manufacturing and distribution; weak enforcement of existing legislation; poor penal sanctions for violations of drug legislation; insufficient regulation by exporting countries and within free trade zones; complex transactions due to proliferation in the number of intermediaries; ever increasing demand and escalating prices of curative and preventive drugs and vaccines and feeble cooperation among stakeholders.⁸³⁵

The need to categorise counterfeiting of medicines as a ‘crime’ was realised ten years ago when the WHO International Conference on Combatting Counterfeit

⁸³² Article 1, Chapter 1, The Medicrime Convention, 2011.

⁸³³ Attaran, A., Bate, R., & Kendall, M. (2011). Why and how to make an international crime of medicine counterfeiting. *Journal of International Criminal Justice*, 9(2), 325-354.

⁸³⁴ Counterfeit Drugs: Guidelines for the development of measures to combat drugs, UN Doc, WHO/EDM/QSM/99.1.1999.

⁸³⁵ Counterfeit Drugs: Guidelines for the development of measures to combat drugs, UN Doc, WHO/EDM/QSM/99.1.1999.

Medicine reached the conclusion that counterfeiting of medicine should be categorised as an international crime, which was articulated in the Declaration of Rome in 2006⁸³⁶ There are other scholars who have propagated in support of the idea to make an international crime of medicine counterfeiting.⁸³⁷ According to Bassiouni, crimes are deserving of being elevated to ‘international crimes’ if they either amount to an offence against the entire international community, or if international cooperation is necessary for effective control over the transgression, or both.”⁸³⁸ And likewise, counterfeiting and falsification of medicines do fit the bill.

However, the Medicrime Convention has taken a step in that direction by criminalising counterfeiting⁸³⁹ and falsification of medicines. Broadly, the Medicrime Convention is divided into eleven chapters wherein the first chapter (Article 1 to 4) states the object and purpose, scope and provides definitions of key terms. The second chapter (Articles 5 to 14) contains the substantive criminal law provisions and the third chapter (Articles 15 and 16) states the provisions of investigations, prosecution, and procedural law. The following chapters four, five and six consist of provisions regarding cooperation of authorities and information exchange, measures for prevention and measures for protection respectively. The last few chapters contain measures regarding international cooperation and follow up mechanisms.⁸⁴⁰

⁸³⁶ WHO. (2006). *Declaration of Rome, Conclusions and Recommendations of the WHO International Conference on Combating Counterfeit Medicines*, 18 February 2006. Section 4.

⁸³⁷ Attaran, A., Bate, R., & Kendall, M. (2011). Why and how to make an international crime of medicine counterfeiting. *Journal of International Criminal Justice*, 9(2), 325-354.

⁸³⁸ Bassiouni, M. Cherif. (1983). Penal Characteristics of Conventional International Criminal Law. *Case w. Res. J. int'l L.* 15 27. 28-29.

⁸³⁹ As per definition, the term ‘counterfeit’ as used in the Medicrime Convention implies ‘falsified’ as understood in the EU because it is similar to the definition of a falsified medicinal product, as stated in the Directive 2011/62/EU (the FMD).

⁸⁴⁰ Chapters 7 to 11, The Medicrime Convention. 2011.

This chapter will focus on some specific provisions most relevant to the thesis. Specifically, the definition of the term counterfeiting (*Article 4*) will be analysed followed by the meaning of the term ‘similar crimes’ (*Article 8*). Thereafter, the particular provisions that address the issue of jurisdiction (*Article 10*); protection of victims, particularly regarding investigations (*Article 15*) and prosecution (*Article 16*) will be discussed.

7.2.3. Main provisions

The term ‘counterfeit’ is defined in the Medicrime Convention as: ‘a false representation as regards identity and/or source’ (*Article 4*), and ‘similar crimes’ as the unauthorised manufacture or supply of medicinal products or the marketing of medical devices that do not comply with conformity requirements (*Article 8*). The term ‘similar crimes’ denotes production, stock-piling, trafficking, offering for sale of medical products, by passing intentionally the obligatory supervision/control of medicines authorities.⁸⁴¹

The term used in the Medicrime convention is ‘counterfeiting’ which is different from the term used in the FMD, which uses the term ‘falsified medicinal products’.⁸⁴² Although the terms used are different,⁸⁴³ a closer examination of the terms reveals that the meaning of the term ‘counterfeiting’ as used in the Medicrime Convention is actually in consonance with the term ‘falsified medicinal product’ as understood in the FMD. The FMD incorporates a more detailed definition, which includes false representation with regard to origin,

⁸⁴¹ Article 8, The Medicrime Convention, 2011.

⁸⁴² Article 1 (1) (c), Falsified Medicines Directive 2011/62/EU.

⁸⁴³ See Chapter 1, Section 1.6 for discussion on terminology.

source, and history.⁸⁴⁴ Both the Medicrime Convention and the FMD⁸⁴⁵ specifically state that all issues related to IPRs violation are not addressed by the Convention and the Directive respectively. Therefore, although the terminology used is different in the two legal instruments, the practical implications are not totally divergent with respect to the definition of the term ‘counterfeiting’ and ‘falsified medicinal product’. The definitions are in consonance with each other is so far as both the Medicrime Convention and the FMD exclude IPRs issues but the FMD provides a broader definition. It also includes false description of history of the medicinal product.

The Medicrime Convention takes a significant step forward in terms of introducing serious measures against counterfeiting and falsification of medicines as it is the first international regulation that aims to prosecute the manufacture and sale of counterfeit drugs⁸⁴⁶ and a convention that obliges the signatory States to prosecute criminally the manufacture and trafficking of counterfeit drugs.⁸⁴⁷ The convention also addresses those products that have not procured proper authorisation⁸⁴⁸ before they were put on the market, under Article 8⁸⁴⁹ It would encompass the manufacture, stockpiling for supply, importing, exporting, supplying and offering to supply of medicinal products without authorisation. As for the medical devices – it would entail those not complying with the standards. In this manner, the convention puts an obligation on the signatory States to treat placement of products without authorisation, as crimes, since they pose a threat to public health. These provisions are aimed at the black market in unauthorised

⁸⁴⁴ Article 1 (1), Directive 2011/62/EU.

⁸⁴⁵ See Directive 2011/62/EU.

⁸⁴⁶ Articles 5 and 6, Chapter 2, The Medicrime Convention, 2011.

⁸⁴⁷ Article 16, Chapter 3, The Medicrime Convention, 2011.

⁸⁴⁸ Article 7, Chapter 2, The Medicrime Convention, 2011.

⁸⁴⁹ Article 8, Chapter 2, The Medicrime Convention, 2011.

steroids.

The Medicrime Convention is the first international convention that sets up offences with criminal intent: the manufacturing of falsified/counterfeit medical products (Article 5); supplying, offering to supply and trafficking in falsified/counterfeit medical products (Article 6); the falsification of documents (Article 7); ‘similar crimes’ (Article 8); and under Article 9, the Convention addresses aiding or abetting to commit the offences also as criminal offences. The interpretation of the concept of “attempt” is left up to the individual States. The only guideline stated in the preamble of the Convention indicates, that principle of proportionality⁸⁵⁰ must be considered. In essence, the principle of proportionality seeks to enforce the fact the law must only be applied to the extent that is necessary to achieve the objectives of the Convention.

Within the EU, the Medicines Directive (Directive 2001/83/EC)⁸⁵¹ forbids putting a product on the market without market authorisation. However, as the case studies⁸⁵² have also revealed, having rules, such as in the Medicines Directive, the FMD (Directive 2011/62/EU), and civil measures, as provided for in the Enforcement Directive,⁸⁵³ alone have not helped in curbing the proliferation of counterfeit and falsified medicinal products in the EU. Therefore, these provisions of criminal measures in the Medicrime Convention, as adopted by four Member States⁸⁵⁴ and if adopted by the EU, would strengthen the legal framework against the proliferation of counterfeiting and falsified medicinal products.

⁸⁵⁰ Principle of proportionality is stated in Article 5 of the TEU. The criteria for its application is stated in Protocol (No.2) on the application of the principles of subsidiarity and proportionality annexed to the Treaties.

⁸⁵¹ Article 6, Directive 2001/83/EC.

⁸⁵² See Chapter 3.

⁸⁵³ See Directive 2004/48/EC.

⁸⁵⁴ The Medicrime Convention has been ratified by Spain, France, Belgium and Hungary from amongst the EU Member. (Status as of 14.7.2017). For updated status, see <http://www.coe.int/en/web/conventions/full-list/-/conventions/treaty/211/signatures>.

Article 10 of the Convention deals with matters of jurisdiction and it is clear⁸⁵⁵ that the main aim of inclusion of this provision is to ensure no criminal acts get a chance to seep through the gaps in the legal framework. The principle of territoriality is applicable in the strictest sense since the Medicrime Convention lays the foundations for States to take legislative action and other initiatives to apply sanctions against offences taking place in its territory.

However, as seen in the case studies, the problem that arises, is the purposeful spread of their actions in different States by the counterfeiters. For instance, Operation Volcano,⁸⁵⁶ headed by the Italian authorities, revealed that the legitimate market authorisation holder transferred the products to the illegitimate authorisation holder and the goods switched from being in the legal supply chain to being in the illegal supply chain and then finally ended in the legal supply chain after having been falsified.⁸⁵⁷ The fake authorisations showed that the goods were moved from Italy to different Member States like Latvia, Malta, Cyprus, and Romania, and then back to Italy.⁸⁵⁸ Therefore, the matter of jurisdiction has been accurately identified by the Medicrime Convention as being crucial to enhance greater coordination and cooperation between signatory States, as generally envisaged in chapter VII of the Medicrime Convention.⁸⁵⁹

The Convention provides for the promotion of national and international cooperation.⁸⁶⁰ Under these provisions, the convention establishes methods of

⁸⁵⁵ Cabezas, M. D., & Piqueras, A. J. (2011). Medicrime: The international convention of the Council of Europe as a tool to combat counterfeit medicines. *Pharmaceuticals Policy and Law*, 13(1, 2), 41-55.

⁸⁵⁶ See more in Chapter 3, Section 3.2.

⁸⁵⁷ See more in Chapter 3, Section 3.2.

⁸⁵⁸ *ibid.*

⁸⁵⁹ See Chapter 7, Articles 21 and 22, The Medicrime Convention. 2011.

⁸⁶⁰ *ibid.*

cooperation and delineates how to establish an interface between the various authorities in different sectors such as the commercial and industrial sectors. Further, the preventive measures as proposed by the Convention that the States need to implement pertain to an obligation to train personnel in control and monitoring activities. It would involve training the police, customs authorities and regulatory authorities, awareness-raising campaigns about counterfeit medical products, and authorisation of interventions on websites. This provision would enhance enforcement of the legal instruments and thereby aid in the implementation of the existing rules.

The Medicrime Convention addresses issues such as protection of victims,⁸⁶¹ by providing for - that victims must have access to information. This entails all information relevant to their case, necessary for the protection of their health; thereby assisting the victims in their physical, psychological and social recovery. The provisions regarding investigation and prosecution (Articles 15 and 16) aim at eradicating pressure on the victim by the criminal to withdraw their complaint and this is achieved by the provision that the proceedings can be initiated *ex-officio* and not only by the victim himself/herself. Further, the signatories to the Convention will be obliged to take necessary legislative and other measures to protect the rights and interests of victims, including the provision of legal aid, access to information and protection from intimidation.⁸⁶²

7.2.4. Critical analysis of Medicrime Convention

The main contribution of the Medicrime convention is the criminalisation of acts pertaining to counterfeit medicine. It is the first international convention of its

⁸⁶¹ Chapter 6, Articles 19 and 20, The Medicrime Convention. 2011.

⁸⁶² Chapter 6, Article 20, The Medicrime Convention. 2011.

kind to do so and for that reason alone, is important. It provides tools to the signatory States to criminalise the act of counterfeiting and associated acts of falsifying accompany documents, which have proven to be a menace in the EU, as indicated by the case studies.⁸⁶³

The Medicrime Convention introduces many crucial provisions required to fight counterfeiting in the pharmaceutical sector in its bid to achieve its aim of ‘criminalisation of counterfeiting’. If adopted by all the Member States in the EU, it would significantly enhance the legal framework that governs the counterfeiting and falsification of medicinal products in the EU and bridge the gap provide for the missing harmonised rules in the sphere of Criminal law. However, there are certain areas that can still be improved in the Medicrime Convention.

The Convention addresses the term counterfeit in a very broad manner and leaves out definition of certain key relevant terms. For example, Article 5 of the Convention states that manufacturing a counterfeit medicine is a criminal offence. It includes adulteration as a crime but does not define the term explicitly.⁸⁶⁴ It is equally important to define this term, in addition to defining the concept of victim and counterfeit medical product. As discussed in Chapter 1, clarity with regard to the terminology used and in legal instruments is extremely important.⁸⁶⁵ This is because, the terms that are left undefined or omitted in legal instruments become the shield of protection of criminal acts carried out in context of falsification and counterfeiting of medicines.⁸⁶⁶

⁸⁶³ See Chapter 3.

⁸⁶⁴ Council of Europe. (2009). Council of Europe Convention on the counterfeiting of medical products involving threats to public health, Explanatory Report. 16 fin., paragraph 44. 7.

⁸⁶⁵ See Chapter 1, Section 1.6.

⁸⁶⁶ Cabezas, M. D., & Piqueras, A. J. (2011). Medicrime: The international convention of the Council of Europe as a tool to combat counterfeit medicines. *Pharmaceuticals Policy and Law*, 13(1, 2), 41-55.

Thus, it is extremely rare that an action is initiated against adulteration and other related crimes because of the omission of these acts in the legal instruments. One of the recorded cases where action was taken is from the US in 2011, when the Food & Drug Authority (FDA) imposed a sanction on the pharmaceutical company Glaxosmithkline for distributing adulterated medicinal products after the accusation of an employee responsible for product quality supervision for the company's products made in a factory in Puerto Rico. In the case, a criminal fine and forfeiture of 150 million USD and a civil settlement under the False Claims Act and related state claim for 600 million USD was levied.⁸⁶⁷ The result of lack of clarity of the definition of the terms counterfeiting, adulteration, etc. can heighten legal uncertainty, when the different States will apply the Convention. For instance, the Spanish criminal code distinguishes between adulteration and counterfeiting by classifying both actions as crimes against public health.⁸⁶⁸ However, it is not the case in the majority of States.

