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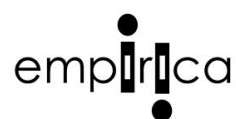
Transposition measures of Member States in relation to the pharmaceutical legislation

(Art. 118a of Directive 2001/83/EC)

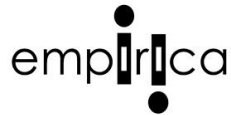
Final Report



Transposition measures of Member States in relation to pharmaceutical legislation



This study was carried out for the European Commission DG Health and Food Safety (SANTE) by



Authors: Karl Stroetmann, Jonas Rennoch (empirica), Arndt Sinn, Michael Berg, Uriel Möller, Simon Maly (ZEIS)

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EUROPEAN COMMISSION

Directorate-General for Health and Food Safety
Unit B4 — Medicinal products – Quality, safety, innovation

Contact: Agnes Mathieu-Mendes

E-mail: SANTE-PHARMACEUTICALS-B4@ec.europa.eu

*European Commission
B-1049 Brussels*

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**Transposition measures of Member
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Luxembourg: Publications Office of the European Union, 2017

PDF	ISBN 978-92-79-73869-2	doi: 10.2875/41105	EW-04-17-864-EN-N
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0 EXECUTIVE SUMMARY

Context: Global attention to the danger of falsified medicinal products is gaining momentum. Weak, ineffective or dangerous medicinal products are a serious threat to patient safety and public health.

Objectives: In 2011, to address the threat of falsified medicines, Directive 2011/62/EU amended Directive 2001/83/EC to include measures aimed at preventing the entry of falsified medicinal products into the legal supply chain. Article 118a of the Directive includes the requirement for Member States (MS) to introduce penalties related to the falsification of medicinal products, active substances and excipients.

This report outlines the measures in place or taken by Member States to transpose, implement and enforce Article 118a of the Directive and gathers and assesses relevant information regarding the effectiveness of those measures. It includes:

- The penalties in place in each Member State
- A Member States overview with respect to these measures
- An assessment of the effectiveness of the measures
- Recommendations on improving the achievement of the objectives of Article 118a.

The study gives an overview of the situation in the EU in mid-2017 and should feed into the Commission Report to be sent to the European Parliament and Council in January 2018. In any case, Member States should have notified the European Commission of the national provisions adopted by January 2013.

Methods: Based on a review of the literature, a questionnaire was developed and tested to collect information on national transposition measures, as well as empirical data or estimates of falsified medicinal products in legal and illegal markets. An assessment of the effectiveness of sanctions was also requested. The questionnaire was distributed to a network of criminal and pharmaceutical law experts covering all 28 Member States. The results were checked with the Commission "Expert group on the delegated act on safety features for medicinal products for human use".

To obtain further quantitative data, an additional questionnaire was circulated to more than 110 relevant Member State, EU and international organisations.

Results: Comprehensive information and legal data were collected for all EU Member States. Detailed tables per Member State were provided to the European Commission. They cover the overall country situation, the provision of Art. 118a Directive 2001/83/EC in national language, details on national provisions sanctioning illegal conduct with medicinal products, active substances, and excipients (in both national language and English), and further details on the types of sanctions/penalties applied.

A synthesis comparing the transposition of the Directive across all Member States with respect to criminal penalties, "civil"¹ penalties, and administrative sanctions is presented in this report. The majority of transposition measures introduced after 2011 are related to *administrative* law, as the legal systems of most Member States already contained *criminal* sanctions with respect to falsified medicinal products, active substances and excipients.

Sanctions concerning falsified medicinal products

Twenty-two Member States (BE, CZ, DK, DE, EE, ES, IE, EL, FR, HR, IT, CY, LT, LU, HU, MT, NL, AT, PT, SI, SK, UK) provide for *criminal* penalties for any type of misconduct with respect to falsified medicinal products (manufacturing, distribution, brokering, import, export, and distance sales). Yet, two of these Member States

¹ On this terminology, see below section 1.4.

require a causal link of the conduct to concrete danger to health (ES, PT). Of the six Member States that do not sanction all forms of conduct through criminal law provisions, one (FI) has criminal penalties for manufacturing, distribution, import and distance sales. Five Member States (BG, LV, PL, RO, SE) provide for either criminal or "civil" penalties depending on the conduct; e.g., four of them (LV, PL, RO, SE) have implemented only "civil" penalties for export, whereas all of them – except for BG – feature criminal penalties for manufacturing, distribution and brokering.

Sanctions concerning active substances

Seventeen Member States (BE, CZ, DK, DE, EE, EL, IE, ES, FR, HR, IT, LU, HU, NL, AT, PT, SK) provide for criminal penalties for any type of illegal conduct with respect to (falsified) active substances². Yet, two of these Member States require a causal link of the conduct to concrete danger to health (ES, PT). Of the remaining eleven, four (LT, RO, SI, SE) have implemented only "civil" penalties, and two Member States (BG, LV) have either criminal or "civil" penalties depending on the type of conduct (manufacturing, distribution, import or export). For the remaining five countries, three (PL, FI, UK) have implemented criminal penalties for all activities except export, one has implemented criminal penalties for manufacturing and distribution (MT) and one has implemented "civil" penalties for all activities except export (CY).

Sanctions concerning excipients

Concerning misconduct with respect to *excipients*³, ten Member States (BE, DK, EL, ES, FR, HR, LU, NL, AT, PT) provide for criminal penalties for any type of unlawful conduct with (falsified) excipients (manufacturing, distribution, import and export). Yet, two of these Member States require a causal link of the conduct to concrete danger to health (ES, PT). Two countries (SI, SE) have implemented "civil" penalties. Two countries (CZ, SK) have implemented "civil" penalties for violating manufacturing rules, and provide for administrative sanctions with respect to other types of misconduct. Two countries (CY, FI) provide sanctions for unlawful conduct except for export. Four countries (LV, HU, PL, RO) cover manufacturing and distribution with either criminal, "civil" or administrative sanctions while not providing any sanctions for import and export. Four countries (EE, IE, IT, LT) have only implemented sanctions for unlawful manufacture involving excipients. The remaining four countries (BG, DE, MT, UK) have no specific penalties in relation to excipients.

Type of sanctions

Administrative sanctions, such as the revocation of a licence, were often in place before Directive 2011/62 EU entered into force. However, some countries have introduced new, special provisions in direct transposition of Article 118a Directive 2001/83 EC. These mostly concern rules on good practices, such as Art. 122 of the Polish Medicines Act, which holds that the marketing and the distribution of a medicinal product or an active substance may be prohibited if the product is found non-compliant with the quality requirements set for it.

The situation regarding "civil" penalties is more complex. Seventeen Member States amended their "civil" penalties applicable to medicinal products, active substances and/or excipients. However, the amount of non-criminal fines varies greatly from Member State to Member State. The applicability of these penalties also varies. In some Member States, "civil" penalties are treated as sanctions of different intensity ("quantity") that apply to the same misconduct which criminal penalties apply to (IE, NL, UK). In other Member States, "civil" penalties are considered sanctions of different quality that do apply only to less severe misconduct, to which criminal

² Article 1(3a) of Directive 2001/83/EC: Active substance: Any substance or mixture of substances intended to be used in the manufacture of a medicinal product and that, when used in its production, becomes an active ingredient of that product intended to exert a pharmacological, immunological or metabolic action with a view to restoring, correcting or modifying physiological functions or to make a medical diagnosis.

³ Article 1(3b) of Directive 2001/83/EC: Excipient: Any constituent of a medicinal product other than the active substance and the packaging material.

penalties –covering only grave misconduct– do not apply (mutual exclusion: DE, ES, IT, PT).

Concerning *criminal* penalties, the situation is even more complex, despite the efforts of the MEDICRIME Convention of the Council of Europe.⁴ The severity of sanctions vary greatly across the EU. For the same misconduct, in one Member State there might be no criminal penalty, while in another the same conduct is punished by up to 10 years imprisonment.⁵ Some countries do not criminalise conduct involving falsified or adulterated medicinal products specifically, but only the manufacture or sale etc. without a required license (LV, NL, SE). In these MSs, falsifying medicinal products is criminalised only to the extent that the medicinal products are manufactured *without a license* or considered falsified goods (NL). Many Member States do not criminalize illegal activity with medicinal products that are not falsified (e.g. manufacturing without a license, see AT and PT). Three Member States (ES, LV, PT) require that the conduct caused danger or harm to human health for criminal penalties to apply. The majority criminalise unlawful activity involving active substances, but only a few misconduct involving excipients.

Enforcing authorities

Data on *enforcing authorities* across Member States are also presented. Authorities mentioned are ministry of health, medicines agency, police and prosecutor in general, special police and/or prosecution department, customs in general, special customs department, and other. The picture is very heterogeneous across Member States regarding which agency is responsible for levying criminal, civil or administrative sanctions.

Assessment of effectiveness

This is complemented by a summary assessment of the *effectiveness of different sanctions and the impact of penalties* introduced by Member States on both the legal and illegal market. This suggests that the *illegal* market can be successfully tackled by criminal penalties, but less so by administrative sanctions. The manufacturers of illegal or falsified medicinal products regularly act abroad and out of the reach of law enforcement agencies of the EU Member States. The distributors of these potentially dangerous medicinal products in the *illegal* market within the EU rarely seek or possess licenses. Consequently, administrative sanctions cannot be applied effectively. On the other hand, criminal penalties and administrative sanctions are suitable to safeguard the *legal* market, the actors of which depend on licenses to participate in the strictly regulated legal trade.

The respective national experts were also asked to assess the effectiveness of the different sanctions in dissuading the falsification and illegal trade of medicinal products. The vast majority of experts could not provide an estimate. This is most likely related to a lack of reliable empirical data and insufficient time to assess the overall situation based on concrete experience stretching over several years.

Even through the separate survey no reliable, standardised empirical data were available. The few data reported were very heterogeneous and cannot be aggregated or compared. The same holds for data assembled by earlier studies. It is therefore not possible to derive from them any conclusions on the effectiveness of the sanctions or longer-term trends.

⁴ The "Medicrime Convention" has been the first international criminal law instrument to oblige States Parties to criminalise – inter alia – the manufacturing of falsified medical products, supplying, offering to supply and trafficking in falsified medical products, The Convention seeks to fight the dangers to public health caused by the falsification of medical products and similar crimes, as clearly stated in its preamble ("does not seek to address issues concerning intellectual property rights"). Its purpose and core objective is to fight falsified medicinal products by criminalisation because of their serious threat for public health, see <https://www.coe.int/en/web/medicrime/home>.

⁵ See graph 3 below.

Conclusions and recommendations:

Despite the existence of criminal penalties for the various types of unlawful conduct in relation to (falsified) medicinal products, active substances and excipients, considerable challenges remain. Whether existing sanctions have indeed a broader and concrete impact, i.e. are “effective” as required by Article 118a, will, to a major extent, not depend so much on the wording of the sanctions and the extent of punishment provided for, but rather on widespread enforcement, the concrete level of prosecution and – most importantly – actual conviction. Enforcement policies and efforts vary greatly between Member States.