The Medicrime Convention requires under Article 8(a) (i), to enact criminal offences against unauthorised activities such as generic drug companies making stockpiles or marketing drugs without proper authorisations. Up until now, such deviations were considered a civil wrong, however after the implementation of the Convention, such offences will become criminal in nature and thus may even entail imprisonment as a punishment. The alarming fact that 30 % of drug launches infringe, might probably have a chilling effect on the generic drug

⁸⁶⁷ The United States Department of Justice. (26 October 2010) *GlaxoSmithKline to Plead Guilty & Pay 750 USD to Resolve Criminal and Civil Liability Regarding Manufacturing Deficiencies at Puerto Rico Plant*. Press Release number: 10-1205. Washington DC.

⁸⁶⁸ Compare Art. 362 Organic Law 10/1995, 23 November of the criminal code), Bernaus José F, Bernaus Carlos G. *Adulteración y falsificación de medicamentos*. Ed. Quorum 2006:256 in M.D. Cabezas and A.J. Piqueras (Pharmaceuticals Policy and Law (2011)).

industry.⁸⁶⁹ Another common concern is the Convention may penalise honest mistakes of medicine manufacturers.⁸⁷⁰ For instance, an unintentional mistake on part of an authorised seller of false representation could also lead to prosecution similar to the case of Heparin products manufactured by Baxter.⁸⁷¹ Those products had to be taken off the market since they contained an unknown contaminating substance. Criminal punishment for such acts can appear too severe.

The Medicrime Convention is also significant because it governs the rights of ‘victims’, which has not been addressed in this context previously. Further, it provides for concrete measures for setting up international cooperation and encompasses follow-up mechanisms. Despite the revolutionary measures and innovative nature of the Medicrime Convention, it lacks the support and involvement of some of the key nations such as the US, the UK and China.⁸⁷² Another drawback is that in respect to some provisions, the Medicrime Convention appears like a buffet of legal provisions, which allows for picking and choosing selective provisions that may be adopted or disregarded. This room for making adjustments before adoption can result in inconsistencies between the signatory States.⁸⁷³

Despite the room for manoeuvrability, the Medicrime Convention is the first step towards achieving harmonisation with respect to criminalisation of acts of

⁸⁶⁹ Ludwig, S. P., Kosinski, K. B., & Harris, J. (2005). Hatch-Waxman in the Federal Courts: From 1994–2004. *Drug development and industrial pharmacy*, 31(2), 215–222.

⁸⁷⁰ Attaran, Amir, & Roger Bate. (2010). A counterfeit drug treaty: great idea, wrong implementation. *The Lancet* 376: 1446–1448.

⁸⁷¹ Briones, S. (2008). Heparin recall: another crisis for China & the FDA. *Health Law Perspectives*, 24.

⁸⁷² It is believed by some scholars that lack of involvement of key countries is more due to political reasons such as the locus of power shifting from International organisations such as the WHO, WTO to COE. (Amir Attaran et al. 2011).

⁸⁷³ For instance, in case of jurisdiction, the fact that a Party can reserve jurisdiction based on nationality of the victim or the perpetrator will corrode the full benefit of the provision, as also indicated by M.D. Cabezas and A.J. Piqueras (2011).

counterfeiting and falsification of medicinal products. If the EU ratifies the Medicrime Convention, then all the Member States would in effect be obliged to provide for the provisions of the Medicrime Convention. This would strengthen the enforcement mechanisms as regards falsified medicines because even though the Medicrime Convention uses the term ‘counterfeit medicine’, it is concerned with, what is understood in the EU as ‘falsified’ medicines. In other words, the Medicrime Convention does not address the IP violation. For the purposes of combatting falsified medicines in the EU, if the Medicrime Convention is ratified, it would harmonise the criminal enforcement against falsified medicinal products, at least from the perspective of public health and safety. It would inevitably have a positive impact on the IP violations because if there are less falsified medicines, there will obviously be less counterfeit medicinal products. This is because the product that is falsified inevitably violates the IP rights of the right holder. Therefore, even though the Medicrime Convention does not concern itself with IP violations, it will result in a proportionate decrease in incidents of counterfeiting of medicinal products by virtue of decrease in falsification of medicinal products.

7.3. ACTA

The Anti- Counterfeiting Trade Agreement (ACTA)⁸⁷⁴ was a multi-national plurilateral trade agreement conceived in 2010 with the main aim of articulating an agreement with global application in combatting counterfeiting and be instrumental for enforcement of IP rights by establishing global standard. It was negotiated outside the purview of traditional international organisations such as

⁸⁷⁴ ACTA, 2011.

the WTO or WHO and as a result was a target of much criticism⁸⁷⁵ for lack of transparency.⁸⁷⁶ The purpose of including ACTA⁸⁷⁷ (despite the fact that it was not passed by the EU,⁸⁷⁸ and has effectively failed), is to seek inspiration in order to improve the legal framework that governs counterfeiting and falsification of medicines in the EU.

It needs to be reiterated that counterfeiting and falsification of medicines lies at the intersection of Medicine law, IP law and Criminal law, as discussed in Chapter 1.⁸⁷⁹ In the EU the FMD governs the Medicine law aspects;⁸⁸⁰ the Enforcement Directive⁸⁸¹ and the Customs Regulation⁸⁸² deal with the IP law aspects and there is no harmonisation at the EU level with regard to the Criminal law area. The only instrument that deals with criminal measures is the COE initiative – the Medicrime Convention,⁸⁸³ which has been ratified by four Member States so far.⁸⁸⁴ It contains criminal measures against counterfeiting and falsification of medicines specifically. Another feature of these legal instruments is that the FMD deals specifically with the falsified medicines, and thus the other two legal instruments that address the IP law sphere, govern the IPRs in general are not tailored to address counterfeiting and falsification of medicines, in particular.

⁸⁷⁵ Dür, A., & Mateo, G. (2014). Public opinion and interest group influence: how citizen groups derailed the Anti-Counterfeiting Trade Agreement. *Journal of European Public Policy*, 21(8), 1199-1217.

⁸⁷⁶ McManis, C. R. (2009). The proposed anti-counterfeiting trade agreement (ACTA): two tales of a treaty. *Hous. L. Rev.*, 46, 1235.

⁸⁷⁷ ACTA, 2011.

⁸⁷⁸ See The European Parliament. (2012). *European Parliament rejects ACTA*. Press Release July 4 2012. Reference no.:20120703IPR48247.

⁸⁷⁹ Chapter 1, Section 1.2.

⁸⁸⁰ See Directive 2011/62/EU.

⁸⁸¹ See Directive 2004/48/EC.

⁸⁸² See Regulation 608/2013.

⁸⁸³ The Medicrime Convention. 2011.

⁸⁸⁴ The Medicrime Convention has been ratified by Spain, France, Belgium and Hungary from amongst the EU Member. (Status as of 14.7.2017). For updated status, see <http://www.coe.int/en/web/conventions/full-list/-/conventions/treaty/211/signatures>.

The ACTA had the goal to combat counterfeiting in the context of IPRs in general and was not specifically tailored to the needs to combat counterfeiting and falsification of medicines in the EU. In that respect ACTA resembled the other legal instruments in the EU such as the Enforcement Directive and the Customs Regulation, which address counterfeit medicinal products in the EU as part of other IPRs, and from the IP law perspective. On the other hand, the FMD addresses the falsified medicinal products from the Medicines law perspective and omits the IP law perspective in the EU. Likewise the Medicrime Convention only addresses medicinal products from the public health and safety perspective and not the IP law perspective.

7.3.1. Background

ACTA came about in 2010, with the aim to deliver a framework that would be internationally applicable and compatible to curb counterfeiting and enforce IP rights. Prior to ACTA, Trade Related Aspects of Intellectual Property Rights (TRIPS), existing since 1994, was the only, and till date continues to be the hallmark agreement of enforcement of IP rights at the global level. There were questions raised regarding the reason underpinning the inception of ACTA, associated inadequacy or insufficiency of TRIPS and the absence of ACTA negotiation under the WTO regime or any other internationally recognised forum. Some of the answers to the questions raised lie in the area of international politics and diplomacy rather than in purely legal regulatory arena, for instance, lack of transparency⁸⁸⁵ in the process of negotiations; forum-shifting⁸⁸⁶ where developed countries dominated the process and developing countries and their interests were

⁸⁸⁵ Levine, D.S. (2011). Transparency Soup: The ACTA Negotiating Process and “Black Box” Lawmaking. *American University Journal of International Law and Policy*, 26 (3). 811.

⁸⁸⁶ Mercurio, B. (2012). Beyond the text: the significance of the anti-counterfeiting trade agreement. *Journal of International Economic Law*, 15(2), 361-390.

not represented satisfactorily.

ACTA was conceptualised in the wake of rise in counterfeiting and the impending need for an international agreement for enforcement of IP rights. There was and continues to be no dearth of statistics that indicate the critical loss of the right holders due to counterfeiting world over.⁸⁸⁷ Counterfeiting is not limited to a specific sector or to a specific industry. Therefore, there was and still is an urgent need to update and build upon the TRIPS as an international agreement on the enforcement of IP rights. Numerous bilateral and multilateral agreements, as discussed in Section 7.4⁸⁸⁸ have been put forward at regional level, such as, TPP, RCEP, TTIP and of course ACTA was one such effort at the international level to combat counterfeiting.

However, due to the new challenges presented by technological development, it was agreed that one such international agreement was necessary or a revision was important for the sake of a universal international agreement on enforcement of IPRs. ACTA involved the United States, the European Community, Switzerland, Japan, Australia, Republic of Korea, New Zealand, Mexico, Jordan, Morocco, Singapore, the United Arab Emirates, and Canada.⁸⁸⁹

The ACTA consisted of civil measures (Article 7 to 12), criminal measures (Article 23 -26), as well as measures for border enforcement (Article 14-22). In addition, there were also measures that dealt with enforcement of IP rights and enhancement of IP enforcement practices. Another important angle in the ACTA

⁸⁸⁷ Recent estimates claim that the trade has grown by 90 per cent since 2005, with an approximate turnover of \$200 billion, suggesting it has now overtaken marijuana and prostitution as the largest illicit market for traffickers (IRACM 2013; see also Finlay 2011) in Hall, A., & Antonopoulos, G. A. (2016). Introduction. In *Fake Meds Online*. 1-17. Palgrave Macmillan UK.

⁸⁸⁸ See more Section 7.4.

⁸⁸⁹ ACTA, 2011.

was the enforcement of IP in the digital environment. Due to a number of reasons that will be discussed in Section 7.3.4, the ACTA was rejected by the European Parliament when the European Parliament did not ratify ACTA in 2012.⁸⁹⁰

Several of the civil, criminal, border, digital and international measures that were incorporated in the ACTA, constitute a part of the legal instruments in the EU in one form or another. The civil measures that formed a part of ACTA are available under the Enforcement Directive.⁸⁹¹ The Customs Regulation entails the provisions that mirror border measures as perceived in the ACTA.⁸⁹² The criminal measures in the ACTA have no equivalent at the EU level that can be attributed to the lack of harmonisation at the EU level in that sphere of Criminal law. But the Medicrime Convention would harmonise the criminal enforcement in context of falsified medicines, if ratified by the EU.

7.3.2. Main relevant provisions

In the ACTA, Section 2 dealt with the civil enforcement measures under Articles 7 to 12. It contained measures such as availability of civil procedures to right holders on the basis of merits of a case. Injunctions were provided for under Article 8, which accorded the judicial authorities with the power to issue orders to parties to desist from an infringement of an IPR which would in effect, prevent goods from entering the channels of commerce. The section on civil remedies dealt with provision of damages, and other remedies for possible incorporation into the laws of the signatory States, in addition, to information related to infringement, which may be passed. Provisional measures that could be

⁸⁹⁰ The European Parliament. (2012). *European Parliament rejects ACTA*. Press Release July 4 2012. Reference no.:20120703IPR48247.

⁸⁹¹ Directive 2004/48/EC.

⁸⁹² Regulation 608/2013.

undertaken, such as seizures, or taking other information or products into custody the goods that were suspected of infringing IPRs were also spelt out in this section. The provisions on civil measures follow a construct based on the TRIPS agreement and much of what has been part of the TRIPS agreement has seen the distillation into the national laws of the signatory States. For instance, the civil measures that are enumerated in the ACTA, are reminiscent of TRIPs Agreement and have similar if not identical provisions in the Enforcement Directive,⁸⁹³ discussed in Chapter 5 in greater detail.

Section 4 of ACTA, was perhaps the most controversial of all the provisions of ACTA.⁸⁹⁴ Article 23 provided for measures that were supposed to be undertaken in case of wilful trademark counterfeiting on a commercial scale. The second part of Article 23, constituted a measure with foresight, wherein criminal procedures and penalties were to be imposed in cases of wilful importation, domestic use in course of trade and on commercial scale of labels or packaging.⁸⁹⁵ In one of the legal case studies - Operation Singapore (*R v. P. Gillespie*),⁸⁹⁶ as discussed in detail in Chapter 3, false packaging was used and the accused was sentenced to three years of imprisonment on charge of counterfeiting. In the EU, false packaging has been an issue since 2010, as also reported in the EU Customs report on enforcement⁸⁹⁷ especially in the luggage of passengers and continues to be an issue.

The measure incorporated under Section 3 of the ACTA, dealt with the provision

⁸⁹³ See Chapter 5.

⁸⁹⁴ McManis, C. R. (2009). The proposed anti-counterfeiting trade agreement (ACTA): two tales of a treaty. *Hous. L. Rev.*, 46, 1235.

⁸⁹⁵ Article 23 (2) ACTA, 2011.

⁸⁹⁶ See Chapter 3, Section 3.3.