In order to strengthen enforcement, this study recommends the following measures:

When assessing the effectiveness of legal penalties of criminal law (based on abstract, abstract-concrete, concrete endangerment crimes), implementing the concept of crimes of *abstract* endangerment can be regarded as the most effective one in the fight to prevent falsified medicines to reach the market. Criminal law provisions that require no proof of concrete danger or harm have a lower burden of proof and are easier to enforce. Sanctioning conduct involving *falsified* medicinal products is only effective, dissuasive and proportionate if covered by (at least) abstract-concrete endangerment crimes. Consequently, Bulgaria, Latvia, Portugal and (depending on interpretation) Spain could strengthen their transposition of Article 118a of Directive 2001/83 EC.

Regarding the implementation of improved measures, it should be ensured that a maximum penalty of at least three years imprisonment is implemented by the Member States to meet the requirements of the “European Investigation Order” to facilitate international legal assistance. For the mere manufacture or sale of falsified medicinal products (abstract danger), this is not the case in Belgium, Bulgaria, Czech Republic, Denmark, Finland, Greece, Latvia, Lithuania, Luxembourg, Malta, Portugal, Romania, Sweden, Slovakia, Slovenia, Spain and UK.⁶ For the manufacture or sale of dangerous falsified medicinal products (abstract-concrete danger), this is not the case in Belgium, Bulgaria, Czech Republic, Denmark, Finland, Latvia, Lithuania, Malta, Portugal, Sweden, Slovakia, (to some extent) Spain and UK.⁷

Additionally, preventive measures such as the upcoming end-to-end verification system should be used to strengthen criminal prosecution. Art. 80 (i) of Directive 2001/83/EC in conjunction with Art. 30 of the Delegated Regulation (EU) 2016/161 already imposes the necessary obligation on persons who are authorised or entitled to supply medicinal products to the public to report the “case of suspected falsification” immediately to “the relevant competent authorities”. It is recommended to ensure that this mandatory information flow reaches public prosecution in the Member States involved in the supply chain of that suspicious batch. It is not enough to remove the medicinal product from circulation: penalties have to be imposed, as required by Article 118a of the Directive 2001/83/EC.

Finally it is important to provide for an evidence-based assessment of the success, the general effectiveness, and specific effects of certain measures or specific penalties on the amount (or value) of falsified medicines in the market in years to come. In order to achieve this aim, improvements to data collection and integration are necessary.

⁶ See Graph 3 below.

⁷ See Graph 4 below.

1 CONTEXT, OBJECTIVES AND METHODOLOGICAL APPROACH

This chapter briefly introduces into the overall topic, explores the objectives of this study, and sketches the methodological approach applied to gather evidence. Furthermore, it points to certain limitations of the study to be noted.

1.1 Context and background

Global attention to the challenge which falsified medicines pose for the health and safety of people is gaining momentum. Weak, ineffective or even deadly medicinal products are causing a serious hazard for health systems and the life of millions of patients.⁸ Organised crime is reaping huge profits.⁹ As the European Commission recently noted, “the ‘cases’ of falsified medicines reported to date are not sufficient to provide reliable statistics,” but the trend of “falsified medicines in the legal supply chain ... seems to be on the rise.”¹⁰

The media are also paying increasing attention to the impact on the health of people, the implications for patient safety and trust in health systems. Demands for more active political interventions are rising, such as a recent thematic evening on German public broadcasting (ARD) and information on their website.^{11, 12, 13}

1.2 Goal and objectives

Issues around falsified medicinal products have been an important topic at EU and Member State levels for quite some time. In 2011, Article 1 (25) of Directive 2011/62/EU inserted Article 118a into Directive 2001/83/EC, and thereby penalties to prevent the entry of falsified medicinal products into Member State health systems. Strict rules should ensure that medicines are safe and that the trade in medicines is rigorously controlled.

That article also stipulated that “by 2 January 2018, the Commission shall submit a report to the European Parliament and to the Council giving an overview of the transposition measures of Member States as regards penalties, together with an evaluation of the effectiveness of those measures.” To contribute towards this obligation, this study has carried out a comprehensive review of the national measures to transpose Article 118a of Directive 2001/83/EC.

The overarching goal was to gather and assess measures taken by Member States to transpose, implement and enforce Article 118a of the Directive 2001/83/EC and to collect relevant information regarding the effectiveness of those measures. Accordingly, in this final report the focus is on

- The national transposition measures undertaken by each Member State

8 It is estimated that more than 1 m people die yearly because of falsified medicines : Harrich, Daniel, Harrich-Zandberg, Danuta. *Pharma-Crime: Kopiert, gepanscht, verfälscht – Warum unsere Medikamente nicht mehr sicher sind* (Pharma Crime: copied, adulterated, falsified – Why our medicines are no longer safe). Heyne, 2017

9 Council of Europe. *MediCrime Convention of 2011 and Medicrime Factsheet of 15.12.2015*. Available from www.coe.int/en/web/medicrime/home; Harrich, Daniel, Harrich-Zandberg, I.c., p. 32; Sinn. *Organisierte Kriminalität 3.0*. Springer, 2016, p. 22; Sinn. *Risiken und Nebenwirkungen bei Arzneimittelkriminalität*, in: Zoche, Peter / Kaufmann, Stefan / Arnold, Harald (Ed.). *Grenzenlose Sicherheit? Gesellschaftliche Dimensionen der Sicherheitsforschung*, LIV-Verlag, 2016, p. 207 ff. with further references

10 Commission Staff Working Document. *Impact Assessment. Accompanying the document Commission Delegated Regulation (EU) No .../... 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*. {C(2015) 6601 final}, {SWD(2015) 188 final}. Brussels, 2.10.2015, SWD(2015) 189 final, p. 6

11 <http://www.daserste.de/unterhaltung/film/themenabend-medikamente/index.html>

12 <http://www.faz.net/aktuell/wirtschaft/unternehmen/gefaelschte-harvoni-hepatitis-tabletten-auf-deutschen-markt-gelangt-15044107.html>

13 <http://www1.wdr.de/mediathek/audio/wdr5/wdr5-leonardo-hintergrund/audio-gefaelschte-medikamente-kontrolle-mangelhaft-100.html>

- A Member States overview with respect to these measures
- An assessment of the effectiveness of the measures
- Recommendations to improve the achievement of the objectives of the Directive.

The timing encompasses the period from entering into force of the Article 118a of Directive 2001/83/CE (2011) until mid-2017.

1.3 Methodological approach

The methodological approach was guided by the goal to ensure the reliability of the information on relevant legal provisions and to collect as good empirical data as possible.

Collecting legal information

After an initial comprehensive review of relevant literature and papers, the next step was the development of a questionnaire appropriate to ensure that all respective national transposition measures could be identified, and that any empirical data available on falsified medicinal products and the effectiveness of sanctions could be gathered.

The questionnaire was developed in close collaboration with the client, based on earlier experience by the team in the "Research Project on Internet Commerce and Pharmaceutical Crime (ALPhA)".¹⁴ It was pre-tested by three especially experienced legal experts from the ZEIS¹⁵-network.

The questionnaire was then distributed to the ZEIS network of criminal and pharmaceutical law experts covering all 28 Member States. The responses were thoroughly reviewed by the ZEIS team regarding the legal questions and by the empirica team regarding quantitative empirical data on the volume or value of falsified medicines identified in that country. A cross-check with earlier information available from the ALPhA project and other sources was also performed.

The questionnaire turned out to be well suited to the study's objectives; it was comprehensible in the different national legal contexts, and comprehensive. The English translation of national law was provided by the experts themselves or by an external legally skilled translator. When necessary, specific issues were discussed and clarified with the experts by telephone.

In a final step, validation of all results collected was assured by a triangulation process involving the members of the "Expert group on the delegated act on safety features for medicinal products for human use".¹⁶ This group assembles national experts, usually government or national agency representatives, of all EU Member States. They critically reviewed and validated the information and, where available, quantitative data obtained via the earlier steps.

Furthermore, the team presented the preliminary results of the study at the "17th meeting of the expert group on the delegated act on safety features for medicinal products for human use" on June 30th of 2017 in Brussels. This allowed for further clarification of open issues.

In summary, information and data gathered concerning the legal provisions met expectations and provide a solid basis for responding to the study questions in the following chapters.

14 On the ALPhA project, see <https://www.alpha.uni-osnabrueck.de/en/home.html>

15 ZEIS is the "Zentrum für Europäische und Internationale Strafrechtsstudien" (Centre for European and International Studies of Criminal Law) at the University of Osnabrück: <http://www.zeis.uni-osnabrueck.de/>

16 <http://ec.europa.eu/transparency/regexpert/index.cfm?do=groupDetail.groupDetail&groupID=2719>

Collecting quantitative data

The questionnaire also included questions concerning the volume (or value) of falsified medicines identified in the country. Unfortunately for most countries no data were available, and the data obtained was very heterogeneous and could not be aggregated or compared.

Therefore, the team directly approached more than 110 potentially relevant organisations for additional data in all Member States and EEA countries, as well as at the international level. Among them were national statistics offices, ministries, regulatory agencies, state police and customs authorities.

At the international and European Union level, additional organisations were approached, among them various United Nations Statistics Offices, the World Trade Organisation (WTO), Eurostat, Europol, The Alliance for Safe Online Pharmacies (ASOP), The Pharmaceutical Security Institute (PSI).

The collection process involved approaching them by e-mail, via their contact form on their website, or by telephone.

This additional data collection effort led to very few, often cursory and non-standardised data.

1.4 Limitations of the study

Legal issues and terminology

The subject of this study is the transposition of Article 118a of Directive 2001/83 EC, not the transposition of Directive 2001/83 EC as a whole. The objective is an assessment whether the 28 Member States have effective, dissuasive and proportionate sanctions regarding falsified medicinal products, active substances and excipients. Consequently, the study does not include an analysis if all requirements of Directive 2001/83/EC are transposed.

The terminology on “civil penalties” was not understood by all experts. Although this problem was overcome with further explanations, the study team recommends a different terminology in the future: “non-criminal (or administrative) fines”.

It should also be noted that pharmaceutical law is developing rapidly in the Member State. For example, a new pharmaceutical criminal law will be introduced in Sweden shortly. Slovakia has recently adopted a new section of its Criminal Code criminalising conduct with respect to falsified medicinal products. Germany has also recently introduced changes to its Medicinal Products Act with relevance for civil and administrative sanctions.

Quantitative data

The study team was warned by experts about the considerable difficulties in gathering empirical data in the field of falsified medicinal products and on applicable sanctions.

Very few and no standardised, comparable data on falsified medicines were available. This concerns their incidence in the legal supply chain, as well as illegal markets.

Although we attempted to gather quantitative data covering the period 2009 – 2016, the lack of EU-wide data and differences in data collection by national agencies made it impossible to aggregate data within a single country or across countries, or to identify meaningful trends.