⁸⁹⁷ European Commission. (2015). Report on EU customs enforcement of intellectual property rights. Results at the EU border 2015. Luxembourg. Publications office of the European Union.

of border measures, set in Articles 14 to 22. Article 14 enumerates the provisions with respect to small consignments and personal luggage, wherein ACTA would have been applicable to goods sent in small consignments for commercial purposes but not to small quantities of goods of a non-commercial nature contained in travellers' personal luggage. This provision is also reminiscent of the provisions of the Customs Regulations 608/2013.⁸⁹⁸

In addition, there were provisions for penalties, seizure, forfeiture and destruction of goods.⁸⁹⁹ Article 26 of ACTA provided for ex-officio criminal enforcement, wherein each signatory State would be obliged to provide in relevant cases, the power to its authorities to act upon their own initiative investigation or legal action with respect to the criminal offences mentioned in ACTA. For these offences, the States were also obliged to provide for criminal procedures and penalties. This provision was perceived to be of draconian nature with a potential for misuse due to lack of typical checks and balances on the use of this provision.⁹⁰⁰ In the EU, there is resistance to harmonisation of criminal law in general, and also resistance towards criminal enforcement of IPRs.⁹⁰¹

The civil and criminal enforcement measures available in case IPR violations would have been extended to issues arising in the digital environment as well. The measures would include expeditious remedies to prevent infringement and also remedies, which would constitute a deterrent to further infringements. In addition, there were measures to avoid creation of barriers to legitimate activity including

⁸⁹⁸ Customs Regulation 608/2013.

⁸⁹⁹ Article 25, ACTA, final text, 2011.

⁹⁰⁰ Shepard, A. (2013). ACTA on Life Support: Why the Anti-Counterfeiting Trade Agreement Is Failing and How Future Intellectual Property Treaties Might Avoid a Similar Fate. *Wash. U. Global Stud. L. Rev.*, 12, 673.

⁹⁰¹ The failed attempt to introduce criminal enforcement of Intellectual Property Rights at the EU level in 2007. *See also* the withdrawal was announced in the 'Withdrawal of obsolete Commission proposals in the Official journal of the European Union. (18 September 2010), 2010/C 252/9.

electronic commerce, and consistent with national laws, preservation of fundamental principles such as freedom of expression, fair process and privacy.

Chapter 4 of the ACTA dealt with provisions for encouraging international cooperation, which was built upon the basic premise that protection of IPR was important irrespective of the nationality of the right holder or the location of the right holder. In an international environment, where IPRs exist in a global format, it is necessary that the protection is also extended in the same format.⁹⁰²

7.3.3. Critical analysis of ACTA

The main reason for negotiating ACTA was to combat the large scale of intellectual property rights violations and for the protection of rights holders in the international arena. However, it was marred by lack of faith due to lack of transparency⁹⁰³ in the manner in which it was negotiated. It was also blamed for ‘forum – shifting’,⁹⁰⁴ away from the WTO and pre-existing forums for negotiating of international Intellectual Property rules. ACTA provoked a public outcry of unexpected proportion, with associated views ranging from labelling ACTA as an “end of democracy”,⁹⁰⁵ to “censorship of the internet”, to “restriction of access to live-saving AIDS medicines in developing countries”. Concerns were also raised

⁹⁰² Moreover, cooperation between States on the subject of enforcement of IPRs was encouraged as well as capacity building and technical assistance to be extended to other countries that were signatories to the Agreement. This cooperation would have included law enforcement cooperation with respect to criminal enforcement and border measures, as covered by ACTA. In addition, the ACTA also included the provision for sharing of information between States, which would have contributed greatly to the creation of a database of potential counterfeiters, and would have aided in catching criminals in a speedier manner. This would have resulted in greater protection of IPRs as well as would have strengthened the enforcement of IPRs.

⁹⁰³ Levine, D.S. (2011). Transparency Soup: The ACTA Negotiating Process and “Black Box” Lawmaking. *American University Journal of International Law and Policy*, 26 (3). 811.

⁹⁰⁴ Mercurio, B. (2012). Beyond the Text: The Significance of the Anti-Counterfeiting Trade Agreement. *Journal of International Economic Law* 15(2), 361-390.

⁹⁰⁵ The lack of transparency during the negotiating process (despite Parliaments’ request to make the ACTA negotiating documents public, the documents were not made public), also contributed to affirm the anti-democratic sentiment against ACTA in the EU.

as to whether the ACTA was in consonance with the *acquis communautaire* of the EU and with the World Trade Organisation (WTO) Agreement on the Trade Related Aspects of Intellectual Property Rights (the TRIPS). Even though there were voices that defended ACTA, such as defence offered by the then European Commissioner for Trade, stating his opinion that “ACTA is not an attack on your liberties; it is a defence of your livelihoods,”⁹⁰⁶ these voices were drowned by those who opposed the Agreement. Adding to the mix of confusion was the timing of the EU Parliament’s vote, which happened before the Court of Justice (CJEU) response to European Commissions’ request on clarification on whether ACTA was incompatible with EU’s fundamental rights and freedoms, including freedom of expression and information and data protection, and the right to property in case of intellectual property.⁹⁰⁷ In July 2012, the European Parliament rejected the Proposal for a Council Decision on the conclusion of ACTA.⁹⁰⁸

Contrary to the criticism levied upon ACTA, it did go a step further than TRIPS (still recognised and respected Agreement pertaining to Intellectual Property Rights). ACTA offered more solid provisions, which probably erred on the side of being too strict. Secondly, ACTA also addressed the element of cross-border infringements in more concrete terms, when compared to TRIPs. However, as the final draft of ACTA indicated, it needed to be tempered down from its original form. It also became evident from the manner of negotiation of ACTA, that equal

⁹⁰⁶ De Gucht, K. (29 February 2012). European Commissioner for Trade, ACTA – State of Play, 1st Exchange of Views with the Committee for International Trade of the European Parliament. Brussels.

⁹⁰⁷ The question put forward by the Commission to the CJEU was, “*Is the Anti-Counterfeiting Trade Agreement (ACTA) compatible with the European Treaties, in particular with the Charter of Fundamental Rights of the European Union?*” See European Commission. Press Release IP/12/354. See also Statement by Commissioner De Gucht, K. (22 February 2012). On ACTA (Anti-Counterfeiting Trade Agreement). Brussels. Europa Press Release MEMO/12/128.

⁹⁰⁸ Proposal for a Council Decision on the conclusion of the Anti-Counterfeiting Trade Agreement between the European Union and its Member States, Australia, Canada, Japan, the Republic of Korea, the United Mexican States, the Kingdom of Morocco, New Zealand, the Republic of Singapore, the Swiss Confederation and the United States of America, 24 June 2011, COM (2011) 0380.

emphasis needs to be placed in the manner of negotiations, which should be fair and transparent as well as the technical content of the Agreement, if it is to be unanimously agreed upon at the international level.

An analysis of the main provisions of the ACTA and the comparison of ACTA with the EU legal instruments governing counterfeit and falsified medicines in the EU reveals that the civil measures are pre-existing in the Enforcement Directive⁹⁰⁹ and the border measures are adequately covered by the Customs Regulation.⁹¹⁰ Moreover, the criminal measures that the ACTA provided for are not addressed by any one harmonised legal instrument at the EU level. Although the Medicrime Convention provides for the criminalisation of counterfeiting of medicinal products, it has not been ratified by all the Member States yet. Further, it addresses the violations from the public health and safety perspective and not IPR infringements, from the IP law perspective. In addition, the ACTA addressed the criminal enforcement of IPRs in general from an IP law perspective, which is still not harmonised at the EU level.

Therefore, ACTA can serve as a blueprint when harmonisation of IP law with regard to criminal enforcement of IPRs is re-considered in the EU since it has articulated the criminal offences associated with violations of IPRs under Article 23. However, for the purposes of regulating criminal enforcement of counterfeiting and falsification of medicinal products in the EU, the Medicrime Convention is a good starting point. But, there is an evident gap with respect to criminal enforcement of counterfeiting of medicines where there is a categorical violation of IPRs. Therefore, even though the ACTA as a whole need not be

⁹⁰⁹ Articles 8 to 11, Directive 2004/48/EC.

⁹¹⁰ Articles 17 to 26, Regulation 608/2013.

transposed into EU legal instruments, the specific measures on criminal enforcement of IPRs are extremely relevant.

7.4. Multilateral and bilateral agreements

7.4.1. Background

The proliferation in the number of bilateral and multilateral agreements clearly indicates a developing dissatisfaction and inadequacy of the international agreements in the IPRs domain. The agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS)⁹¹¹ as negotiated in 1994 is the only international agreement in the realm of IPRs that is widely recognised and implemented. Since TRIPs, no new international agreements have seen success. Specifically, the failure of ACTA in 2012 after years of negotiations; the most recent set back which might lead to ultimate rejection of Trans Pacific Partnership (TPP)⁹¹² due to withdrawal by the United States;⁹¹³ as also the inadequacy of Medicrime Convention - indicated by the few countries that have ratified the Convention illustrate the lack of success of any international agreement on the issue.

While, on one hand, most attempts at international agreements are not seeing

⁹¹¹ The agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) came into being in 1994. As is evident by the large number of bilateral and multilateral agreements regarding enforcement of IPRs, there is widespread belief that TRIPs either needs to be amended or abandoned in favour of a more contemporary agreement that addresses the needs of the technological developments that has taken place in the past two decades also in context of IPRs.

⁹¹² TPP negotiations reached a successful conclusion in October 2015. The 12 TPP parties were Australia, Brunei, Canada, Chile, Japan, Malaysia, Mexico, New Zealand, Peru, Singapore, United States, and Vietnam; See also Thow, A. M., & Gleeson, D. (2017). Advancing public health on the changing global trade and investment agenda: comment on "the trans-pacific partnership: Is it everything we feared for health?". *International Journal of Health Policy and Management*, 6(5), 295.

⁹¹³ Schott, J. J., & Lu, Z. L. (2017). Asia-Pacific Regionalism after the TPP. *17-1 US-China Cooperation in a Changing Global Economy*, 134.

fruition, on the other hand, there is a distinct proliferation in the number of multilateral, plurilateral and bilateral agreements. For instance, EU and Canada are working on a Comprehensive Economic and Trade Agreement (CETA)⁹¹⁴ covering classic free trade issues, wherein substantive and the enforcement provisions are modelled after the beginning of ACTA in 2009 and CETA is still under negotiations.⁹¹⁵ Another example is the Trans-Atlantic Trade and Investment Partnership (TTIP)⁹¹⁶ between EU and the US, which also contains provisions on IP protection. In addition, Trans Pacific Partnership (TPP)⁹¹⁷ has also been underway since 2005, however, after the US withdrawal from the negotiations of TPP, the future of TPP in its current form is uncertain. In 2012, Regional Comprehensive Economic Partnership (RCEP),⁹¹⁸ which is a large scale free-trade agreement began to take form between ASEAN member states and Australia, China, India, Japan, Korea and New Zealand. Likewise, RCEP has also dedicated a chapter on IP enforcement. In the Pacific region, the Trans-Pacific Partnership is being negotiated between the Members of the P4 free trade Agreement of 2005, (Brunei, Chile, New Zealand, and Singapore) and Australia, Canada, Japan Malaysia, Mexico, Peru, the United States and Vietnam. TPP also contains provisions on IP enforcement.

As the titles of the various agreements suggests, these are trade agreements, which

⁹¹⁴ Griller, S., Obwexer, W., & Vranes, E. (Eds.). (2017). *Mega-Regional Trade Agreements: CETA, TTIP, and TiSA: New Orientations for EU External Economic Relations*. Oxford University Press.

⁹¹⁵ THE EU Parliament voted in favour of CETA on February 15, 2017. It still needs to be ratified by the national parliaments before it can become fully effective.

⁹¹⁶ Griller, S., Obwexer, W., & Vranes, E. (Eds.). (2017). *Mega-Regional Trade Agreements: CETA, TTIP, and TiSA: New Orientations for EU External Economic Relations*. Oxford University Press.

⁹¹⁷ Schott, J. J., & Lu, Z. L. (2017). Asia-Pacific Regionalism after the TPP. *17-1 US-China Cooperation in a Changing Global Economy*, 134.

⁹¹⁸ Lee, Y. S. (2016). The Eagle Meets the Dragon—Two Superpowers, Two Mega RTAs, and So Many in Between: Reflections on TPP and RCEP. *Journal of World Trade*, 50(3), 475- 496.

focus on the economic partnerships. In general, the Trade and Investment Agreements (TIAs) have been criticised for the potential negative impact on health.⁹¹⁹ If the TPP and TTIP become a reality, the impact would be on more than half of world trade.⁹²⁰ The impact of these trade agreements will also be felt on those countries that are not signatories to the agreements since by default these trade agreements would be setting the standard and rules for rest of the world. Adherence to these rules would be inevitable if a country would like to remain competitive in global trade.⁹²¹ In addition, the formation of the mega-regional trade agreements coincides with the timing of increase in the number of trade disputes that concern public health protection.⁹²² Thus, the main focus of discussion of multilateral and bilateral agreements will be with reference to counterfeiting in the pharmaceutical sector. The main parameters that can serve as tools to determine the relevance of the TIAs in terms of counterfeiting in the pharmaceutical sector can be shortlisted to enforcement measures as well as sector specific measures with reference to the pharmaceutical sector.

7.4.2. IP perspective

The issue of enforcement of IPRs at the International level was first considered seriously in the TRIPs Agreement. However, the provisions regarding the

⁹¹⁹ Kapczynski, A. (2015). The Trans-Pacific Partnership—Is It Bad for Your Health?. *New England Journal of Medicine*, 373(3), 201-203; See also Luo, J., & Kesselheim, A. S. (2015). The Trans-Pacific Partnership agreement and implications for access to essential medicines. *Jama*, 314(15), 1563-1564; Also see Weiss, M., Middleton, J., & Schrecker, T. (2015). Warning: TTIP could be hazardous to your health. *Journal of Public Health*, 37(3), 367-369.