2 UNDERSTANDING OF ARTICLE 118A OF DIRECTIVE 2001/83/EC

2.1 Legal and illegal markets

When considering legislation on medicinal products, a distinction has to be made between the legal and illegal markets of medicinal products. The medicinal products traded in the legal market have usually been tested, produced and distributed in ways that ensure their effectiveness and safety for treating patients. In spite of this, it regularly happens that falsified medicinal products end up in legal supply chains.¹⁷

On the other hand, illegal and falsified medicinal products are mostly traded at online market places, via social media, the darknet and online forums. They often fetch very low prices that reflect the minimal production costs as well as the absence of measures to ensure their effectiveness and safety. This illegal medicinal product market seems to be growing quickly.

The widespread consumption of falsified and illegal medicinal products could have a devastating effect on public health.¹⁸ Since they often contain insufficient or no active substances, they are unable to properly treat patients.¹⁹ Additionally, harmful substances mixed into these products can pose a serious threat to the health of the consumer that is hardly ever detected. Nevertheless, many consumers are willing to take the risk to buy medicinal products in the illegal market – to save money, to buy so-called life-style drugs, and for various other reasons.²⁰

To prevent falsified medicinal products entering the legal supply chain, EU-legislation has recently introduced two important preventive measures:

The upcoming end-to-end verification of the manufacturing and distribution of medicinal products is an important step to secure the legal supply chain. With the end to end verification, it is possible to track each medicinal product from its manufacturing to its sale in pharmacies or retailers. This should ensure that falsified medicinal products are not introduced into the legal market somewhere down the supply chain, especially at the wholesale level.

Additionally, a so-called EU-Security-Logo has been introduced allow for the identification of certified, legal online pharmacies thereby preventing the illegal online sale of medicinal products to consumers and patients. It is a widespread method of criminals, often tied to organised crime, to sell medicinal products via “online pharmacies” that pretend to be legal.²¹ This way, responsible consumers, which do not

17 Harrich, Daniel, Harrich-Zandberg, Danuta. Pharma-Crime: Kopiert, gepanscht, verfälscht – Warum unsere Medikamente nicht mehr sicher sind (Pharma Crime: copied, adulterated, falsified – Why our medicines are no longer safe). Heyne, 2017, pp. 20 ff. reporting on eight cases of enormous relevance in Germany alone (period 2009 to 2016), among them anti-cancer medicinal products like Sutent and Avastin. In the current crime case of high relevance a German pharmacist produced cytostatic products and reduced the quantity of active ingredients substantially to maximise his profit. Prosecutors accused the pharmacist of providing low-dose medicinal products in almost 62,000 cases. Available from <http://www1.wdr.de/nachrichten/ruhrgebiet/bottrop-apotheker-skandal-kontrollen-100.html>

18 Lybecker, Kristina. Illicit trade in counterfeit medicines, in : OECD (2016), Illicit Trade: Converging Criminal Networks. OECD Review of Risk Management Policies, p. 103 ff.

19 Harrich, Daniel, Harrich-Zandberg, I.c., pp. 86, 88 reporting on the cytostatic pharmaceutical “MabThera” which was falsified (without active substances) and smuggled into the legal supply chain by re-importers who also falsified the package

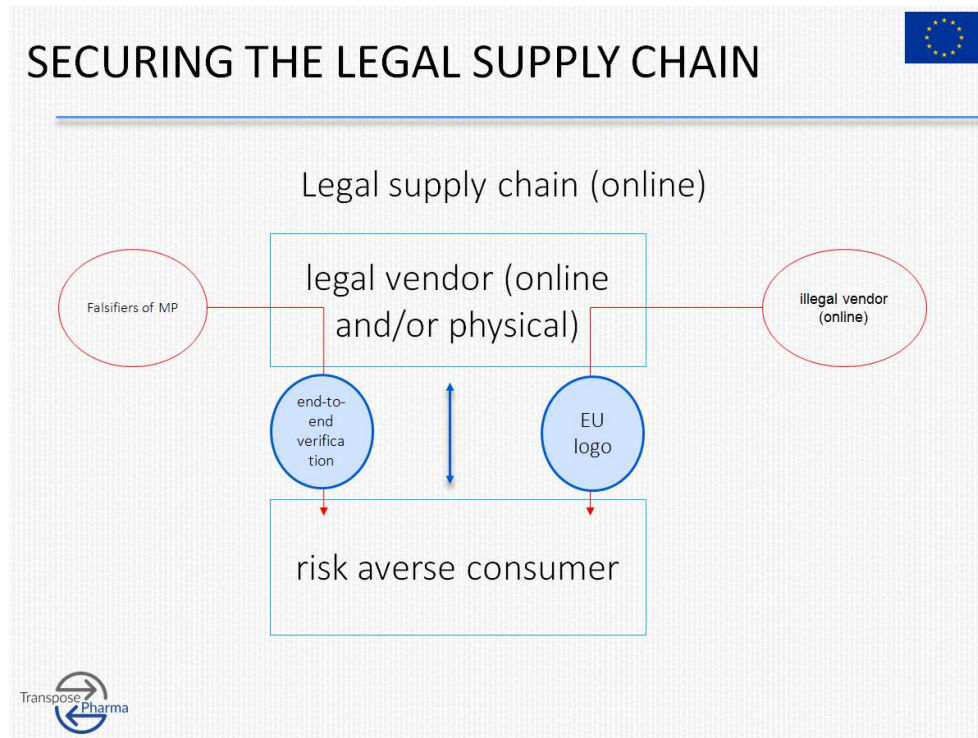
20 Cf. World Customs Organisation. Illicit Trade Report 2015. Brussels, Dec. 2016. There see Chapter 3 on “IPR, Health and Safety - Medicines and Pharmaceutical Products”, pp. 82 ff.; Harrich, Daniel, Harrich-Zandberg, I.c., pp. 41 ff. reporting on the German «Männerapotheke»/«Pillendienst»-Case where a highly organized crime group made profit of about 21.5 Mio. EUR within three years out of 300,000 internet orders from selling mainly life-style pharmaceuticals like Viagra and slimming products. Details also available from <http://www.maz-online.de/Lokales/Potsdam/Handel-mit-gefaelschtem-Viagra-Chef-der-Pillenbande-muss-lange-in-Gefaengnis>

21 Hall, Alexandra, Antonopoulos, Georgios A., Di Nicola, Andrea. FAKECARE. Search and Stop. Guidelines to tackle the online trade of falsified medicinal products. Trento, 2015, p. 15 ff. Available from http://fakecare.com/images/pdf/FAKECARE-Guidelines_for_LEAs.pdf

want to take the risk of buying medicinal products in the illegal market, are nevertheless tricked to purchase illegal or falsified medicinal products, often for the legal market price.

Both measures aim to block the supply of illegal/falsified medicinal products by criminals to patients and consumers, as illustrated in Graph 1:

Graph 1: Securing the legal supply chain I



With Article 118a of the Directive 2001/81 EC, EU-legislation also includes provisions on prosecutions. This article, introduced by Directive 2011/62/EU, requires Member States to

"lay down the rules on penalties applicable to infringements of the national provisions adopted pursuant to this Directive and [to] take all necessary measures to ensure that those penalties are implemented. The penalties must be effective, proportionate and dissuasive".

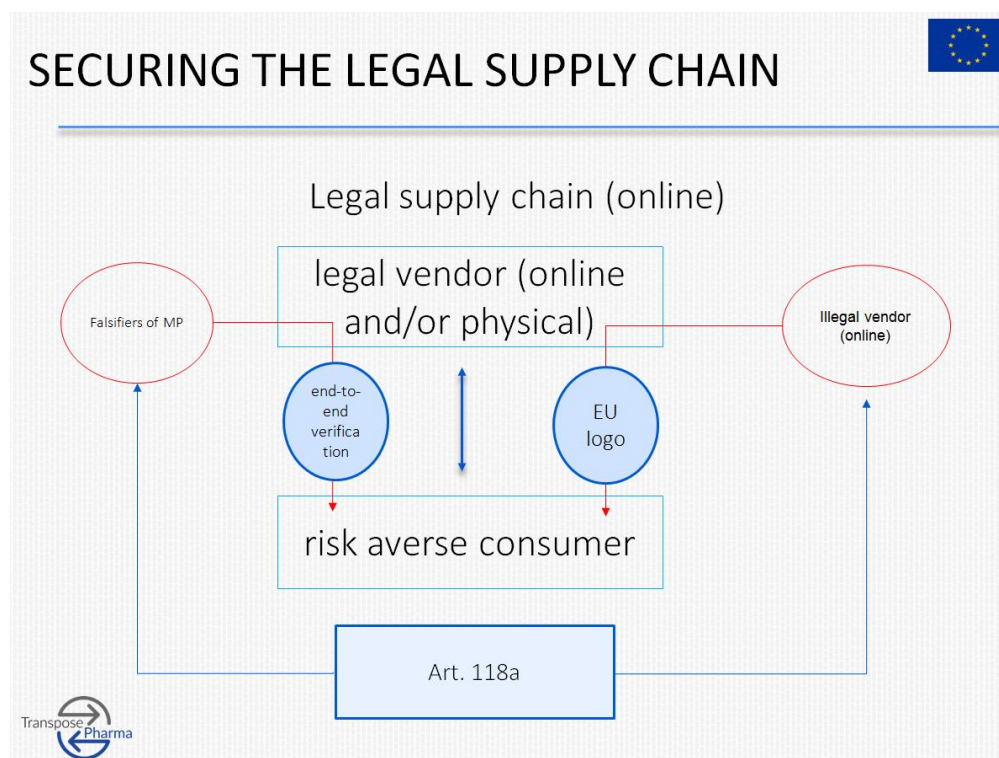
This means that the laws of the Member States have to fulfil the following requirements:

1. Applicable penalties must be in place;
2. The penalties must be effective, proportionate and dissuasive; and
3. Member States must make sure that the penalties are implemented.

Furthermore, it is stipulated that the penalties

"shall not be inferior to those applicable to infringements of national law of similar nature and importance."

This allows for the *sanctioning/prosecution* of the falsification and the distribution of medicinal products, targeting the perpetrators and not simply blocking supply. This scenario is illustrated in Graph 2:

Graph 2: Securing the legal supply chain II

2.2 The adoption of penalties

The rules on penalties as laid down and implemented by all 28 Member States are the starting point for the legal analysis of the transposition of Article 118a. For the purpose of this study, these rules were subdivided into criminal penalties, civil penalties and administrative sanctions. According to Article 118a, the sanctions should cover activities concerning falsified medicinal products, active substances and excipients.

On criminal law penalties, the ALPhA project has already acquired extensive data. This data was corroborated and updated by the current study. The different techniques of the "rules on criminal penalties" have a direct correlation with effectiveness, proportionality and dissuasiveness. It is therefore important to not only examine whether Article 118a of Directive 2001/83 EC is transposed or not, but also to assess the mode of transposition. Certain types of offences, such as abstract and abstract-concrete endangerment crimes, lower the burden of proof for prosecution and are more efficient than penalties that require proof that harm was actually caused by the criminal act (*actus reus*). These different techniques will be explained, analysed and compared for the 28 Member States in chapter 4.

When analysing the concrete transposition by Member States, it becomes important to note that several countries differentiate between conduct involving falsified medicinal products in themselves that may not necessarily harm patients or individuals, and conduct involving falsified medicinal products which indeed may harm or have harmed a person. This renders the analysis quite complex. However, this differentiation is necessary in order to guarantee the EU-wide comparability of the different penal provisions and is made when necessary.

Beyond simply recording whether a country has transposed Article 118a, the decisive criterion towards assessment is the effectiveness of penalties, ensured by their dissuasiveness and proportionality. As it does not matter whether the penalties existed before Directive 2011/62 EU, the analysis of the transposition of Article 118a includes existing legal measures within the 28 MSs, regardless of when the measures were taken (see below points 5 and 6). For example, a country might not have changed "rules on penalties applicable to infringements of the national provisions adopted

pursuant” to the Directive, because equivalent penalties already applied. In that case, the penalties existing before Article 118a did not have to be changed to transpose Article 118a (see the detailed analysis below in chapter 4).

To identify not only the current legal situation, but the measures taken as a result of Article 118a of Directive 2001/83/EC (“direct transposition”), the study also asked the experts to identify which existing penalties and sanctions were direct transpositions of Directive 2011/62/EU. This was facilitated by the documents provided of all transposition measures reported to the EC. As a result, the study team is able to say which countries have changed their sanction regime and how they were changed (chapter 4). This helps to identify which countries have acted regarding sanctions/penalties and which have not.

2.3 Implementation of penalties

The assessment of that the implementation of penalties depends on several aspects. Two key factors are easily enforced penalties and sufficient resources dedicated to enforcement of the penalties.

Resource allocation is not evaluated as part of this study. This is a very complex task which would require a dedicated study to assess the level of resources necessary to effectively enforce sanctions regarding pharmaceutical infringements and related crime. We are not aware of any such study.

On the other hand, implementation could be measured by the sanctions that Member States have already applied. Unfortunately, the data gathered (see below chapter 5.3) does not allow for a comprehensive comparison.

Implementation also depends on applicability of the legal instrument, in this case the nature, form and structure of the penalties. The easier it is for the police, customs or other authorities to impose a sanction, the more easily penalties are implemented. This point is analysed in chapters 4.1 and 5 of this report.

2.4 Assessment of the transposition of Article 118a

Article 118a requires that MSs provide for sanctions concerning falsified medicinal products, active substances, and excipients. The legal situation regarding all three types of substances and all three types of sanctions will be presented in the following chapter in the form of country reports for all 28 MS. Furthermore, summary tables on these details will be presented in chapter 4.

Article 118a also requires that those sanctions are “effective, proportionate and dissuasive.” This can only be assessed following a legal and empirical analysis. Although a MS has sanctions for all types of substances, these sanctions may be ineffective and could therefore be strengthened as discussed in chapter 4.

3 SITUATION OF NATIONAL TRANSPOSITION MEASURES OF EACH MEMBER STATE

This chapter provides summary country reports for all Member States. Each one is structured to contain information about the three substances and three types of sanction that are the subject of this study:

- a) falsified medicinal products, active substances, excipients
- b) criminal, "civil", administrative sanctions.

Criminal penalties are sanctions such that upon conviction of a crime, a person may for example have to pay a monetary fine and/or spend a period of time in prison. Usually criminal penalties are combined with criminal proceedings against natural persons.

Civil penalties are financial sanctions of non-criminal nature, which are imposed by public authorities. In some Member States (e.g. Germany) legal persons cannot be prosecuted criminally because a legal person is considered a merely legal construct, incapable of criminal guilt. Consequently, only non-criminal ("civil") fines apply. This further complicates the comparison between the 28 Member States. The maximum fines in this report (criminal and "civil") generally refer only to natural persons.²² Additional information on maximum fines for legal persons, that may or may not be higher than those for natural persons, can be found in the Annex.

Administrative sanctions are levied by an administrative agency responsible for enforcing administrative rules. This may be the suspension of a marketing authorisation, of a manufacturing authorisation, of a licence etc.

Since the legal systems of the Member States vary greatly, the reports are structured around the three substances *or* the three types of sanctions, depending on which approach the legislator of the respective Member State has chosen. It should be noted that, beyond the specific laws and regulations mentioned here, in every Member State general bodily harm or personal injury is always (also) covered by general criminal law and sanctions foreseen there.

More detailed information has been provided to the European Commission on the provision of Art. 118a Directive 2001/83/EC in national language, details on national provisions sanctioning illegal conduct with medicinal products, active substances, and excipients, as well as details on the types of sanctions/penalties applied and the type of authorities involved for each Member State.

3.1 BE – Belgium

In Belgium Directive 2011/62/EU has partially been transposed by the Act of 20th June 2013 amending the Belgian Act of 25th March 1964 on Medicinal Products (*Loi du 25 mars 1964 sur les médicaments*). However, no major changes have been made with regard to the rules on penalties applicable to conduct concerning falsified medicinal products.²³ Thus, the rules on penalties, which were applicable before the transposition act, are still in force.

According to Article 16 § 3 Nr. 3 of the Belgian Act on Medicinal Products the manufacturing of falsified *medicinal products* is punishable by imprisonment of one month to one year and a fine of 200 EUR to 240,000 EUR. It is important to point out, that the defendant must intend to sell, offer for sale, deliver, supply, distribute, import

²² Depending on the expert answers for the Member State, the mentioned fines refer only to legal persons (for example in Slovenia). For further details on this see the country reports and the Annex.

²³ Article 18 of the Belgium Act of 20th June 2013 added infringements of the following three articles to the list of criminal offences in Article 16 of the Belgium Act of 25th March 1964 on Medicinal Products: Article 7ter (implementation of Article 117a of Directive 2001/83/EC), Article 8 (implementation of Article 116 of Directive 2001/83/EC) and Article 12octies (implementation of Article 85b of Directive 2001/83/EC).

or export the falsified product. Furthermore, the same penalty is imposed on anyone, who sells, offers for sale, delivers, supplies, distributes, imports or exports falsified medicinal products. Besides, the mere possession of falsified medicinal products, which are intended to be sold, offered for sale, delivered, supplied, distributed, imported or exported constitutes a criminal offence. In their entirety, the respective criminal offences are set up as endangerment crimes of abstract danger.

According to Article 16ter of the Belgian Act on Medicinal Products the penalties shall be doubled if the offence has led to the death of another person, has affected his physical and mental health, was committed by a person as a medical practitioner, manufacturer or supplier, was committed by using large-scale distribution systems, including the Internet, or if the act was committed in the context of a criminal organization or by a person who was already convicted of similar infringements.

Civil penalties are not applicable for the infringements of the Belgian Act on Medicinal Products. Administrative sanctions, such as the suspension or revocation of licenses, may be imposed in the event of non-compliance with the legal requirements on the holders of wholesale distribution or manufacturing authorizations (Art. 12bis and Art. 12ter of the Belgian Act on Medicinal Products).

3.2 BG – Bulgaria

In Bulgarian law, conduct that involves medicinal products and active substances is almost exclusively addressed via the Bulgarian Medicinal Products in Human Medicine Act (MPHMA). It contains several “civil” penalties (fines) and administrative sanctions in article 272 and 281 till 284c MPHMA i.a. These were amended or introduced in 2012 in view of Directive 2011/62 EU.

Since 2013, manufacturing, import, selling, storing, or providing medicinal products without marketing authorisation i.a. can be sanctioned with fines (“civil” penalties) of up to 50,000 BGN (ca. 25,000 €), see articles 281, 282, 283, 284a, 284b, 284c, 287b, 289, 289a, 290 c, 290 d, 290e, 290 f, 291 MPHMA. Infringements can also lead to revocation of licenses, closing of factories or suspension of practice permits i.a. (administrative sanctions), see article 272, 276, 277, 291, 293 MPHMA.

The legal situation is less regulated regarding active substances. Since 2012 a fine (“civil” penalty) of up to 20,000 BGN (ca. 10,000 €) can be applied to anyone who manufactures, imports, exports, sells or keeps active substances in violation of the MPHMA, see Art. 285b. According to article MPHMA, in case of violation of the rules for Good Manufacturing Practice for active substances the commissioning can be prohibited and the operation of sites and equipment can be stopped (administrative sanctions). Most administrative sanctions only apply to medicinal products (see above). For conduct involving excipients, no “civil” or administrative penalties apply.

No criminal penalties apply to conduct involving (falsified) medicinal products, active substances or excipients as such. Article 228, 231, 232, 324, 350, 354 of the Bulgarian Penal Code (PC) do not apply or apply only under special circumstances:

Art. 228 PC addresses “the production of low-quality products”, but only “managers or control bodies” are capable of committing that crime. This means that, according to our expert, only the production of illegal or falsified medicinal products within the legal supply chain is covered. This is also the case of art. 324 PC, which covers practicing a profession or a craft without the respective capacity within the legal supply chain. Art. 231 PC covers offering for sale false or low quality “industrial commodities”, but that does not encompass medicinal products.

Art. 232 PC covers cheating buyers with falsified commodities, which might cover manufacturing and selling falsified medicinal products. Yet “cheating buyers” might be hard to prove in the individual case (a concrete buyer has to be cheated) or not be the case at all, when falsified medicinal products are apprehended before they are sold. Art. 350 PC also does not apply, because pharmaceuticals/medicinal products are not products/foodstuffs in Bulgarian Law. Lastly, art. 354 PC contains an offence associated with the regime of highly active or poisonous substances, which are not narcotic substances and therefore could cover medicinal products. However, the

substances concerned by this provision are not destined for human consumption. The article contains an offence against the environment and not against public health; (falsified) medicinal products or active substances are therefore not covered by this provision. In conclusion: in Bulgarian Law, falsifying a medicinal product or distributing falsified medicinal products etc. is by itself not a crime. This lack of simple abstract endangerment crimes substantially raises the burden of proof for the prosecution.

However, art. 234a applies to export and import of (falsified) medicinal products: Whosoever carries out foreign trade activity without permit required by the law or by a decree of the Council of Ministers or in violation of such issued permit shall be punished by imprisonment of up to five years, a fine of 5,000 to 10,000 BGN and revoking of rights (...). Article 242 PC might also apply. This provision penalizes concealing commodities from customs and other cross border conducts against the customs regime that can entail export and import of medicinal products under special circumstances (repeated infringement, using falsified documents etc.).

3.3 CZ- Czech Republic

The legislator of the Czech Republic amended the Czech Act on Pharmaceuticals (Act. no. 378/2007 Coll.) by Act. no. 70/2013 Coll. from 19th February 2013, entered into force on 2nd April 2013 to transpose Art. 118a of Directive 2001/83/EC. However, the introduced provisions only cover "civil" and administrative sanctions.