⁹²⁰ TPP: 26 %; TTIP: 43.6 % (Source: WTO 2014). 'WT/TPR/OV/ 16', obtained from the World Bank's World Development Indicators, WTO Statistics and UNSD Comtrade database.

⁹²¹ Jones, E., Deere-Birkbeck, C., & Woods, N. (2010). *Manoeuvring at the Margins: Constraints Faced by Small States in International Trade Negotiations*. Commonwealth secretariat; See Yu, K. (2014). TPP and Trans-Pacific Perplexities, 37 *Fordham Intl. L. J.* 1129-1182 (2014); Also see McNeill, D., Barlow, B., Birkbeck, C. D., Fukuda-Parr, S., Grover, A., Schrecker, T., & Stuckler, D. (2017). Trade and investment agreements: Implications for health protection. *Journal of World Trade*, 51(1), 159-182.

⁹²² WTO, Overview of Development in the International Trading Environment – Annual Report by the Director General (2014). WT/TPR/OV/14, 21 Nov. 2011; In 2015, the WTO Technical Barriers to Trade (TBT) Committee received fifty-four specific trade concerns. About 33 % of the concerns related to public health issues.

enforcement of IP rights in the TRIPS Agreement were not free from criticism. The TRIPS Agreement was criticised and debated upon even at the incipient stage.⁹²³ It was observed that the difficulties predicted in the discussions, such as the problematic and cumbersome process of bringing a dispute before the WTO, also subsequently came true.⁹²⁴ In fact, the US and the EU would have liked to have certain provisions regarding enforcement such as border measures extending to all IP rights specified in the TRIPS Agreement, which did not take place. As a consequence, most of the TIAs entered into by US and the EU with other countries contains specific measures pertaining to enforcement.

Looked through the lens of cleaning the pharmaceutical sector of counterfeiting products, it is apparent from the study of the TIAs that most of the TIAs deal specifically with the enforcement of IP rights. Therefore, the focus is on the measures, such as what can be done if a trade mark is violated and the civil, criminal and border measures available in order to enforce the rights as well as ensure safety of products. Specifically as regards the pharmaceutical sector, the measures pertain more with specific reference to protection of patents, violations of trademarks, copyrights and the traditional form of IP rights. For instance, Article 9^{bis} 2 of RCEP,⁹²⁵ which is closely reflected in Article 18.74 of the TPP,⁹²⁶ provides for the courts to use techniques such as taking into consideration lost profits and the market price or suggested retail price of goods in calculating damages for trademark or copyright infringement. Likewise Article 18.74 and 18.77 of the TPP are mirrored in Articles 9^{bis} 6 and 9^{quarter} 6 of RCEP, concerning

⁹²³ Reichman, J. H., & Lange, D. (1998). Bargaining around the TRIPS agreement: the case for ongoing public-private initiatives to facilitate worldwide intellectual property transactions. *Duke J. Comp. & Int'l L.*, 9, 11. 34-39.

⁹²⁴ Watal, J. (2014). Is TRIPS a Balanced Agreement from the Perspective of Recent Free Trade Agreements? In *EU Bilateral Trade Agreements and Intellectual Property: For Better or Worse?* (41-57). Springer Berlin Heidelberg.

⁹²⁵ Article 9, RCEP.

⁹²⁶ Articles 18.74 and 18.77, TPP.

destruction of infringed goods. These Articles also allow for destruction of materials and implements employed for creation of those goods. The criminal measures for the enforcement of IP violations proposed in ACTA, have also been proposed in the TPP, under Articles 18.77, and under Article 9^{quarter} 1 of RCEP.

These measures propose to criminalise any copyright and trademark infringements that occur on a ‘commercial scale’. The TIAs do not specifically address the steps necessary to fight counterfeiting although the goals of most TIAs reflect that counterfeiting and piracy need to be controlled and weeded out.⁹²⁷ In fact, it is highlighted in preparatory documents⁹²⁸ that the IP law umbrella does not deal adequately with the issue of counterfeit medicine⁹²⁹ since it is considered an area of Medicine law and Medicine law focuses its attention of the Regulation of medicine.

Therefore, the problem of counterfeit medicine falls between the cracks of otherwise strong and sound foundations of IP law and Medicine law. For instance, when addressing the issues of pharmaceutical sector IP law focuses on and deals with issues such as length of patents protection; and trademarks protection of pharmaceutical companies. However, the real problem lies in the fact that strong measures need to be instituted to specifically address counterfeiting in the pharmaceutical sector, besides the Medicrime Convention, whose primary focus is on criminalising counterfeiting of medicines; also there are no agreements that directly address this issue at the International or EU level. Apparently, it requires a

⁹²⁷ For example, Article 1 (6) of the proposed TTIP states that the parties shall promote increased access to high – quality medicinal products, address the threat of antimicrobial resistance and fight against falsified medicinal products.

⁹²⁸ Morin, J-F. (April 2011). Sustainability Impact Assessment Relating to the Negotiation of the Intellectual Property Chapter of the Comprehensive Economic and Trade Agreement (CETA) Between the EU and Canada. Université libre de Bruxelles.

⁹²⁹ Oxfam Canada and Oxfam Québec. (July 15, 2009). *Submission regarding the Anti-Counterfeiting Trade Agreement*. 1; Essential Action, *Letter to the foreign Affairs and International Trade Canada*, (July 2, 2009). 5.

fishing expedition to find the most relevant rules to be applied in the sudden situations that emerge, which are hard-pressed for time.

A common element in the multilateral and bilateral agreements is that most of the agreements recognise in their broad general goals that the agreement seeks to achieve the protection of health and safety as an important goal.⁹³⁰ However, the focus of the IPR regulatory framework is not on counterfeiting. Most of the focus of IPR regulatory framework is structured around regulatory issues, such as patent life span, trademarks violations and is not on necessary steps to be followed if a counterfeit drug is discovered.

Regulatory cooperation appears to be a common thread in the multilateral and bilateral agreements.⁹³¹ There are two main problems that arise in this regard. Firstly, the focus of most bilateral and multilateral agreements is not on counterfeiting in pharmaceutical sector, as the main theme. Secondly, the regulatory cooperation would largely result through the mechanism of specialised Committees.⁹³² The potential consequence of these committees would be that a number of additional steps would be added and consequently the entire regulatory process would become long-winded.⁹³³ In general, transparency, public access to information and public participation in the regulatory cooperation are acknowledged as important core values, especially as an aftermath of ACTA, where such important values were not accorded paramount importance.

⁹³⁰ Council of the European Union. (14 September 2016). *Comprehensive Economic and Trade Agreement between Canada, of the one part, and the European Union and its Member States, of the other part*. In Legislative Acts and other instruments. Interinstitutional File: 2016/0206 (NLE). Henceforth, referred to as 'CETA' Council of the European Union. (5 August 2016). Draft CETA, Article 19 (Cooperation against illicit drugs); Article 20 (Law enforcement cooperation and the fight against organised crime and corruption); and Article 21 (Money laundering and the financing of terrorism); and Article 22 (Cybercrime). Brussels. Document number 5368/16.

⁹³¹ CETA, Article 21.

⁹³² In CETA, 8 specialised committees would be formed that would be responsible for carrying out the regulatory processes.

⁹³³ Ronan, O. B. (2016). *Moving Regulation out of Democratic Reach: Regulatory Cooperation in CETA and its Implications* (No. 158). Kammer für Arbeiter und Angestellte für Wien, Abteilung Wirtschaftswissenschaft und Statistik.

However, a careful analysis of some of the multilateral and bilateral agreements reveals that emphasis on these values can be misplaced. For example, in the case of CETA, penalties and enforcement measures do not exist as regards Labour and Environment issues as well as Sustainable Development. In the context of Labour, Environment and Sustainable Development, clear emphasis is placed on transparency, public access to information and public participation. However, in other areas, where enforcement measures and penalties exist, there is an absence of these democratic features. As a result, a regulatory chill may be experienced and the absence of these democratic features can be a nail in the coffin, if such mishaps are not rectified in the subsequent drafts of the multilateral and bilateral agreements.

Another broad problem with the multilateral and bilateral agreements (CETA, TTIP, and TPP) is the strong influence of domestic set up of the stronger party to the agreement, in the final agreement. For instance, Canada and the United States have a lower level of regulation but a higher level of punitive damages (in case of harm caused by the negligence of the manufacturer), compared to the EU where the emphasis is on a higher level of regulation towards prevention of harm. The most troubling scenario in multilateral agreements is when the process of alignment of regulation leads to lowering of the level of regulation.⁹³⁴

In draft CETA, regulatory cooperation encompasses a vast area including goods, services, investment, and trade. This is not atypical as other agreements such as TPP, TTIP, and RCEP are also expansive in terms of the goods, services,

⁹³⁴ Ronan, O. B. (2016). *Moving Regulation out of Democratic Reach: Regulatory Cooperation in CETA and its Implications* (No. 158). Kammer für Arbeiter und Angestellte für Wien, Abteilung Wirtschaftswissenschaft und Statistik.

investments and trade opportunities that they cover. There are thirty chapters in the proposed TPP draft, concerning improved market access through a reduction in tariffs, and non-tariff barriers, but also disciplines for state-owned enterprises (SOEs); anti-competition rules; transparency and anti-corruption; IP protection; E-commerce, etc.⁹³⁵

These broad multilateral and bilateral agreements have sometimes been accused of projecting the agenda of ‘expansion of power and influence’. The TPP, for instance, has been hailed as the US agenda for expansion in Asia⁹³⁶ while on the other hand, RCEP has been exalted as China trying to flex its muscles in the Asian region.⁹³⁷ These attempts by the rich countries and their companies to steer domestic regulation through international trade agreements that supersede domestic laws may⁹³⁸ result in sacrificing the wider public interest. Bargaining autonomy in policy design in trade off for access to markets may be ill-advised in many cases, especially when it is a question of public health and safety.

7.4.3. Medicines law perspective

Specifically, with reference to the pharmaceutical sector in the multilateral and bilateral agreements, the main aim of the agreements is to enable regulators to improve coordination for an increase in the safety and efficacy of the pharmaceutical sector. The focus, as mentioned in the draft TTIP, is on primarily three key areas of inspections, approvals, and innovation. Inspections have the

⁹³⁵ European Commission. (2015). *The Transatlantic Trade and Investment Partnership, Towards and EU-US trade deal, Inside TTIP, an overview and chapter by chapter guide*. Belgium, Section 2.10 Pharmaceuticals. 31.

⁹³⁶ Gantz, D. A. (2016). The TPP and RCEP: Mega-Trade Agreements for the Pacific Rim. *Ariz. J. Int'l & Comp. L.*, 33, 57.

⁹³⁷ *ibid.*

⁹³⁸ Ronan, O. B. (2016). *Moving Regulation out of Democratic Reach: Regulatory Cooperation in CETA and its Implications* (No. 158). Kammer für Arbeiter und Angestellte für Wien, Abteilung Wirtschaftswissenschaft und Statistik.

main goal of ensuring that the standards set in the EU with respect to inspections of companies are met and the global supply chain is secure. The TTIP recognises that in the current global supply chains, different ingredients are sourced from different suppliers from all over the globe.⁹³⁹ Therefore, the necessity of securing the global supply chain is imperative.

Secondly, the time spent on obtaining approval of medicine in different regions is of crucial importance for the patients as well as the manufacturers. For the patients, it pertains to access of medicines and for the manufacturers, it is not only about putting their product on the market but also about resources spent on obtaining approval. If the method of procuring approval can be streamlined and become reciprocal in different parts of the globe, the manufacturers would be able to save resources in terms of time as well as money, on obtaining approvals in different continents, i.e. if essentially the process of obtaining approvals is the same. Therefore, TTIP stresses the importance of aligning the approval of medicines in addition to coordination on inspections of companies producing medicines.

The third common focus in the multilateral and bilateral agreements is on innovation, in context of the pharmaceutical sector. For instance, the TTIP in Section 2.10 on pharmaceuticals stresses on the importance of sharing expertise and findings and sharing views as regards latest science. In CETA, the provisions directly focussed on counterfeiting in the pharmaceutical sector, include Articles 19-22 that cover cooperation against illicit drugs; law enforcement cooperation and the fight against organised crime and corruption; money laundering and the

⁹³⁹ European Commission. (2015). *The Transatlantic Trade and Investment Partnership, Towards and EU-US trade deal, Inside TTIP, an overview and chapter by chapter guide*. Belgium, Section 2.10 Pharmaceuticals. 31.

financing of terrorism and cybercrime.⁹⁴⁰

Some of the controversial issues that need greater clarity pertain to the pricing of medicines, reimbursing bills, transparency of clinical trial data; and protecting IP in the pharmaceutical sector. Although the EU explicitly maintains its position that no deal will be struck that would override the current legal regime, however, uncertainty still exists regarding these issues and how they will finally be worked out.⁹⁴¹

7.4.4. Critical analysis of the multilateral and bilateral agreements

The various multilateral and bilateral agreements such as CETA, TTP, RCEP and TTIP are still being negotiated. The reason for conducting an analysis of these bilateral and multilateral agreements was mainly to assess if there were some unique features that could inspire change or serve as inspiration to strengthen the legal framework in the EU. As revealed in the foregoing analysis, these TIAs contribute significantly because irrespective of the fact whether a country is party to the agreement or not, the bilateral and multilateral agreements contribute to setting the general standards. For instance, even though ACTA failed, the provisions of ACTA were carried forward in some of the bilateral and multilateral agreements discussed in the previous sections.

A noticeable feature in the TIAs with regard to IP law is that most of the TIAs concentrate on reaching agreements with respect to the enforcement of IP rights

⁹⁴⁰ Council of the European Union. (14 September 2016). *Comprehensive Economic and Trade Agreement between Canada, of the one part, and the European Union and its Member States, of the other part*. In Legislative Acts and other instruments. Inter-institutional File: 2016/0206 (NLE); See also European Council, Council of the EU. (28.10.2016). EU-Canada trade agreement: Council adopts decision to sign CETA. Press Release 623/16.

⁹⁴¹ European Commission. (2015). *The Transatlantic Trade and Investment Partnership, Towards and EU-US trade deal, Inside TTIP, an overview and chapter by chapter guide*. Belgium, Section 2.10 Pharmaceuticals.32.

with specific reference to civil, criminal and border measures. The regulatory issues amongst these broad categories centre around life span of patents, etc. The analysis of these agreements also revealed that there is a lack of attention to the problem of counterfeiting and falsification of medicinal products.

The pharmaceutical sector is addressed in the multilateral and bilateral agreements but the main concentration of the provisions is on improving coordination between countries that are signatories to the agreement. Basically, three key areas in the pharmaceutical sector are recognised to be of core interest in the negotiations – inspections, approvals and innovation. It is obvious that besides a general overall concern for counterfeit and falsified medicinal products, there is a clear lack of focused approach in dealing with counterfeiting or falsification of medicinal products in the multilateral and bilateral agreements.

7.5. Concluding remarks

In this chapter, the initiatives taken at the global plane have been analysed. It became obvious that in the previous decade, the rise in global trade and investment was hailed as the panacea of solving problems of poverty, public health and safety at the international level because it was expected that greater investment would lead to economic growth, which in turn, would lead to reduction in poverty with greater investment in public health.⁹⁴² However, in more recent times, the practical experience has shown that such estimates and claims have not reaped the desired results.⁹⁴³ In fact, TIAs have been cited to be a cause of global

⁹⁴² Feachem, R. G. (2001). Globalisation is good for your health, mostly. *BMJ: British Medical Journal*, 323(7311), 504.

⁹⁴³ Chanda, R. (2002). Trade in health services. *Bulletin of the World Health Organisation*, 80(2), 158-163; Also see Rayner, G., Hawkes, C., Lang, T., & Bello, W. (2006). Trade liberalisation and the diet transition: a public health response. *Health Promotion International*, 21(suppl 1), 67-74.

health inequalities.⁹⁴⁴ Therefore, there is an urgent need to highlight the provisions of TIAs that can impact the pharmaceutical industry, the IP sector with reference to civil, criminal and border enforcements as also help achieve general goals for protection of public health and broad goals and rules for the pharmaceutical sector.

The Medicrime Convention, which has been ratified by only four EU Member States, entails criminal measures that can be instituted for cases involving counterfeit and falsified medicinal products. If ratified by the EU as a whole, it would bring about harmonisation with regard to criminal measures to a certain extent because the Convention leaves some room to pick and choose measures that can be instituted.⁹⁴⁵ The Medicrime is also open to other countries to join.

However, even if the Medicrime Convention is joined by most countries, the scope of the Convention is only specific to public health and safety and does not deal with violation of IPRs in connection with counterfeit and falsified medicines.

The ACTA had attempted to deal with the counterfeiting of IPRs in general (not specifically counterfeiting of medicines), but ACTA failed. The ACTA can, however, serve as a blueprint for institution of criminal measures, when the EU reconsiders that option. As far as the TIAs are concerned, the provisions of ACTA have been carried forward in various bilateral and multilateral agreements to an extent.⁹⁴⁶ However, the need of entering into bilateral and multilateral agreements indicates that at the International level, there is an evident need for global consensus on how counterfeit and falsified medicines should be addressed in concrete terms because counterfeiting and falsification of medicines is a global

⁹⁴⁴ Ottersen, O., Dasgupta, J., Blouin, C., Buss, Chongsuvivatwong, V., Frenk, J., & Leaning, J. (2014). The political origins of health inequity: prospects for change. *The Lancet*, 383(9917), 630-667.

⁹⁴⁵ See Articles 5(3), 6(2), 7(2), and 8(3), The Medicrime Convention 2011.

⁹⁴⁶ See discussion on TPP, TTIP, RCEP and CETA in Section 7.4.

problem and is not restricted to any one continent. The strategy of employing local patchwork solutions to global problems has the drawback that the overall picture is not taken into consideration and the solutions are inclined towards plugging the leaks in the pipe carrying the water and not on replacing the corroded pipe. Sooner or later, the pipe will burst.

While looking for solutions, it can be reiterated that as identified in Chapter 1, the problem of counterfeit and falsified medicines lies at the intersection of Medicine law, IP law and Criminal Law, representing three different perspectives of the same problem. It is necessary to address the problem of counterfeiting and falsification medicines in a cohesive manner, taking into account all three perspectives. A violation of Medicine law, concurrently presents associated infringement of IPR and the consequent illegal activity requires action by the police, activating the Criminal law sphere simultaneously. Therefore, a solution to the problem requires a commensurate response from all three spheres of law and since it is a global problem, a global response is also required.⁹⁴⁷

However, the specific area where the EU legal framework can seek inspiration from global initiatives lies in the area of criminal enforcement. As a first step it would be beneficial for the EU to ratify the Medicrime Convention because that would impact a harmonisation of criminal measures with respect to falsification of medicines.⁹⁴⁸ Even though the Medicrime Convention addresses the problem of

⁹⁴⁷ Therefore, the role of the international organisations such as the WHO (representing the public health and safety perspective), the WIPO (representing the IP interests), the WCO (representing the Customs perspective), and the INTERPOL (representing how to deal with crime) should negotiate a common international Convention. Bilateral and multilateral agreements may find it challenging to resolve a global problem of very specific nature, which is life threatening and a risk to public health and safety. The role of multilateral and bilateral agreements should ideally be of supportive nature, whereby the bilateral and multilateral agreements reinforce the provisions laid down or agreed upon in an international agreement.

⁹⁴⁸ As explained earlier, the Medicrime Convention uses the term 'counterfeit medicine' but implies 'falsification' of medicine.

counterfeiting and falsification of medicines from the public health and safety perspective, the fact that it has potential to decrease the cases of falsification of medicines also implies that there will be a proportionate decline in the number of related cases of counterfeiting since the two problems are interconnected. Moreover, the benefits will positively impact both spheres of law.

Part IV: Evaluation & Conclusion

Part I (Introduction)			
Chapter 1 Introduction		Chapter 2 Legal Theories, Sources and Method	
Part II (Legal Case Studies)			
Chapter 3 Case Studies	Operation Volcano	Operation Singapore	Operation Robin
Part III (Legal Analysis)			
Chapter 4 Analysis of Falsified Medicines Directive	Chapter 5 Analysis of Enforcement Directive	Chapter 6 Analysis of Customs Regulation	Chapter 7 Global Initiatives
Part IV (Evaluation & Conclusions)			
Chapter 8 Are the social objectives of public health and consumer protection met?		Chapter 9 Conclusion	

Part IV, the last part of the thesis, contains two chapters. In Chapter 8, it is analysed whether the law that provides tools to combat counterfeiting and falsification of medicinal products in the EU meets the social objectives of public health and consumer protection as envisaged in the Treaty on the Functioning of the European Union. The final Chapter 9 summarises the thesis and presents the overall conclusion of the thesis, thereby assessing if the objectives of the thesis have been achieved.

Chapter 8: Are the social objectives of public health and consumer protection met?

8.1. Introduction

In this chapter, it is analysed whether the law that provides tools to combat the counterfeiting and falsification of medicinal products in the EU - the FMD,⁹⁴⁹ the Enforcement Directive,⁹⁵⁰ and the Customs Regulation⁹⁵¹ meets the social objectives of public health (Article 9 and 168, TFEU) and consumer protection (Article 12 and 169 TFEU), as envisaged by the TFEU. The chapter begins with the recapitulation of the relevant law. Thereafter, the social objectives of public health and consumer protection as envisaged in the TFEU are identified and clarified. Thereafter, the question of whether the aims of public health and consumer protection are met is analysed.

8.2. Recapitulation of laws that combats counterfeiting and falsification of medicines in the EU

Law governing counterfeiting and falsified medicines encompasses the FMD (Directive 2011/62/EU), the Enforcement Directive (Directive 2004/48/EC) and the Customs Regulation (Regulation 608/2013).⁹⁵² The FMD represents the public health and safety perspective and is the key directive in the sphere of Medicine

⁹⁴⁹ Directive 2011/62/EU.

⁹⁵⁰ Directive 2004/48/EC.

⁹⁵¹ Regulation 608/2013.

⁹⁵² See Chapters 4, 5 and 6 for more discussion.

law concerning falsified medicines. The FMD came into being as an amendment to the Medicines Directive (Directive 2001/83/EC) due to the exponential increase in the number of falsified medicines entering the EU.⁹⁵³ As the name of the Directive suggests, it primarily contains provisions oriented towards protecting the legal supply chain against infiltration of falsified medicines in the EU and ensure the smooth functioning of the Single Market with regard to medicinal products.⁹⁵⁴ The measures that it contains such as introduction of safety features,⁹⁵⁵ defining the role and obligations of the actors involved in the legal supply chain; introduction of a logo to be applied by all legitimate websites based in the EU and selling medicinal products in the EU, are designed to deal with controlling the prevalence of falsified medicinal products in the EU.⁹⁵⁶

The FMD categorically omits dealing with the violation of IP law and hence, counterfeiting of medicines, which is also excluded from the purview of the provisions of FMD.⁹⁵⁷ This is also reflected in the use of the term ‘falsified medicinal product’ and not ‘counterfeit medicinal product’.⁹⁵⁸ However, as discussed in Chapter 1, falsification of medicines inevitably leads to violation of an IP right, such as a trademark right.⁹⁵⁹ For this reason, the violation of IP law and the Medicine law (the FMD) occur simultaneously. Therefore, the IP law instruments, namely the Enforcement Directive and the Customs Regulation also form a part of the applicable law while dealing with the counterfeiting and falsification of medicines.

⁹⁵³ See Recital 2, Directive 2011/62/EU.

⁹⁵⁴ Recital 33, Directive 2011/62/EU.

⁹⁵⁵ Bogaert, B. C., & Burton, C. (2015). The mysteries of the Falsified Medicines Directive-where is the logic on safety features. *London: Script Regulatory Affairs*, 1-3.

⁹⁵⁶ See more in Chapter 4.

⁹⁵⁷ Recital 29, Directive 2011/62/EU.

⁹⁵⁸ See Chapter 1, Section 1.6.

⁹⁵⁹ See Chapter 1, Section 1.2.

The Enforcement Directive (Directive 2004/48/EC),⁹⁶⁰ in tune with the fundamental right to property as enshrined in the Charter of Fundamental Rights of the EU,⁹⁶¹ has the primary objective of enforcement of IP in the EU.⁹⁶² The Enforcement Directive is applicable to protection of the entire gamut of IPRs, including trademarks, copyrights, designs, utility models, geographical indicators, patents, etc. This legislation is instrumental in realising the aims of the Single Market, wherein the IP is protected because it is believed that IP protection creates a conducive environment, which is a fertile ground for innovation, improving competition and investment.⁹⁶³ Thereby, protection of IP in the EU contributes to economic growth.⁹⁶⁴ In context of the counterfeiting and falsification of medicinal products in the EU, the Enforcement Directive provides for protection of rights of the right holder. For instance, in case of counterfeit medicines, the rights of the trademark holder are enforced by applying the provisions of the Enforcement Directive, when the counterfeit medicine is discovered and it is detected that the counterfeit medicine was packaged to wrongfully represent its production by a legitimate manufacturer, such as ‘Roche’.⁹⁶⁵

The Customs Regulation (Regulation 608/2013) is the third legal instrument that contributes to combatting counterfeiting and falsification of medicines in the EU. The counterfeit and falsified medicinal products can enter the EU through diverse routes – over land, by sea, by air, by post or courier services, and in the luggage of

⁹⁶⁰ See Chapter 5 for more details.

⁹⁶¹ European Union. (2012). *Charter of Fundamental Rights of the European Union*. OJ C 326, 26.10.2012, 391-407.

⁹⁶² See Article 17(2), European Union. (2012). *Charter of Fundamental Rights of the European Union*. OJ C 326, 26.10.2012, 391-407.

⁹⁶³ *ibid.*

⁹⁶⁴ Pila, J., & Torremans, P. (2016). *European Intellectual Property Law*. Oxford University Press.

⁹⁶⁵ See Chapter 3, Section 3.2.

passengers.⁹⁶⁶ The Customs Regulation focuses on the enforcement of IPRs at the borders. It empowers the customs authorities to intercept goods suspected of infringing IPRs at the borders,⁹⁶⁷ and under certain circumstances, it empowers the customs authorities to destroy small consignments subject to the consent of the right holders.⁹⁶⁸

Two important considerations that must be underlined are that the FMD falls in the area of public law, whereas the Enforcement Directive and the Customs Regulation lie in the purview of the private law, wherein the private rights of the right holders are asserted and protected. The broad nature of the public law and private law are essentially different.⁹⁶⁹ In addition to the divergent basic nature of the laws, the goals of the legal instruments are also different. The FMD springs from the perspective of public health and safety⁹⁷⁰ and the Enforcement Directive and the Customs Regulation rises from the core idea of protection of IP. These are essentially different streams of law that happen to intersect when dealing with counterfeiting and falsification of medicinal products. As a result, addressing counterfeiting and falsification of medicinal products in the EU is not a result of a cohesive policy and resembles a patchwork approach.

8.3. Social objectives of public health in the TFEU

In order to analyse if the public health goals are met by the legal instruments, it is imperative to cast light on the public health objectives, as envisaged by the TFEU.

⁹⁶⁶ European Commission. (2015). *Report on EU customs enforcement of intellectual property rights. Results at the EU border 2015*. Luxembourg. Publications office of the European Union.

⁹⁶⁷ See Chapter 6 for more detailed discussion.

⁹⁶⁸ Under certain specific conditions enumerated in Article 26, Regulation 608/2013.

⁹⁶⁹ Loughlin, M., & Tschorne, S. (2016). *Public law*. Routledge. 324-337.

⁹⁷⁰ See Article 168, TFEU.