While in the Czech Republic a dedicated criminal law explicitly referring to the conduct with medicinal products does not exist the unlawfully conduct with (falsified) medicinal products has to be covered by "general" regulations, such as Sec. 251 Czech Criminal Code (CC) (Unauthorised business activity: imprisonment of up to two years or injunction), Sec. 156 CC (Endangering public health through defective foodstuffs and other products: imprisonment of up to two years, injunction, confiscation of property or pecuniary penalty) or Sec. 268 CC (Violation of trademark rights: imprisonment of up to two years, injunction, pecuniary penalty or forfeiture of assets). These penalties are set up as generally effective and easy to enforce endangerment crimes of abstract danger.

With view to "civil" penalties, the core provisions imposing fines are Sec. 107 and 108 Act on Pharmaceuticals – Act. no. 378/2007, which are both transposition measures. According to them natural or legal persons – also acting as entrepreneurs – are committing an administrative offence if they place on the market falsified medicinal products, Sec. 103 (1) c), 108 (8) Act on Pharmaceuticals – Act. no. 378/2007 and can be fined up to 20,000,000 CZK (775,000 EUR). Other "civil" sanctions relate to distributors if they fail to verify the safety features of outer packages of medical products to prove that they are not falsified (Sec. 105 (2) m): fine up to 2,000,000 CZK = 77,400 EUR) or manufacturers if they fail to observe the manufacturing authorisation or rules of Good Manufacturing Practice in the quality control of medicinal products, active substances, excipients, intermediate products or packaging, Sec. 104 (3).

Furthermore, administrative measures have been introduced into the Czech Act on Pharmaceuticals, Sec. 108 a), b). These concern the possibility of confiscation and forfeiture of medicinal products which are connected with an offense. Other administrative sanctions are the suspension or revocation of marketing authorisation, Sec. 34 (4), and trading authorisations also with regard to unlawful conduct with active substances and excipients, see Sec. 101 (5) a), b) in conjunction with Sec. 64 l), m), p, 76, 77 Act on Pharmaceuticals.

3.4 DK – Denmark

In Denmark all types of conduct referring to falsified medicinal products are regulated by the Danish Medicines Act (DMA), consolidated Act no. 506 of 20th April 2013.

One key criminal law provision is § 38a DMA prohibiting – as an endangerment crime of abstract danger – any manufacture, import, export, storage, distribution, brokering

or dispensing of *falsified medicinal products*. According to § 104 DMA the punishment is a fine or imprisonment up to 18 month. Further punishment is imposed on a person holding an authorisation to manufacture or distribute medicinal products but does not immediately inform the competent authority and the marketing authorisation holder of the medicinal product in case of information that a medicinal product he manufactures or distributes is, or may have been, falsified, § 42 subsec. 1, 2 DMA in conjunction with § 104 DMA.

“Civil” penalties and administrative sanctions are also laid down in the Danish Medicines Act. The Danish Medicines Agency can, for example, prohibit the sale and dispensing of a medicinal product and order that the product should be withdrawn from the market if the qualitative or quantitative composition of the medicinal product is not as declared, § 46 subsec. 1 iii DMA, or if there are indications that the medicinal product presents a serious risk to public health, § 46 subsec. 1 vii DMA. However, a failure to comply with a mandatory injunction from the Danish Medicines Agency (§§ 46, 46a DMA) is a criminal offence and the action is subject to a criminal penalty pursuant to § 104 DMA.

With view to Danish legislation regarding criminal activities with *active substances* provisions are laid down in the Danish Medicines Act and the Executive Orders no. 1358 and 1360 of 18th December 2012.

According to § 50a subsec. 1 DMA manufacturing, import and distribution of active substances intended for use in the manufacture of medicinal products for human use, and which are covered by a marketing authorisation, must only be permitted for persons having registered their company with the Danish Medicines Agency. Infringements are punished with a criminal penalty, § 104 subsec. 1 DMA (fine or imprisonment up to four months).

Besides, an obligation of holders of a manufacturing authorisation exists to inform the competent authority in a case of suspected falsified active substances, § 50d DMA. Again, § 104 subsec. 1 DMA imposes a fine or imprisonment up to four months.

“Civil” penalties and administrative sanctions are possible, but as with medicinal products most infringements of rules are criminal offences subject to a criminal penalty pursuant to § 104 DMA. § 10 subsec. 1 iii Executive Order no. 1358 obliges manufacturers to ensure) that active substances are used in compliance with Good Manufacturing Practice (GMP) and distributed in compliance with Good Distribution Practice (GDP). Infringements can lead to fines pursuant to § 46 subsec. 1 Executive Order no. 1358.

According to *excipients* rules are laid down in the Danish Medicines Act (see § 39b) and the Executive Order no. 1358 of the 18th December 2012 on Manufacture and Import of Medicinal Products and Intermediate Products (which contains excipients, § 2 subsec. 2 DMA). § 39 DMA states that any manufacture, import, export, storage, distribution and providing of intermediate products intended for further processing into medicinal products is subject to authorisation from the Danish Medicines Agency. Infringements are punishable as criminal offences according to § 104 subsec. 2 DMA with a fine or imprisonment for up to 18 months. As for active substances manufacturers processing excipients have to comply with rules of GMP underpinned by sanctions.

3.5 DE – Germany

In Germany amendments were made to the German Medicinal Products Act (“Arzneimittelgesetz” – AMG) to transpose Art. 118a Directive 2001/83/EC. The amending law was of 19th October 2012 and resulted in transposition measures regarding criminal penalties, “civil” penalties, and administrative sanctions.

The German legislator decided to locate criminal law provisions regarding the conduct with (falsified) medicinal products mainly not in the core criminal law, the German Criminal Code (“Strafgesetzbuch”), but in supplementary penal provisions, the Medicinal Products Act (AMG), and set up provisions requiring an *abstract endangerment*. According to § 8 subsec. 2 AMG (transposition measure) it is

prohibited to manufacture falsified medicinal products, to put them on the market or to trade them in another way. The same applies to medicinal products, which by deviating from recognized pharmaceutical rules, are of considerably reduced quality, § 8 subsec. 1 no. 1 AMG, and those which bear misleading names, specifications or presentations, § 8 subsec. 1 no. 2 AMG. § 73 subsec. 1b, sent. 1 AMG constitutes the prohibition to introduce falsified medicinal products to Germany. The legal consequences of infringements arise from § 96 no. 3, 18e AMG (fine or imprisonment up to one year) and § 95 subsec. 1 no. 3a AMG (fine or imprisonment up to three years). Aggravating factors like endangering the health of a large number of persons or a considerable pecuniary gain are listed in § 95 subsec. 3 no. 1 lit. a, b. The punishment in these cases is imprisonment of one to ten years.

Apart from the presented key criminal provisions, the Medicinal Products Act (AMG) contains a tremendous number of additional penal provisions which are mostly not only composed of references to other provisions of the AMG but of references to executive orders; these regulations are partly a blanket and referring back to the AMG. Such chains of referring lead to an unclear complexity that confuses law enforcement authorities – prosecution tends to focus on more “common” provisions like fraud and IP-related crimes – and even courts²⁴ and is at the edge of being an infringement of the constitution because of violating the principle of legal certainty (“*nullum crimen sine lege*”)²⁵ founding in Art. 103 subsec. 2 German Constitution (“Grundgesetz”) and in Art. 7 subsec. 1, sent. 2 ECHR, too.

In addition to the criminal law provisions in the Medicinal Products Act one provision of the core criminal law is applicable to the conduct with falsified medicinal products: § 314 subsec. 1 no. 2 Criminal Code (“Causing a common danger by poisoning”) punishes a person with imprisonment from one to ten years if he poisons or releases noxious substances into objects intended for public sale or use or sells, offers for sale or otherwise distributes poisoned objects or those into which noxious substances have been released. Generally, the provision is held applicable to medicinal products²⁶ and aggravating factors increase punishment considerably: causing the death of another person by at least gross negligence leads to imprisonment for life or not less than ten years.

Negligently committing § 96 no. 3 AMG is an administrative offense resulting in a fine – as a “civil” penalty – of up to 25,000 EUR, § 97 subsec. 1 no. 1 AMG. § 97 subsec. 2 AMG lists more than 30 additional administrative offenses that lead to the mentioned “civil” penalty, e.g. the infringement of the obligation to notify authorities or to submit a report.

Administrative sanctions are recorded in the Medicinal Products Act, too, e.g. a manufacturing authorisation can be withdrawn or suspended according to § 18 subsec. 1 AMG.

In view of *active substances* the same criminal law provisions of the Medicinal Products Act as for (falsified) medicinal products are applicable as well as the mentioned aggravating factors.

According to administrative sanctions the provisions for medicinal products are often applicable too, e.g. § 20a AMG states that the rules for revoking or suspending a manufacturing licence are applicable also to active substances.

With view to *excipients* (in German law rarely translated to “Hilfsstoff” but more often to “Arzneiträgerstoff”) these are neither covered by the protection of the core criminal

²⁴ See for example the mistakes in the application of the German Medicinal Products Act by the LG Potsdam in BGH, Beschl. V. 27.4.2016 – 1 StR 448/15.

²⁵ Sinn. Risiken und Nebenwirkungen bei Arzneimittelkriminalität, in: Zoche, Peter / Kaufmann, Stefan / Arnold, Harald (Ed.). Grenzenlose Sicherheit? Gesellschaftliche Dimensionen der Sicherheitsforschung, LIV-Verlag, 2016, p. 216 ff.

²⁶ Lackner, Karl / Kühl, Kristian. Strafgesetzbuch, Beck, 28th Ed. 2014, § 314, recital 2; Heine, Günter / Bosch, Nikolaus, in: Schönke, Adolf / Schröder, Horst (Ed.), Strafgesetzbuch, Beck, 29th Ed. 2014, § 314, recital 6 with further references.

law provisions of the Medicinal Products Act (§§ 95, 96 AMG) nor by explicitly provided civil or administrative sanctions established by this act or by the German Ordinance on the Production of Medicinal Products and Active Substances ("Arzneimittel- und Wirkstoffherstellungsverordnung" – AMWHV).

3.6 EE – Estonia

In 2014, the Estonian legislator introduced § 194 into the Estonian Penal Code (PC) in order to transpose Art. 118a of Directive 2001/83 EC. According to this provision, illegal moving of *medicinal products* across a state border with the intention of trafficking thereof, possession of counterfeit²⁷ medicinal products with the intention of manufacture, production, marketing, supply, mediation or trafficking thereof, is punishable by a pecuniary punishment or up to three years' imprisonment. The illegal manufacture of medicinal products that are not "counterfeit" (falsified) is not covered by § 194 PC, but by § 372-2 PC.

The criminal penalty of § 372-2 PC, that predates Directive 2011/62 EU, applies when activities in a field relating to health services are exercised without a required activity license. It therefore covers unauthorised manufacturing, sale and other conduct involving medicinal products, since they require an activity license, and punishes such activity by a pecuniary penalty or up to three years imprisonment.