The ‘Social Europe’,⁹⁷¹ a term utilised by the working group XI of the European Convention⁹⁷² mirrors the social values. In other words, the Union is required to take into consideration certain common values while formulation and execution of its policies.⁹⁷³ These common values are the promotion of employment, social protection and welfare, education, and health. The larger social objectives are a reflection of the idea of liberal man and humanity⁹⁷⁴ where the citizens have the opportunities to participate in a self-determined way and the State acts as the facilitator and sets parameters and policies. In addition to the maintenance of law and order, the State is also responsible for the promotion of policies that allow the citizens to exercise their rights and freedoms.⁹⁷⁵

The issue of public health and safety has been a concern of the Union Law since the EEC Treaty. Since then the exercise of market freedoms, i.e. free movement of goods, services, people, and capital could be restricted because of reasons concerning public health.⁹⁷⁶ Subsequently, an exclusive title of competence regarding public health was introduced by the Treaty of Maastricht,⁹⁷⁷ which was amended by the Treaty of Amsterdam.⁹⁷⁸ The Treaty of Lisbon⁹⁷⁹ brought about significant changes, which are evident especially with reference to the substantive

⁹⁷¹ Gronden, J., Szysczak, E., Neergaard, U., & Krajewski, M. (2011). Introduction. *Health Care and EU Law*, 1-16.

⁹⁷² See Final Report of Working Group XI on Social Europe of 4 February 2003. (2003). Brussels. CONV 516/1/03 REV 1

⁹⁷³ Geiger, R., Khan, D. E., & Kotzur, M. (Eds.). (2015). *European Union Treaties; a Commentary: Treaty on European Union: Treaty on the Functioning of the European Union*. Hart, 217.

⁹⁷⁴ *ibid.*

⁹⁷⁵ *ibid.*

⁹⁷⁶ Geiger, R., Khan, D. E., & Kotzur, M. (Eds.). (2015). *European Union Treaties; a Commentary: Treaty on European Union: Treaty on the Functioning of the European Union*. Hart, 678.

⁹⁷⁷ European Union. (1992) *Treaty on European Union (Consolidated Version)*, *Treaty of Maastricht*, 7 February 1992, OJ C 325, 24.12.2002, 5-32.

⁹⁷⁸ Council of the European Union. (1997). *Treaty of Amsterdam Amending the Treaty on European Union, The Treaties Establishing the European Communities and Related Acts – Consolidated version of the Treaty on European Union*. OJ C 340, 10.11.1997, 145.

⁹⁷⁹ European Union. (2007). *Treaty of Lisbon amending the Treaty on European Union and the Treaty establishing the European Community*, signed at Lisbon. OJ C 306, 17.12.2007, 1- 271.

amendments that were brought about in Article 168. In general terms, the responsibilities or the competencies regarding governing public health are shared between the Union and the Member States as provided for in the Article 4 para 2 lit k. TFEU (shared competencies) and Article 6 para 2, TFEU (competence to support, coordinate or supplement). In other words, the Union does not have the authority to pursue its own health policies as it has a supplementary role to the Member States.⁹⁸⁰ The Union can, however, encourage and support cooperation between the Member States in the area of public health.

A close examination of two provisions, Article 9 and 168 in the TFEU, is warranted because they are especially relevant for understanding the public health goals, as envisaged in the TFEU.

8.3.1. Article 9, TFEU

The Article 9 of the TFEU is a horizontal clause⁹⁸¹ that concerns social protection in the EU. It states that while defining and implementing the policies and related pursuits, the Union should take into consideration certain key elements such as protection of health and the guarantee of adequate social protection.⁹⁸² Although, being a horizontal clause, the provision does not extend any subjective individual rights, but it springs into action when specific policies are implemented. Through Article 9 of the TFEU, human health has been included in the general horizontal

⁹⁸⁰ Geiger, R., Khan, D. E., & Kotzur, M. (Eds.). (2015). *European Union Treaties; a Commentary: Treaty on European Union: Treaty on the Functioning of the European Union*. Hart. 679.

⁹⁸¹ In the EU law, in many policy fields, horizontal clauses are used as regulatory instruments. These clauses function as constitutional objectives would function in a national constitution. The horizontal clauses reflect the goals across policies like public health, consumer protection etc. See more in Geiger, R., Khan, D. E., & Kotzur, M. (Eds.). (2015). *European Union Treaties; a Commentary: Treaty on European Union: Treaty on the Functioning of the European Union*. Hart. 216.

⁹⁸² See CFREU, Article 3(3). In addition to Article 9, TFEU, Article 3 (3) of the CFREU also have a similar provision for social protection and social justice.

health policy, in addition to other basic qualities.⁹⁸³ Besides having under its purview an area of general health, there are also specific provisions dealing with protection of health and safety of workers.⁹⁸⁴ The specific legislative basis of the policy on human health is enshrined in Article 168 of the TFEU (discussed below in Section 8.2) and is also mirrored in Article 35 of the CFREU. Although the horizontal clause - Article 9, has been at the centre of criticism for its lack of enforceable subjective rights,⁹⁸⁵ it is significant for the interpretation of secondary legislation in the EU, since the secondary legislation (Directives, Regulations, Recommendations etc.) has to be in consonance with the objectives of the primary legislation (TEU, TFEU, and CFREU).

8.3.2. Article 168

The legislative basis of the policy on human health is entailed in Article 168, which clarifies, specifies, and enlarges the competence of the Union in the public health sphere. The specific significance of public health is underlined by Article 168(1), wherein it is required that all Union policies and activities ensure a high level of protection of public health in determining and implementing the Union policies. This horizontal level requirement implies that public health concerns are to be ensured in all policies and activities and not restricted to health regulations.⁹⁸⁶ Article 168 defines the concept of general health,⁹⁸⁷ preventing physical and mental illness. Secondly, the scope of the Article includes

⁹⁸³ See Article 9, TFEU which introduces a horizontal clause on social protection, whereby the Union is required to promote high level of employment, guarantee adequate social protection, fight against social exclusion, high level of education, training and protection of human health.

⁹⁸⁴ Articles 153 para 1, 115, 36, 53 para 2, 62 TFEU.

⁹⁸⁵ See VHVH/Gassner, Article 9 AEUV mns 13 et seq, in Geiger, R., Khan, D. E., & Kotzur, M. (Eds.). (2015). *European Union Treaties; a Commentary: Treaty on European Union: Treaty on the Functioning of the European Union*. Hart. 218.

⁹⁸⁶ Cabezas, M. D. (2012). Current trend in pharmaceutical law in EU. *Pharmaceuticals Policy and Law*, 14(2-4), 195-207.

⁹⁸⁷ Article 168 para 1, TFEU.

‘monitoring, early warning of and combatting the serious cross-border threat to health’. Likewise, the problem of counterfeiting and falsification is also a cross-border issue that is a health scourge mandating attention at the EU level. Further, Article 168 also includes provisions that encourage cooperation and complementarity of health services in cross-border situations.⁹⁸⁸

Article 168 also provides for setting of high standards of quality, safety for medicinal products and devices used for medical use.⁹⁸⁹ In accordance with this provision, under the Directive 2001/83/EC, there is an obligation on the Member States to provide for a market authorisation procedure in order to authorise the use of medicinal products.⁹⁹⁰ However, Article 168 is limited from empowering the Union to enact legally binding acts in the area of health. The organisation and delivery of health services and medical care are competencies that belong to the Member States. Therefore, primarily it is the Member States that are responsible for defining their health policy.

The specific ambitions of Article 168 can be summarised to mean betterment of public health, prevention of physical and mental illnesses and diseases; promotion of research to identify causes, transmission and prevention of diseases; reduction of drug-related health damage; initiating measures to set high standards of quality and safety for medicinal products and devices for medical use;⁹⁹¹ and monitoring serious cross-border threats to health. In relevant cases, sharing information with a

⁹⁸⁸ Article 168, para 1, TFEU.

⁹⁸⁹ Article 168 (4) (c), TFEU.

⁹⁹⁰ Case C-319/05 *Commission v. Germany* (2007) ECLI:EU:C:2007:678

⁹⁹¹ *See* Article 168, para 4 (c).

view to prevent the spread of diseases is also encompassed in these provisions.⁹⁹²

8.4. Social objectives of consumer protection in the TFEU

In addition to provisions of explicitly stating the importance of public health in the TFEU, there are provisions related to protection of consumers,⁹⁹³ which are extremely relevant to the thesis because the protection of the consumers against counterfeit and falsified medicines also falls under the goals of consumer protection. The origin of consumer protection laws in the EU can be traced back to the case law beginning with the *Cassis* decision.⁹⁹⁴ In this case, the CJEU explicitly stated that if a product is legally marketed in one Member State, it may be marketed in another Member State as long as it does not come in conflict with consumer's interest.

An independent policy on consumer protection was first introduced in the EU in the Treaty of Maastricht in 1992.⁹⁹⁵ The Treaty of Amsterdam brought about deeper changes and under Article 153 TEC and provided a competence for measures to be formulated in the sphere of consumer protection. It was under 153 TEC that a horizontal policy was first introduced with respect to protection of consumers that meant that the requirements of consumer protection always had to be taken into consideration while formulation and implementation of all Union policies. Subsequently, in the Treaty of Lisbon, the horizontal clause in Article 153 TEC was moved to Article 12 of the TFEU and the rest of the provisions were

⁹⁹² Geiger, R., Khan, D. E., & Kotzur, M. (Eds.). (2015). *European Union Treaties; a Commentary: Treaty on European Union: Treaty on the Functioning of the European Union*. Hart. 677.

⁹⁹³ Micklitz, H. W., Reich, N., & Weatherill, S. (2004). EU Treaty revision and consumer protection. *Journal of Consumer Policy*, 27(4), 367-399.

⁹⁹⁴ Case C-120/78 Rewe Zentral AG (1979) ECLI:EU:C:1979:42 also known as *Cassis de Dijon*.

⁹⁹⁵ European Union. (1992) Treaty on European Union (Consolidated Version), Treaty of Maastricht, 7 February 1992, OJ C 325, 24.12.2002, 5-32.

articulated under Article 169 of the TFEU.⁹⁹⁶

The term consumer protection implies protection of the core interests of the consumer, i.e. usually protection against unfair trade, credit practices, involving consumer goods, as also protection against faulty and dangerous goods.⁹⁹⁷ The TFEU does not define the term consumer, however, it implies that a consumer is a natural person who functions in personal, private and not commercial capacity.⁹⁹⁸ The CJEU has articulated that usually, a consumer is assumed to be a reasonably well-informed, observant and circumspect average person.⁹⁹⁹

The protection of consumers is also a shared competence between the Union and the Member States.¹⁰⁰⁰ In the EU, the Member States have the primary responsibility of consumer welfare and protection, while the Union plays a complementary role of supporting, supplementing and monitoring the protection of consumers through its policies.¹⁰⁰¹ The Member States can make stricter policies than the Union to safeguard interests of the consumers as long as the policies made by the Member States are aligned with the other provisions of the Union in the TEU, TFEU, and CFREU.

8.4.1. Article 12, TFEU

Consumer protection as a horizontal clause is explicitly provided for in Article 12 of the TFEU. By horizontal clause, it is implied that all union policies and

⁹⁹⁶ Geiger, R., Khan, D. E., & Kotzur, M. (Eds.). (2015). *European Union Treaties; a Commentary: Treaty on European Union: Treaty on the Functioning of the European Union*. Hart, 683.

⁹⁹⁷ Black, H.C., Nolan, J.R., & Nolan-Haley, J.M. (1990). *Black's Law Dictionary*. (Sixth Edition). St. Paul, Minn. West Publishing Co.

⁹⁹⁸ CJEU Case C 269/95 *Benincasa* (1997) ECR I-3767.

⁹⁹⁹ Weatherill, S. (2013). *EU consumer law and policy*. Edward Elgar Publishing. 57.

¹⁰⁰⁰ As articulated in Article 4, para 2. lit f of the TFEU.

¹⁰⁰¹ *ibid.*, 684.

activities need to take into account the principles of consumer protection.¹⁰⁰²

However, there is no obligation to optimise or prioritise any particular aspects of consumer protection and is presented as one of the several criteria that needs to be balanced while the formulation of Union policies. The term consumer protection entails protection of interests of the consumers with respect to the protection of health, safety and the economic interests of consumers; and promotion of the right to consumer information, education and the formation of consumer interest groups.

8.4.2. Article 169, TFEU

In addition to Article 12 of the TFEU, the issue of consumer protection is also governed exclusively in Title XV, Article 169 of the TFEU. It provides for the promotion of consumers interests and states that the Union shall contribute to the protection of the health, safety and economic interests of the consumers as well as promote the right to information, education and to organise themselves in order to safeguard their interests.¹⁰⁰³ In this context, various directives have been adopted that focus on protecting the interests of the consumers, e.g. Directive 2001/95/EC on general product safety, Directive 97/55/EC concerning misleading advertising, and Directive 2011/83/EU on consumer rights.

Further, Article 169 para 2 lit a, TFEU mentions that the Union has the responsibility for legal harmonisation in the internal market as articulated in Article 114 TFEU. In practice, it is one of the important provisions to actualise a common consumer protection policy because it provides more detailed guidelines

¹⁰⁰² Twigg-Flesner, C. (2010). Time to do the job properly—the case for a new approach to EU consumer legislation. *Journal of consumer policy*, 33(4), 355-375.

¹⁰⁰³ Geiger, R., Khan, D. E., & Kotzur, M. (Eds.). (2015). *European Union Treaties; a Commentary: Treaty on European Union: Treaty on the Functioning of the European Union*. Hart. 682.

to ensure the protection of consumers.

8.5. Does the law that provides tools to combat counterfeiting and falsification of medicinal products, meet the social objectives of public health and consumer protection?

In Section 8.3, the public health goals as envisaged in the TFEU have been elaborated, and in Section 8.2, the law providing tools to combat counterfeiting and falsification of medicinal products has been recapitulated. The public health goals can be summarised as improvement of public health of the citizens in the EU, prevention of disease and illnesses, reduction in drug related damage, ensuring high standard and quality of medicines, monitoring of serious cross-border threats and information sharing to prevent the spread of diseases between Member States.¹⁰⁰⁴

As asserted in Chapter 1, the problem of counterfeiting and falsification of medicines lies at the intersection of Medicine law, IP law, and Criminal law.¹⁰⁰⁵ In the sphere of Medicine law, the FMD regulates the provisions in the EU and addresses falsification of medicines. In the sphere of IP law, counterfeit medicines are dealt with in the Enforcement Directive and the Customs Regulation. As evident, so far, in the field of Criminal law, there is no harmonisation at EU level.

¹⁰⁰⁴ See Article 168, TFEU.

¹⁰⁰⁵ See Chapter 1, Section 1.2.

However, if EU ratifies the Medicrime Convention¹⁰⁰⁶ then there would be a level of harmonisation of criminal measures that may be instituted pertaining to counterfeiting and falsification of medicines. Since there is intersection of three spheres of law while dealing with counterfeit and falsified medicinal products, an assessment of each of these legal instruments against the goals of public health as envisaged in Articles 9 and 168 of the TFEU is required.

At the outset, it must be emphasised again that public health is a shared competence between the Union and the Member States.¹⁰⁰⁷ The Member States hold the primary responsibility with regard to defining their health policies and organising the delivery of healthcare services. Although the Union can make broad overarching policies, which affect the EU in general and the Union exclusively makes those policies that may not expedient to be formulated at the national level because the matter in question is related to most Member States. But the primary power with regard to healthcare rests with the Member States and as a result of this provision, there are no common Union health policies in the EU. The achievement of a Single Market with respect to the pharmaceutical sector has not seen much movement since its formulation because of the reason of shared competences and the Member States holding most of the authority and power.

Another significant aspect with respect to the legal instruments that contain tools to be employed to combat counterfeiting and falsification of medicines is that the legal instruments also need to uphold the objectives of the Single Market,¹⁰⁰⁸ in addition to achieving the social goals of public health and consumer protection. Although the objectives of the Single Market of the Union are not in conflict with

¹⁰⁰⁶ Council of Europe. (2011) Council of Europe convention on counterfeiting of medical products and similar crimes involving threats to public health. Strasbourg. Council of Europe. (Also known as the Medicrime Convention). Council of Europe Treaty Series. No.211.

¹⁰⁰⁷ Under Article 4(2) (k) and Article 6(2) of the TFEU.

¹⁰⁰⁸ Article 26, TFEU.

the social objectives of public health and consumer protection, yet there is an evident need for a careful balance. The Single Market objectives, enshrined in Article 26,¹⁰⁰⁹ call for an area without frontiers allowing free movement of goods, services, capital, and persons, with an overarching goal to achieve an overall integration with no barriers. Thus, the legal instruments not only have to consider the social goals but have to be mindful of the overall objective of the Single Market.

8.5.1. Have the public health objectives been achieved?

Since Article 9 is a horizontal provision, the secondary legislation is expected to respect the objectives of the primary legislation. Therefore, the FMD, the Enforcement Directive, and the Customs Regulation are required to be in consonance with the provisions of Article 9, TFEU, which in addition to other social protections¹⁰¹⁰ states that protection of human health has to be ensured. However, in practice, the rising numbers and circulation of counterfeit and falsified medicinal products in the EU indicate that the aim of protection of human health has not been totally achieved. The FMD has taken steps such as the introduction of safety features,¹⁰¹¹ introduction of the logo¹⁰¹² on online websites dealing in sale of medicinal products, which are measures directed towards protection of human health. However, the FMD addresses only the legal supply chain, whereas the illegal supply chain also contributes heavily to circulation of

¹⁰⁰⁹ Article 26, TFEU.

¹⁰¹⁰ The other social protections being promotion of high level of employment, provisions of adequate social protection, provision of measures to combat social exclusion, and ensuring high level of education and training.

¹⁰¹¹ Article 54(o) inserted in Directive 2001/83/EC through Article 1(11) of Directive 2011/62/EU. This is further expanded in Commission Delegated Regulation (EU) 2016/16 of 2 October 2015 supplementing Directive. 2001/83/EC of the European Parliament and of the Council by laying down detailed rules for the safety features appearing on the packaging of medicinal products for human use.

¹⁰¹² Article 85c was inserted in Directive 2001/83/EC by Article 1(20) of Directive 2011/62/EU. This is further articulated in Commission Implementing Regulation (EU) No 699/2014 of 24 June 2014 on the design of the common logo to identify persons offering medicinal products for sale at a distance to the public and the technical, electronic and cryptographic requirements for verification of its authenticity.

counterfeit and falsified medicinal products in the EU. The Enforcement Directive and the Customs Regulation aim at enforcement of IPR in the EU and are activated when counterfeit medicines come into play, because the FMD does not address counterfeit medicines. The Customs Regulation has an explicit goal to contribute to eradicating the counterfeit goods harmful to public health and safety.¹⁰¹³

Regarding the public health goals as envisaged under Article 168, the primary aim of improvement of the public health of the citizens in the EU is sought to be achieved through the FMD as well as the Medicines Directive framed in 2001.¹⁰¹⁴ The FMD has specific provisions that supplement the provisions of the Medicines Directive, which in turn strengthen the legal framework that not only contributes towards improving public health but also towards the other goals of prevention of disease and illnesses and reduction in drug related damage. Specifically, the introduction of safety features in the FMD is geared towards ensuring high standard and quality of medicines. The Enforcement Directive and the Customs Regulation also contribute in specific ways such as the Enforcement Directive contains the civil measures like injunctions,¹⁰¹⁵ preliminary and precautionary measures¹⁰¹⁶ (seizures, etc.) that may be employed in the case of IPR infringement. The Customs Regulation is significant because it empowers the customs authorities to initiate corrective action when counterfeit or falsified medicines are discovered at the borders. The measures relating to destruction of small consignments under certain circumstances¹⁰¹⁷ can be crucial in dealing with

¹⁰¹³ Recital 11, Regulation 608/2013.

¹⁰¹⁴ Directive 2001/83/EC on the Community code relating to medicinal products for human use, as regards the prevention of the entry into the legal supply chain of falsified medicinal products.

¹⁰¹⁵ Article 11, Directive 2004/48/EC.

¹⁰¹⁶ Article 9, Directive 2004/48/EC.

¹⁰¹⁷ Article 26, Regulation 608/2013.

entry of counterfeit and falsified medicines in the EU. The Enforcement Directive and the Customs Regulations, thus, with the employment of these measures contribute towards public health protection.

However, with respect to monitoring of serious cross-border threats and information sharing to prevent the spread of diseases between the Member States, there is a definite scope for improvement. The escalating number of counterfeit and falsified medicinal products in the EU¹⁰¹⁸ is indicative of the fact that the legal instruments are not able to optimally meet all the goals regarding public health in the EU. Firstly, the Enforcement Directive categorically limits itself from cross-border applicability.¹⁰¹⁹ The problem is that counterfeiting and falsification of medicinal products is typically a cross-border issue, as illustrated in the legal case studies.¹⁰²⁰ Therefore, it is a significant stumbling block as regards counterfeit medicines and in the case of infringement of their rights, the right holders have to pursue the cases individually in each Member State since the orders of one Member State are not valid in another Member State. The Customs Regulation empowers the customs authorities to take action on goods intercepted at the borders. However, despite the Customs Regulation encouragement of information sharing, there is an evident lack of formal coordination and cooperation between the Member States to realise this objective.

Further, with regard to information sharing for prevention of spread of disease, as envisaged under Article 168, as part of its goals for ensuring public health in the EU, the provision of Rapid Alert System in the Medicines Directive serves this

¹⁰¹⁸ Recital 2, Directive 2011/62/EU

¹⁰¹⁹ Recital 11, Directive 2004/48/EC.

¹⁰²⁰ Chapter 3.

purpose,¹⁰²¹ it requires that the Member States inform the relevant agencies in case of detection of falsified medicines in any one Member State.

Therefore, the law governing counterfeiting and falsification of medicines in the EU strives towards meeting the public health goals envisaged in Article 9 and 168 in the TFEU. The legal instrument in the sphere of Medicine law that specifically focuses on the falsification of medicines- the FMD, has introduced, for example, safety features to be employed in designated medicinal products, i.e. the logo has to be displayed on websites selling legitimate medicinal products. These measures are geared towards realising the goals of public health as outlined in the TFEU. Additionally, the Enforcement Directive and the Customs Regulation have also significantly contributed towards realising the goals enshrined in Articles 9 and 168. The Customs Regulation has specific provisions to monitor serious cross-border threats to health by empowering the customs authorities to check the packages and materials entering the EU borders.

However, the legal instruments have not been entirely successful in achieving the public health goals yet. There is scope for improvement especially with respect to monitoring cross-border threat to health, sharing of information to prevent spread of disease, reduction in drug-related damage caused to health especially due to proliferation of counterfeit and falsified medicines in the EU.

8.5.2. Are the consumer protection goals are met?

The goals of consumer protection have been discussed in Section 8.4, which explained that the TFEU: Articles 12 and 169 provide for consumer protection in

¹⁰²¹ Article 117a, Directive 2001/83/EC.

the EU. The Article 12, being a horizontal clause, states that all Union policies have to accord due regard to the protection of consumers. And in Article 169, detailed provisions pertaining to protection of consumers are listed with reference to health, safety, economic interests, the rights to consumer information, education and formation of consumer's interest groups. The legal instruments that provide tools to combat counterfeiting and falsification of medicines in the EU (the FMD, the Enforcement Directive and the Customs Regulation) have been discussed in Chapters 4, 5, and 6¹⁰²² and summarised above.¹⁰²³ Since the secondary legislation is required to be in consonance with the primary legislation (TEU, TFEU, and the CFREU), the aims of consumer protection are integrated in the secondary legislation in general, by virtue of Article 12. As a result, the FMD, the Enforcement Directive, and the Customs Regulation being secondary legislation present due regard for Article 12.

The counterfeiting and falsification of medicinal products work against public health and safety goals of the TFEU, as illustrated by the case studies in Chapter 3.¹⁰²⁴ The Union policies need to ensure that the consumers are protected against counterfeit and falsified medicines in accordance with the provisions listed in Articles 12 and 169. The FMD, through its provisions with regard to safety features to prevent manipulation of medicinal products;¹⁰²⁵ the logo for online websites selling medicinal products;¹⁰²⁶ running frequent awareness campaigns¹⁰²⁷

¹⁰²² See Chapters 5, 6, and 7 for more details.

¹⁰²³ See Section 8.2.

¹⁰²⁴ See Chapter 3 for more details.

¹⁰²⁵ Article 1(11) of Directive inserted Article 54(o) in Directive 2001/83/EC. It was translated into Commission Delegated Regulation (EU) 2016/16 of 2 October 2015 supplementing Directive 2001/83/EC of the European Parliament and of the Council by laying down detailed rules for the safety features appearing on the packaging of medicinal products for human use.

¹⁰²⁶ Article 1 (20) of Directive 2011/62/EU inserted Article 85c in Directive 2001/83/EC. It was translated into Commission Implementing Regulation (EU) No 699/2014 of 24 June 2014 on the design of the common logo to

– pays attention to consumer protection in the context of falsified medicines in the legal supply chain. The Enforcement Directive has the goals of protection of IPRs in the EU. Through its provisions of enforcement such as injunctions,¹⁰²⁸ preliminary and precautionary measures,¹⁰²⁹ the Enforcement Directive facilitates the enforcement of rights of the IPR holders. Thereby, the Enforcement Directive protects the consumers from counterfeit goods.

The Customs Regulation empowers the customs authorities' to intercept goods at the borders¹⁰³⁰ and this provision is especially useful while dealing with counterfeit and falsified medicines. By virtue of Customs Regulations, under certain conditions, the customs authorities also have the power to destroy small consignments.¹⁰³¹ This is a significant provision that has a far reaching impact because the counterfeit and falsified medicines have mostly been known to arrive in small consignments.¹⁰³²

The legal instruments that provide the tools to combat counterfeit and falsified medicines in the EU contain measures that pay attention to consumer protection, as discussed in the preceding paragraph. However, the fact that despite these measures the number of counterfeit and falsified medicines is still on the rise in the EU,¹⁰³³ implies that the consumers are not adequately protected against counterfeiting and falsification of medicines.

identify persons offering medicinal products for sale at a distance to the public and the technical, electronic and cryptographic requirements for verification of its authenticity.

¹⁰²⁷ Article 1(26) of Directive 2011/62/EU. See also European Commission. (2015). '*Buying Medicines Online, Think you know what you are getting?*' Brussels. European Commission

¹⁰²⁸ Article 11, Directive 2004/48/EC.

¹⁰²⁹ Article 9, Directive 2004/48/EC.

¹⁰³⁰ Articles 17 and 18, Regulation 608/2013.

¹⁰³¹ Article 26, Regulation 608/2013.

¹⁰³² See Chapter 3 for more details.

¹⁰³³ Recital 11, Directive 2011/62/EU.

However, there are certain issues in the legal framework, which result in a continued increase in the prevalence of counterfeit and falsified medicines in the EU and are thus harmful to the consumers. Firstly, as identified in Chapter 1, the problem of counterfeiting and falsification of medicines lies at the intersection of three streams of law – Medicine law, IP law and Criminal law.¹⁰³⁴ The problems related to falsified medicines are addressed by the FMD, however, each falsified medicine inevitably has an element of counterfeiting and thus, results in violation of IPRs.¹⁰³⁵ However, this element of IP violation is not addressed by the FMD because it delimits itself from dealing with counterfeiting.¹⁰³⁶ In fact, the IP law deals with counterfeiting of medicines and therefore to enforce these rights across the EU in the context of enforcement of the IP rights, the Enforcement Directive and Customs Regulation are activated. Therefore, the consumers, right holders, as well as the authorities lack clarity regarding application of law. Either the case is dealt with only from one perspective, or the complaint falls through the gaps or due to the crucial loss of time in identifying the right authority to deal with the case, the evidence is lost. This state of affairs is deduced from the lack of case law on the subject, and the overwhelming increase in statistical information indicating increase in counterfeiting and falsification of medicinal products.¹⁰³⁷

The Criminal law is not harmonised at the EU level, therefore the role of organised crime, as illustrated in the legal case studies¹⁰³⁸ in the counterfeiting of medicines largely goes unattended at the EU level. It is dealt with sporadically at the national level by the Member States. As evident, the problem of counterfeit

¹⁰³⁴ Chapter 1, Section 1.2.