The Estonian criminal law on medicinal products therefore consists of typical abstract endangerment crimes (§ 372 PC) and the rather untypical penalization of possession (abstract endangerment) etc. *with intent* to manufacture etc. (§ 194 PC).

Additional "civil" and administrative sanctions are regulated in the Medicinal Product Act (MPA). This statute has been changed profoundly since 2014, but only § 101 MPA was changed as a direct transposition measure of Directive 2011/62 EU:

According to § 104 MPA, a violation of the requirements for handling medicinal products or the brokering requirements provided for in subsection 26 (82) of the MPA is penalized with a fine of up to 300 fine units (1 fine unit equals 4 € = 1,200 €). Administrative sanctions consist of suspension/and or termination of sales and dispensing of medicinal products if they might be falsified or dangerous etc., § 101 MPA. This can result in an administrative fine of up to 9,600 Euros for natural persons, § 102 MPA.²⁸ Additionally, the criminal code contains sanctions that can be considered "administrative" in their effect, see for example occupational bans (§ 49 PC). Regarding active substances, all mentioned provisions of the MPA apply, see § 5 MPA. This means that "civil" sanctions (§ 104 MPA) and administrative sanctions (§ 101 MPA) cover active substances as well. The criminal offence in § 194 PC covers only medicinal products. On the other hand, § 372 PC addresses activity without a license more generally and therefore extends to activity with active substances without a license. No provisions cover excipients as such. Yet, requirements of the quality of the excipient are established by the manufacturer of the medicinal product who is also responsible for the correct use of the excipient. In case of a manufacturing violation involving excipients, administrative sanctions according to § 101 MPA might apply.

3.7 IE – Ireland

In 2013, the Irish legislator introduced several new provisions, in order to transpose Art. 118a of Directive 2001/83/EC. Among them the most significant change was the introduction of criminal penalties through the Medicinal Products (Control of Manufacture) (Amendment) Regulations 2013, the Medicinal Products (Control of Wholesale Distribution) (Amendment) Regulations 2013 and the Medicinal Products (Control of Placing on the Market) (Amendment) Regulations 2013.

²⁷ This terminology does not restrict the provision to intellectual property crimes according to the expert opinion.

²⁸ For legal persons, a fine of up to 32,000 € can apply.

According to these provisions – inter alia – the manufacture, the distribution, the placing on the market, placing into circulation, introduction into the State, sale or supply, the import, the export and the brokering or sale by wholesale of a medicinal product is forbidden, if the relevant person knows, or there are sufficient grounds to suspect, that the product in question is a falsified medicinal product [Regulation 14B of the Medicinal Products (Control of Manufacture) Regulations 2007, Regulation 14B of the Medicinal Products (Control of Wholesale Distribution) Regulations 2007 and Regulation 39 of the Medicinal Products (Control of Placing on the Market) Regulations 2007]. According to Sec 32 (4) of the Irish Medicines Board Acts a person who contravenes the abovementioned regulations shall be guilty of an offence. The penalties depend on the kind of conviction (summary conviction or conviction on indictment). However, the maximum penalty is a fine of 120,000 euros (300,000 Euros in the case of a repetitive offence) and imprisonment of ten years. The same penalty regime applies to the unlawful manufacture, distribution, import and export of active substances [Regulation 14C and Regulation 14D of the Medicinal Products (Control of Manufacture) Regulations 2007, as amended by the Medicinal Products (Control of Manufacture) Regulations 2013]. Furthermore, the unlawful use of excipients in a medicinal product or in the manufacture of a medicinal product constitutes a criminal offence and is punished with the same penalties [Regulation 14 B (2) of the Medicinal Products (Control of Manufacture) Regulations 2007, as amended by the Medicinal Products (Control of Manufacture) (Amendment) Regulations 2013 in conjunction with Sec 32 (4) of the Irish Medicines Board Acts].

In their entirety, the respective criminal offences are set up as endangerment crimes of abstract danger. As a result, the regulations can be enforced easily, for there is no need for the prosecution to prove any concrete danger or harm caused by the defendant's conduct.

The Irish legislator does not provide civil penalties. In addition to criminal sanctions, the Irish legislature also provides administrative sanctions. These regulate, in particular, the authorisation procedure for the marketing of medicinal products and see a differentiated possibility of revoking this authorisation in certain individual cases. The regulations do not refer directly to the penal sanctions, but regulate, on a purely administrative level, the conditions for granting and revoking authorisations to deal with medicinal products.

3.8 EL – Greece

For the purpose of transposing Art. 118a of Directive 2001/83/EC, the Greek legislation has adopted the Interministerial Decision No. 3221, which entered into force on 29th April 2013. The law contains "civil" penalties as well as administrative sanctions but does not provide criminal penalties itself. However, Art. 175 (3) c) sent. 2 of the Interministerial Decision Nr. 32221/29.4.2013 clarifies that offenders handling falsified medicinal products or failing to comply with the Ministerial Decision's regulation regarding active substances and excipients are also subject to the sentences of Art. 281 of the Greek Penal Code.

According to Art. 281 (1) of the Greek Penal Code the manufacturing, processing and placing on the market of food, beverages, medicines or other objects whose use can cause harm to health or danger to human life is punished by imprisonment of at least three months. Therefore the criminal offences are set up as endangerment crimes of abstract-concrete danger. On the basis of this fact, higher requirements are placed on dangerous behaviour.

Pursuant to Art. 175 (3) a) to c) of the Interministerial Decision Nr. 32221/29.4.2013 "civil" penalties apply to the conduct with falsified medicinal products, active substances and excipients. The manufacturing, distribution, brokering, import, export, and the online sale of falsified medicinal products are subject to an administrative fine ("civil" penalty) of up to 100,000 EUR. The same applies to the production, distribution, import and export of active substances and the use of excipients being not in compliance with the rules of the Interministerial Decision.

As a transposition measure the Interministerial Decision Nr. 32221/29.4.2013 also contains administrative sanctions. These arrangements include the possibility of suspending, revoking or amending a marketing authorisation, provided that harmfulness, a lack of therapeutic efficacy or a discrepancy between the declared and the actual qualitative and quantitative composition of a medicinal product is found, Art. 168. Under similar conditions a withdrawal from the market is possible pursuant to Art. 169.

3.9 ES – Spain

Spanish legislation on medicinal products, active substances and excipients follows a sanction-based approach. The Penal Code (PC) contains all applicable criminal penalties, while the Royal Legislative Decree 1/2015 (RLD 2015) contains “civil” penalties and administrative sanctions. While the criminal code was changed in accordance to the Medicrime Convention, the RLD was changed following article 118a of Directive 2001/83 EC.

The Spanish Penal Code provides for a rather detailed regulation on offences starting with article 362 PC. These criminal penalties apply equally to medicinal products, active substances and excipients. Anyone who imports, exports, announces or advertises, offers, exhibits, sells, facilitates, expends, sends, packages, supplies etc. falsified medicinal products, active substances or excipients can be punished with up to four years of imprisonment. In case of medicinal products that are not falsified (or when it cannot be proven that they are falsified), these conducts can be punished with up to three years imprisonment if the required authorisation was not given (art. 361 PC). However, the Spanish criminal law requires that these conducts must have caused danger to the health or life of people (or public health). This form of offence is an unusual crime of concrete endangerment. A concrete causation of danger must be proven by the state (prosecution), which heightens the burden of proof problematically. However, the danger must not be caused to an individual person, but to several persons or “public health”. This abstract object (public health) of the offence lowers the burden of proof for the prosecution. It might be that no single instance of danger to health/life of one concrete person must be proven. In that case the provisions of the Spanish criminal law on falsified medicinal products, active substances and excipients (art. 362 etc PC) or unauthorised conduct with medicinal products (art. 361 PC) would be equivalent to abstract-concrete endangerment crimes. A final assessment on this point could not be made in the timeframe of this study. Therefore, Spain is mentioned as a country with only concrete endangerment crimes since it remained unclear whether the criminal law provisions have to be interpreted as abstract-concrete endangerment crimes, that is, how high the burden of proof for the prosecution is.

Regarding “civil” penalties and administrative sanctions, the regulations are rather detailed as well. Starting with article 111 RLD 2015, manufacturing, importing, exporting, distributing and selling etc. falsified medicinal products or manufacturing, importing, exporting, distributing etc. medicinal products or active substances without authorisation, can be fined with up to 1,000,000 € and sanctioned with suspension and revocation of licenses etc. Additional administrative sanctions are provided in article 15 Royal Decree 782/2013 (revocation of authorisation etc.). Failure by the manufacturer of the medicinal products to fulfil obligations relating to excipients used in the manufacture of medicinal products can be fined and sanctioned by revocation of licenses etc. (see article 111 paragraph 2 b (34) RLD 2015).

3.10 FR – France

In 2013 the French legislator has introduced several new provisions into the *Code de la santé publique* in order to transpose Art. 118a of Directive 2001/83 EC.

The most significant transposition measure has been the introduction of criminal penalties through Art. L5421-13 Code la santé publique. According to this provision the manufacture, trading, distribution, advertising, offering for sale, selling, importing

and exporting of falsified medicinal products is punishable by imprisonment of up to five years and a fine of 375,000 euro. The same penalty applies to such conduct involving falsified active substances and excipients (Art. L 5438-4 Code de la santé publique). These criminal offences are set up as endangerment crimes of abstract danger. Therefore, the regulations can be enforced easily, because there is no need for the prosecution to prove any concrete danger or harm caused by the defendant's conduct.

An increased penalty of seven years' imprisonment and a fine of 750,000 euro may be imposed, if the product is dangerous to human health, the act was committed by authorised manufacturers, importers, and retailers or by an organized group or if the offense was committed on a telecommunications network intended for an indefinite public, such as the internet.

Besides, the fact for manufacturers, importers, and distributors of active substances, of not complying with the good manufacturing practices is sanctioned by civil penalties (Article L5438-1 Code de la santé publique).

3.11 HR – Croatia

The Croatian legislator introduced criminal and "civil" penalties as well as administrative sanctions to transpose Art. 118a of Directive 2001/83/EC. The amendments related mainly to Section XIX of the Croatian Criminal Code, dealing with criminal offences against people's health, and to the Croatian Medicinal Products Act.

Both Codices are applicable to criminal penalties whereas for civil penalties and administrative sanctions the Croatian Medicinal Product Act is relevant.

Regarding criminal penalties, Art. 185 of the Croatian Criminal Code is the key provision imposing – as an provision of abstract danger – imprisonment from six months to five years in the case of manufacturing, offering to procure, storing, export, import and putting on the market falsified medicinal products, active substances or excipients (subsec. 1, 2). Aggravating factors like acting by way of abusing trust someone enjoys as an expert, manufacturer or supplier, or committing an offence via services for mass distribution such as information society services including Internet result in imprisonment of one up to eight years (subsec. 5).

A distinctive feature also introduced by Art. 118a of Directive 2001/ 83 EC is the responsibility of legal persons for criminal offences: Art. 15 and Art. 8 of the Croatian Act on the Responsibility of Legal Persons contain fines and – with an administrative sanctioning effect – the termination of the legal person and security measures like a ban on performance of certain activities or transactions, concessions or subventions, etc.

"Civil" penalties are primarily an imposition of a certain fine (Art. 226 Croatian Medicinal Product Act: 100,000 HRK to 150,000 HRK) and are connected to an enumeration of conducts (see Art. 226, 227 of the Croatian Medicinal Product Act).

Administrative sanctions mainly exist as withdrawal of marketing authorisations. These measures ensue thoroughly from transposing the Directive. For medicinal products, active substances and excipients different provisions address the different types of infringements mentioned in the Directive.

3.12 IT – Italy

The Italian legislator introduced important changes to the law on medicinal products, active substances and excipients as early as 2006. Since then, in addition to the Italian Penal Code (PC), sanctions for infringements of medicinal product law can be found in the legislative decree 219/2006 (LD 219/2006). Some minor changes of LD 219/2006 occurred in 2014 in view of Directive 2011/62 EU.

Regarding unlawful conduct with medicinal products, Italian law follows a twofold approach. The manufacture, sale and distribution of falsified or adulterated medicinal products is criminally punishable with imprisonment ranging from four to 12 years, but

only if those medicinal products are dangerous to public health, see art. 440-3, Art. 64 PC. Dangerousness and "falsified or adulterated" are elements of the crime. The element of dangerousness makes this a crime of abstract-concrete endangerment. If the medicinal products are not dangerous to public health (or the dangerousness cannot be proven) the more than seven paragraphs of article 147 LD 219/2006 apply (and none of the articles of the PC)²⁹. According to art. 147-7bis LD 219/2006 to produce, distribute, import, export, trade and sell falsified medicinal products is punishable with imprisonment ranging from one to three years and a fine ranging from 2,600 euro to 100,000 euro. For activity involving medicinal products that are not falsified or adulterated (or when this cannot be proven) article 147 LD 219/2006 contains criminal law provisions that cover, inter alia, manufacturing medicinal products without a license or trading and distributing unauthorised medicinal products, see art. 147-1, art. 147-2, art. 147-4 etc. An extraordinary feature of Italian law is the specific criminalization of selling medicinal products via the Internet without authorisation, see art. 147-4ter LD 219/2006. Without exception, the crimes in article 147 do not require "dangerousness", which makes them crimes of abstract endangerment. The decrease in dangerousness (or burden of proving the dangerousness) of these offences corresponds with the considerably lower penalties: the maximum criminal penalty according to article 147 LD 219/2006 is three years imprisonment, while the maximum penalty of art. 440-3 PC is 12 years imprisonment.

Non-criminal fines ("civil" penalties) apply according to article 148 LD 219/2006, that stipulates that infringements of medicinal product law can be "administratively" fined, with the maximum amount ranging from 1,800 € up to 180,000 €. Administrative sanctions are provided for in detail by LD 219/2006 and encompass, inter alia, suspension of practice authorisation, closure of pharmacies or point of sales, see art. 144, 148 LD 219/2006. Unlawful activity involving *active substances* is less strictly regulated.³⁰ Art. 147-1 and art. 147-1bis LD 219/2006 cover unlawful activity with active substances, for example manufacturing or importing active substances without authorisation or infringing quality requirements, punished with imprisonment ranging from 6 months to 1 year and a fine ranging from € 10.000 to € 100.000. "Civil" penalties for unlawful activity with active substances apply according to art. 148-3ter and 148-13 LD 219/2006 and reach the amount of 18,000 €. Administrative sanctions entail revocation of manufacturing authorisations and withdrawal/seizure of active substances from the market, see art. 142, 146 LD 219/2006. The falsification of excipients as such is not criminally punishable. However, "civil" penalties apply. The producers of excipients who do not fulfil the requirements of the Legislative Decree no. 219/2006 can be sanctioned with a fine of up to 50,000 €. The only administrative sanctions applicable to excipients are for unlawful production.

3.13 CY – Cyprus

In 2001 the legislator of Cyprus introduced Art. 99 (1) Law Nr. 70 (1) ("Law on medicines for Human Use (Quality, Distribution and Prices Control)") which was amended by Art. 25 Law Nr. 209 (I) in 2012, entering into force on 2nd January 2013. This amendment happened in order to transpose Art. 118a of Directive 2001/83/EC by adding criminal penalties referring to falsified medicinal products (Art. 99 (1) d) Law Nr. 70 (1)), whereas before the referring point for criminal liability was limited to generally unauthorised conduct with medicinal products (Art. 99 (1) a) to c) Law Nr. 70 (1)). The subsequent Law Nr. 209 (I) of 2014 updated this legislation only partially regarding the sale of medicines to the public at a distance.

According to Art. 99 (1) a) to c) Law Nr. 70 (1) the release, manufacture, import or the wholesale of a medicinal product contrary to law is punished with imprisonment of up to five years or / and to a fine of up to 50,000 CYP (\approx 85,000 EUR). The same penalty is imposed on each person who manufactures, distributes, brokers, imports

²⁹ As an exception, article 443 PC (withholding for trade, placing on the market or administering spoiled or imperfect pharmaceuticals) also applies. This provision does not require dangerousness, which results in a considerably lower penalty of six months to three years imprisonment.

³⁰ The criminal penalties provided for by the Italian Penal Code do not apply.

and exports a falsified medicinal product, including the sale to the public through information society services, Art. 99 (1) d) Law Nr. 70 (1). Article 100 Law Nr. 70 (1) of 2001 provides criminal responsibility in case of legal persons.

Furthermore, it is a misdemeanour under Art. 236 f Cypriot Penal Code to manufacture, supply, sell or dispense or deliver a medicinal product or a poisonous or dangerous substance in such a thoughtless manner if this acts endanger human life and health.

According to Article 41B (transposition measure) in conjunction with Art. 97 Paragr. 2b and 2c Law Nr. 70 (1) of 2001 the manufacturing, distribution and import of active substances without license is sanctioned with an administrative ("civil") fine of up to 25,000 CYP (\approx 42,000 EUR) and / or an administrative ("civil") fine of up to 200 CYP (\approx 342 EUR) for each day the offense continues.

Administrative sanctions, such as the confiscation of medicinal products and the withdrawal of a manufacturing authorisation, are also provided, see Art. 53 Law Nr. 70 (1) of 2001.

Art. 97 Law Nr. 70 (1) of 2001 provides for civil penalties for the violation of Art. 41 (θ), which relates to the misconduct of excipients. Specifically, Art. 97 provides for fines of up to 42,000 EUR which may be increased up to 342 EUR for each day for which the violation continues.

3.14 LV – Latvia

The Latvian legislator introduced substantial changes to the Latvian Pharmaceutical Law (PL) in view of Directive 2011/62 EU. Unlawful conduct involving medicinal products and active substances is sanctioned in accordance with the PL, the Administrative Violations Code (AVC, "civil" penalties) and, rarely, the Criminal Code (CC, criminal penalties).

The transposition measures regarding article 118a of Directive 2001/83 EC did not affect any criminal law provisions. Latvian law still does not lay out any specific criminal penalties for conduct involving medicinal products. According to articles 202, 205, 207 and 208 CC certain activity without a required license (manufacture of products, trading, entrepreneurial engagements etc.) is punishable with imprisonment of up to three years, but only when this activity has resulted in harm.³¹ This element of crime is difficult to prove. The applicable criminal law provisions are neither abstract nor abstract-concrete endangerment crimes, but "harm-crimes", requiring proof that the conduct was the cause of physical harm or death. This element of crime is extremely difficult to prove in the case of pharmaceutical crime.³² The Latvian criminal law provisions are therefore very difficult to apply.³³

The newly introduced "civil" penalties according to article 46-1, 46-2 and 46-3 AVC apply in case of violations of the PL such as manufacture of medicinal products without a license, distribution without a license etc. A fine of up to 700 € can be imposed to natural persons. Administrative sanctions are mostly regulated by the PL. According to article 31 and 65 PL (inter alia) authorisations can be revoked and activities (manufacture, distribution etc.) suspended. In the case of a (unlikely) criminal conviction, articles 36 and 70 CC contain sanctions on the administrative level such as restriction of rights. A special feature of Latvian law referring to active substances is

³¹ In case of article 208 CC harm is not an element of the crime, but the activity has to be entrepreneurial and against "special prohibitions", which only rarely applies (activity with medicinal products is not specially prohibited).

³² See on the difficulty to prove that the cause of death or health damage was a falsified medicinal product, Venhuis u.a. Identification of health damage caused by Medicrime 2013, p. 10 onwards.

³³ Some criminal law provisions might apply in case of certain types of medicinal products, see art. 248 CC, but according to our experts this is rarely the case.

the applicable “civil” penalty. While most unlawful conduct involving active substances cannot be sanctioned with a fine, the manufacture, export, import and distribution of falsified active substances shall be fined with up to 700 € (for natural persons), see art. 46-1 AVC. Administrative sanctions for unlawful conduct with active substances are provided in article 65 PL (suspension of activity etc.) and, if applicable, art. 36 and 70 CC. There are no sanctions for unlawful conduct with excipients. However, if the excipients are precursors of psychotropic substances, a fine of up to 700 € (for natural persons), may be imposed, see art. 46-1 AVC.

3.15 LT – Lithuania

The Lithuanian legislator introduced several new provisions on non-criminal fines (“civil” penalties) and administrative sanctions that came into force January 2017. Criminal penalties were unaltered by these measures: Manufacturing or handling medicines or medicinal substances without an authorisation continues to be criminally punishable with two years imprisonment according to Art. 275-1 of the Lithuanian Criminal Code (CC), if these medicines could have posed a threat to human health or life. Since the law does not require that any concrete danger was caused, but only that the substances could have posed a threat to human health or life, this typification represents a crime of abstract-concrete endangerment. A special feature of Lithuanian law is that manufacturing medicinal products is only punishable when done with the purpose of handling them, see art. 275-1 CC. The term “handling” is very broad and designed to cover distribution, sale and export. Aggravating factors like a person’s death or a serious impairment to a person’s health result in imprisonment of up to eight years, art. 275-1 (2) CC. Since manufacturing and trading with medicinal products requires a license according to the Lithuanian Law on Pharmacy (LP), article 202 CC applies as well: This provision punishes activity without a required license with imprisonment of up to four years if the additional element of the crime, “large-scale economic activity”, is met.

The “civil” sanctions, newly amended in view of article 118a of Directive 2001/83 EC, are found in article 62 onwards of the Lithuanian Administrative Offences Code (AOC). They now cover unauthorised manufacture, distribution, sale, export, import and brokerage of (falsified) medicinal products, inter alia, in a rather detailed way. The fines can reach up to 1,200 € (in special circumstances such as mass production they can reach higher, see article 66 AOC, e.g.). Administrative sanctions are found mainly in article 23 LP and cover suspension of licenses inter alia.