¹⁰³⁵ Discussed in Chapter 1, Section 1.2.

¹⁰³⁶ Recital 5, Directive 2011/62/EU.

¹⁰³⁷ OECD/EUIPO (2016), *Trade in Counterfeit and Pirated Goods: Mapping the Economic Impact*, OECD Publishing, Paris. It was estimated that the value of imported fake goods worldwide was estimated to be USD 461 million in 2013, compared to the total imports in world trade at USD 17.9 trillion. It was also reported that up to 5% of goods imported into the European Union are fakes.

¹⁰³⁸ See Chapter 3, Section 3.5.2.

and falsified medicinal products inevitably touches three spheres of law simultaneously. In such a situation, only one sphere of law cannot solve the problem in isolation. At the most, the falsification of medicine can be interrupted¹⁰³⁹ or the small consignment carrying counterfeit medicine be destroyed¹⁰⁴⁰ or the individual manufacturing the counterfeit medicine can be put behind bars for a few years.¹⁰⁴¹ These offer temporary solutions to deep-rooted and convoluted problems. However, such complex problems require a thorough and well-coordinated effort, requiring participation of the three streams of laws affected by the problem in order to comprehensively protect the consumers from the harmful effect on their health and safety.

Moreover, there are certain gaps that still exist in the legal instruments, which have been highlighted in the legal analysis of the individual chapters.¹⁰⁴² In context of counterfeiting and falsification of medicines it was highlighted in Chapter 3, in the legal case studies that it is essentially a cross-border activity. The lack of cross border synergies between enforcement authorities, especially concerning cross-border threats and information sharing¹⁰⁴³ needs to be addressed in order to better protect the consumers. Further, the lack of harmonisation of criminal enforcement¹⁰⁴⁴ and low level of penalties for counterfeiting and falsification of medicines also attracts the criminals. Further, the infiltration of the legal supply chain by illegal supply chain¹⁰⁴⁵ also places the consumers in a

¹⁰³⁹ See Chapter 3, Section 3.2.

¹⁰⁴⁰ European Commission. (2017). Report on EU customs enforcement of intellectual property rights: Results at the EU border 2016. Luxembourg. Publication Office of the European Union.

¹⁰⁴¹ Regina v Peter Hugh Gillespie No. 2011/02816/B4 Court of Appeal Criminal Division 29 November 2011 [2011] EWCA Crim 3152.

¹⁰⁴² See Chapter 4, Sections 4.2, 4.3, and 4.4.; Chapter 5, Sections 5.3, 5.4, and 5.5; and Chapter 6, Sections 6.2, 6.3, 6.4, and 6.5.

¹⁰⁴³ Chapter 6.

¹⁰⁴⁴ Chapter 5, Section 5.5.

¹⁰⁴⁵ Chapter 4, Section 4.3.3.1.

vulnerable position. As a result, the legal mechanism to safeguard the consumers against counterfeiting and falsification of medicines is not of optimal level, as yet.

8.6. Concluding remarks

The EU treaties have both social objectives and economic aims that are simultaneously pursued through various policies and legal instruments. Immense importance is accorded to social goals like protection of human health, welfare, and consumer protection, and equal emphasis is laid on realising the economic ambitions like policies that promote competition, innovation and investment resulting in economic growth and development. A fine balance is maintained, which is not always easy to achieve as in the case of the pharmaceutical sector. On the one hand, there are social objectives and values of public health and safety and consumer protection that must be ensured, and on the other hand, the pharmaceutical sector has to remain competitive and the prices have to be kept at reasonable levels in order to encourage innovation.

Moreover, the laws should not be too restrictive, but strict enough to discourage counterfeiting and falsification of medicines. To achieve both the social and economic targets, the EU law needs to engage in a balancing act – to have strong laws to combat counterfeiting and falsification and simultaneously curb the introduction of prohibitively expensive restrictions. Although in theory, the social and economic objectives do not clash with one another, in practice, there is a price – even for the maintenance of public health and safety and economic growth.

The legal instruments that provide tools to combat counterfeiting and falsification of medicinal products in the EU strive to meet the social objectives of public

health and consumer protection through their provisions. However, the legal instruments need to balance the goals of the Single Market¹⁰⁴⁶ against the social objectives of public health and consumer protection.¹⁰⁴⁷

In addition, both public health and consumer protection lie in the area of shared competences,¹⁰⁴⁸ whereby the Union plays a supplementary and supporting role and the Member States shoulder the primary responsibility in designing policies and activities concerning public health and consumer protection. Therefore, the Union can intervene only in limited issues of common interest in the broad public health and consumer protection areas.

Therefore, the given reality is that the goals of public health and safety and consumer protection have to be prioritised simultaneously with achieving goals of the Single Market in the EU. Taking the above into consideration, it can be concluded that the legal instruments are successful in meeting the social objectives of public health and consumer protection to a large extent, with definite scope for improvement especially in areas of serious cross-border threats, criminal enforcement and information sharing to prevent the spread of diseases.

¹⁰⁴⁶ Articles 26 and 114 of the TFEU.

¹⁰⁴⁷ Articles 9, 12, 168, and 169 of the TFEU.

¹⁰⁴⁸ Articles 4 and 6 of TFEU.

Chapter 9: Conclusion

The main objectives of the thesis were, firstly, to analyse how the counterfeiting and falsification of medicinal products are addressed by the law (Directive 2011/62/EU, Directive 2004/48/EC, and Regulation 608/2013) in the EU (*de lege lata*), and secondly, to analyse whether the law providing tools to combat the counterfeiting and falsification of medicinal products meet the social objectives of public health (Articles 9 and 168) and consumer protection (Articles 12 and 169) as envisaged by the Treaty on the Functioning of the European Union.

On the basis of the case studies - Operation Volcano (Italy), Operation Singapore (the U.K), and Operation Robin (Sweden)¹⁰⁴⁹ certain common issues are identified regarding how counterfeit medicines infiltrate the legal supply chain. The common tendencies are primarily by manipulation of the medicinal products as well as through highly organised structures managing counterfeiting and falsification of medicinal products. Further, it is evident that there tends to be an element of cross-border activity, usually involving more than two Member States. In addition, it is noted that the most common method of transportation of medicines is through small consignments, in order to circumvent customs control. One of the frequently used methods of offloading the manipulated products is through online sale of medicines. Finally, the types of medicines being counterfeited and falsified are predominantly life-saving medicines, while life-style drugs are a smaller part of the picture.

The legal case studies reveal that counterfeiting and falsification of medicines is a complex, lucrative business, often involving highly educated players with

¹⁰⁴⁹ Chapter 3.

sophisticated knowledge of the sector. The three case studies also showcase that the counterfeiting and falsification of medicines are on the rise because there are certain gaps in the legal framework which are taken advantage of, by the people involved in counterfeiting and falsification of medicines.

Thereafter, an analysis of the law dealing with counterfeiting and falsification of medicines was conducted in order to identify loopholes, if any, in the existing legal framework. The thesis establishes that the problem of counterfeiting and falsification of medicinal products lies at the intersection of three spheres of law - Medicine law, IP law and Criminal law. This insight provides the foundation for the understanding of the weaknesses in the legal regime that contains tools for combatting counterfeiting and falsification of medicines in the EU.

The study of the FMD, representing the Medicine law perspective, concludes that although initiatives such as the introduction of safety features to prevent manipulation of the medicines are a step in the right direction, especially with respect to the introduction of the anti-tampering devices, there are areas that leave much to be desired. Contrary to a full trace and track system, the choice of using the end – to - end verification system may not be able to detect all cases of falsification of medicines.

Further, it is concluded that even though there is a requirement by law, for authorisation for all the market players, the high instance of forgery of authorisations (both market authorisations and manufacturing authorisations), as well as other related documents, significantly contribute to a marked increase in the falsification of medicines. The absence of a security feature, such as a watermark used in the currency, on the authorisation documents is noted and the urgency of a provision of securing the authorisations is underlined. In addition,

even though the logo to be affixed on all legitimate websites based in the EU has many advantages, a clear provision for withdrawal of the logo in the case of breach of law is a concern that is highlighted. Likewise, a provision of ‘reverse burden of proof’ while importing APIs is noticeably absent in the Medicine law¹⁰⁵⁰ even though the APIs that are imported can be as hazardous to human health as the imported chemicals. Finally, in context of involvement of two or more Member States in a typical case of counterfeiting and falsification of medicines, a gap exists in the legal framework with respect to the sharing of responsibilities between the Member States. A provision on the lines of Article 85c (1) (c) of Directive 2001/83/EC, which clarifies roles of Member States in a specific situation, is absent, but could be potentially beneficial.

Regarding the Enforcement Directive, which addresses the problem of counterfeiting of medicines from IP law perspective, it is deduced that it is primarily the question of violation of trademark rights that is pertinent in the context of counterfeiting of medicinal products, with special reference to the product packaging. Usually, it negatively impacts the goodwill and reputation of the owner of the trademarks. It is concluded that the civil enforcement of IP rights through provisions such as preliminary and precautionary measures encompassing the possibility of seizures, as well as measures such as interlocutory and permanent injunctions have the potential to be more effective with regard to counterfeiting of medicinal products subject to room for cross-border applicability of the provisions.

Since there is no cross-border applicability of the provisions and the Enforcement Directive clearly delimits itself from the cross-border application, dealing with a

¹⁰⁵⁰ See Chapter 4, Section 4.3.2.

case involving counterfeiting of medicines, which is typically a cross-border activity, the legal route is not resorted to, as often. Therefore, the cumbersome process involving an application for same reliefs in multiple Member States for the right holders is not a viable option, in practice. Likewise, the lack of harmonisation of criminal measures in the EU highlights a gap in the enforcement of the IP rights. Therefore, it is concluded that the Enforcement Directive in its present form is not the most effective legal instrument for combatting counterfeiting of medicines in the EU.

The analysis of the Customs Regulation shows that although there are certain key features such as measures that can be taken against small consignments, the pertinent issues such as the counterfeit goods that come through the personal luggage of the travellers, which is usually not subject to regular checks, remain to be addressed effectively. The travellers' luggage has been known to contain packaging material for the counterfeit products manufactured in the EU.¹⁰⁵¹

It is recognised that the Customs Regulation does not address the parallel imports because parallel imports are genuine products. However, in the context of counterfeiting and falsification of medicinal products, it is important to critically consider parallel imports especially because these have been the preferred disguise of many counterfeiters of medicinal products. However, establishing stricter laws would not be in consonance with the basic principle of proportionality recognised in the EU because of the significant advantages of parallel trade in the Single Market.

¹⁰⁵¹ Report on EU Customs Enforcement of Intellectual Property Rights, Results of the EU borders 2016.

It is concluded that the Customs Regulation plays a significant role in controlling entry of counterfeit medicinal products at the EU borders and there is potential to increase critical effectiveness by conducting more frequent checks on small consignments and traveller's luggage. However, it is also recognised that a balance needs to be struck as checking each piece of luggage would be impractical and forbidding travellers from bringing medicines in the EU for personal use would be draconian, and would violate the basic principles of the EU law.

Next, the lack of harmonisation of Criminal law - the third sphere of law that is relevant to combatting counterfeiting and falsification of medicinal products - is emphasised. It is concluded that the Medicrime convention could be particularly useful with reference to criminal enforcement since it could be instrumental in the harmonisation of criminal measures with respect to counterfeiting and falsification of medicines. If the EU ratifies the Medicrime Convention, following the footsteps of the four Member States that have ratified the convention, this important gap in the EU legal framework can be bridged.

In order to seek inspiration to strengthen the legal framework in the EU, the initiatives taken at the global level in this field are analysed. It is concluded that in the ACTA and other multilateral and bilateral agreements - TPP, TTIP, RCEP, and CETA, the protection and enforcement of IPRs is the predominant focus. While considering the pharmaceutical sector the concentration tends to be on promotion of harmonisation of rules pertaining to inspections, approval and innovation of medicinal products. It became apparent that most of the provisions in ACTA that related to civil measures, digital environment, and border enforcement are already imbibed in different EU legal instruments such as the Enforcement Directive, the E-commerce Directive, and the Customs Regulations. However, the provision on criminal measures for enforcement of IPRs has no parallel in the EU legal

framework.

In the EU, the sphere of public health and consumer protection are shared competencies between the Union and the Member States. In that light, it is concluded that the Union, through the secondary legislation, has to a large extent, been successful in meeting the goals with respect to the formulation of laws for ensuring the safety of the medicinal products, protection of the legal supply chain, civil measures for enforcement of IPRs and customs control at the borders. The area of law grappling with counterfeiting and falsification of medicines is a dynamic area and the full impact of some of the legal provisions is expected to unfold in the next five years.

Considering that these developments have taken place in the past decade there is, undoubtedly, scope for improvement, especially in the areas of cross-border cooperation, criminal enforcement and creation of synergies at the institutional level to combat the counterfeiting and falsification of medicines. Since the problem of counterfeiting lies at the intersection of Medicine law, IP law and Criminal law, it would enhance the effectiveness by building synergies between the authorities dealing with these areas of law at national as well as EU level on the same lines as synergies exist with regard to the Rapid Alert system under Article 117a of the Directive 2001/83/EC.

Overall, it is concluded that the legal instruments in the EU provide important and useful tools to combat counterfeiting and falsification of medicines. However, there is a definite scope for improvement. The gaps in the legal framework that have been identified must be taken seriously in order to minimise the risk of serious consequences. Counterfeiting and falsification pose problems in many areas, but in the medicinal sector, the ramifications are especially harmful because counterfeit and falsified medicines have an impact on the health of the people and

can, potentially, be fatal. Therefore, a focussed effort in bridging the gaps in the legal framework in this area is needed, which would enhance the health and safety of the EU citizens.

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