The sanctioning of unlawful conduct with active substances differs from that of medicinal products. Since authorisation is required, the criminal penalties of article 275 and 202 CC could apply where active substances are manufactured or handled without a license. However, “medicinal substances” (art. 275 CC) do not *per definitionem* cover active substances and article 202 CC requires an economic activity of a large scale. Therefore criminal penalties can only apply in special cases. “Civil” penalties for unlawful conduct involving active substances are less detailed than in case of medicinal products but apply specifically to unlawful manufacture, distribution as well as import and distribution to export of active substances, see art. 66-5 AOC. Administrative sanctions for unlawful conduct with active substances are applied according to the articles 23 onwards of the LP and include revocation and/or suspension of licenses for manufacturing and wholesale etc. In case of excipients, the only existing penalty is an administrative sanction, when the good practice requirements of article 24-1 of the LP are not met. They cover revocation and suspension of licenses.

3.16 LU – Luxembourg

In Luxembourg, the penalties applicable to unlawful conduct involving medicinal products, active substances and excipients are regulated in different statutes and decrees [Law on Manufacture and Import of Medicines (1975), respective decree (2004), Law on Regulation of Putting on the Market and Advertising Medicines (1983), respective decree (1992), Law on the Wholesale of Medicines (1995), respective

decree (2004) and Law on the Delivery of Medicines to the Public (1975)]. All of these laws were altered from 2014 to 2017.

According to these provisions the manufacture, distribution, import, export and sale at a distance of medicinal products without a license or by infringing applicable rules is punished with a maximum imprisonment term of six months and a fine of up to 25,000 Euros. The same penalties apply to the unlawful manufacture, distribution, import and export of active substances.

Additionally, the Luxembourg law of 1953 (*»Loi du 25 septembre 1953, ayant pour objet la réorganisation du contrôle des denrées alimentaires, boissons et produits usuels«*) applies in many cases of falsified medicinal products and active substances. The penalties range up to 15,000 Euros and one year imprisonment. If the act was dangerous to human health (abstract-concrete danger), it can be punished with imprisonment of up to 5 years and a fine of 20,000 Euros.

The unlawful manufacture, distribution, import and export of excipients can be sanctioned with an imprisonment term of six months and a fine of 10,000 €.

In Luxembourgian law only criminal fines can be implemented: no "civil" penalties exist.

Administrative regulations are also found in each statute/decreed for the above-mentioned infringements and include revocation of licenses etc.

3.17 HU – Hungary

In Hungary, the penalties applicable to conduct involving falsified medicinal products, medicinal products in general and active substances are mostly of criminal nature. In July 2013 the Hungarian legislator has introduced Art. 186 into the Criminal Code. This legislative action did not serve to transpose Art. 118a of Directive 2001/83/EC but to ratify the Council of Europe Convention on the counterfeiting of medical products and similar crimes involving threats to public health³⁴. However, the newly introduced provision provides imprisonment of up to three years for the falsification of medicinal products and active substances and for related conduct, such as the supply, the offering, the placing on the market, the import, the export and the trade in such products. All crimes are of abstract danger and therefore easy to enforce.

Persons who commit these crimes as healthcare employee, as employee of an authorised manufacturer, as wholesaler or public supplier or in criminal association with accomplices are punishable by imprisonment between one to five years. The same penalty shall be imposed if false or falsified medicinal products, or those which have not been authorised in Hungary are widely distributed to users. If the criminal offense results in permanent disability or serious health impairment the penalty shall be imprisonment between one to five years. If it results in death the imprisonment shall be between two to eight years.

Furthermore, the manufacturing or distribution of medicinal products without a license is sanctioned by civil penalties and constitutes a regulatory offense according to Art. 199/A of the Hungarian Act on Regulatory Offences (Act II of 2012). This offence is punishable with fines or community service.

Conduct involving excipients may only be subject to administrative sanctions in Hungary. Act XCV of 2005 on Human Medicinal Products provides administrative sanctions in case a natural or legal person violates the rules of manufacturing or distribution laid down in this Act. These sanctions can be imposed by the National

³⁴ The "Medicrime Convention" has been the first international criminal law instrument to oblige States Parties to criminalise – inter alia – the manufacturing of falsified medical products, supplying, offering to supply and trafficking in falsified medical products, The Convention seeks to fight the dangers to public health caused by the falsification of medical products and similar crimes. It does not seek the protection of Intellectual Property rights.

Public Health and Nutrition Service. In case of repeated infringements or if the violations cause danger to public health, manufacturers' or distributors' licenses can be withdrawn.

3.18 MT – Malta

In 2013, the Maltese legislator has introduced several new provisions into the Malta Medicines Act, in order to transpose Art. 118a of Directive 2001/83/EC. The most relevant change has been the introduction of criminal penalties through Art. 98 of the act.

According to this provision anyone who knowingly or unknowingly sells or supplies, offers or exposes for sale or supply or has in his possession for the purpose of sale or supply adulterated or falsified medicinal products or active substances is subject to the criminal sanctions listed in the blanco type provision in Art. 99 (1) of the Act. The penalty is a fine of not less than 11,646.87 euro and not exceeding 116,468.67 euro or imprisonment for a term not exceeding two years, or both such fine and imprisonment.

The same penalty applies to the unlawful import, manufacturing, wholesale dealing, and brokering in medicinal products (Art. 99 in conjunction with Art. 37 of the Malta Medicines Act).

In their entirety, the respective criminal offences are set up as endangerment crimes of abstract danger. As a result, the regulations can be enforced easily, for there is no need for the prosecution to prove any concrete danger or harm caused by the defendant's conduct.

However, it is important to point out that the penalties applicable to conduct involving falsified medicinal products; medicinal products in general and active substances are exclusively of criminal nature. Civil penalties are not applicable for the infringements of the Malta Medicines Act. Conduct involving excipients is not subject to penalties at all. However, general administrative sanctions may be applicable. Authorisations relating to the manufacture and marketing of medicinal products may be suspended or withdrawn, e.g. if the requirements for the granting of the authorisation are no longer met (Art. 28 and 41 of the Malta Medicines Act).

3.19 NL – Netherlands

In Dutch Law, the criminal law provisions of the Dutch Medicines Act (DMA), the Law on Economic Offences (LEO) and the Penal Code (PC) were not substantially changed since 2012. Article 337 PC contains a criminal penalty of up to one year imprisonment or a fine for importing, transporting, exporting, selling, offering for sale, delivering, making available or having in storage falsified wares and goods. These can include medicinal products, active substances and excipients. In case of general dangerousness of the conduct (abstract-concrete endangerment crime), the maximum penalty is four years, see art. 337 – 4 PC.

In 2013 however amendments to the key provision containing non-criminal fines ("civil" penalties), article 101 DMA, and some administrative sanctions went into force to transpose article 118a of Directive 2001/83 EC. As of now, the DMA prohibits, inter alia, preparing, importing, delivering, exporting or conducting large scale trade without authorisation or to trading unauthorised medicinal products in large scale (article 18). It is also prohibited to prepare, import, deliver, export or trade in active substances without registration (Art. 38). This covers medicinal products as well, if, as usually, they contain active substances. These unlawful activities (crimes of abstract endangerment) can be criminally punished with up to six years imprisonment according to article 1 and 6 LEO and a fine ("civil" penalty) of up to 450,000 € can be imposed according to article 101 DMA. Administrative sanctions include, inter alia, reprimands and suspension of licenses according to the Medical Disciplinary Code and closure of pharmacy and termination of distribution according to article 115 DMA. Excipients are regulated by the DMA as well. In case of a failure to ensure quality of

excipients when manufacturing medicinal products (see art. 27, 27a DMA), a fine of up to 450,000 € applies according to art. 101 DMA.

3.20 AT – Austria

In 2013, the Austrian legislator introduced several new provisions into the Austrian Medicinal Products Act (*Arzneimittelgesetz*) in order to transpose Art. 118a of Directive 2001/83 EC. Among them, the most significant change has been the introduction of criminal penalties through Art. 82b of the Medicinal Products Act.

According to this provision the manufacture of falsified medicinal products, active substances and excipients is punished with imprisonment of up to three years. The same penalty is imposed on anyone who offers to another, obtains, intentionally stockpiles, imports, exports or otherwise provides falsified medicinal products, active substances and excipients. It is important to note that these offences require the perpetrators intent to actually provide these products to someone else.

A person committing such offences as a doctor, dentist, veterinarian, pharmacist, or midwife is subject to imprisonment of up to five years. The same applies to a person committing the offence repeatedly for the purposes of securing a regular income for himself. If the act results in the death of another person or serious injury of a large number of persons, the offender is subject to up to fifteen years' imprisonment.

Furthermore, it is an offence under Art. 82b of the Austrian Medicinal Products Act to wilfully falsify or manipulate packaging or other documentation with the intention that it be used to distribute or make available medicinal products or their active substances. This offence is punishable by imprisonment of up to one year.

In their entirety, the respective criminal offences are set up as endangerment crimes of abstract danger. As a result, the regulations can be enforced easily, for there is no need for the prosecution to prove any concrete danger or harm caused by the defendant's conduct.

Besides, illegal conduct concerning medicinal products is sanctioned by civil penalties ("Verwaltungsübertretungen") and administrative sanctions, which can be found in Articles 83 subsequent of the Austrian Medicinal Products Act and in Art. 21 of the Austrian Medicinal Products Import Act. According to Art. 85 of the Austrian Medicinal Products Act the Federal Office for Safety in Health Care may revoke the authorisation of a medicinal product if the holder has been sanctioned at least three times for an infringement referred to in Articles 83 (1) and (2) and 84 (4), (12), (16) and (21). However, these provisions do not directly refer to falsified medicinal products but may be applicable, e.g. if medicinal products are provided with incorrect or misleading information, Art. 84 (4) in conjunction with Art. 6 of the Austrian Medicinal Products Act.

3.21 PL – Poland

The Polish legislator has introduced several new provisions into the Polish Medicines Act in order to transpose Art. 118a of Directive 2001/83 EC. The most significant transposition measure has been the introduction of criminal penalties through Art. 124b of the Polish Medicines Act (*Prawo farmaceutyczne*). According to this article the manufacture of falsified medicinal products (including excipients) and active substances is punished with a fine, restriction of liberty or imprisonment of up to five years. The same penalty is imposed on anyone who supplies or provides such products, gratuitously or for consideration. Illegal conduct concerning medicinal products and active substances that have not been falsified (such as the manufacturing, distribution and import of products without a license) is sanctioned by other criminal provisions, which can be found in Articles 124 to 127a of the Polish Medicines Act. The maximum penalty for these offences is a two-year prison sentence. In their entirety, the respective criminal offences are set up as endangerment crimes of abstract danger. As a result, the regulations can be enforced easily, for there is no need for the prosecution to prove any concrete danger or harm caused by the defendant's conduct.

Civil penalties, that can be found in Articles 127b subsequent of the Polish Medicines Act, are applicable – inter alia – for the unlawful export of medicinal products (Art. 127b) and the professional use of medicinal products which have either expired or do not comply with statutorily prescribed quality requirements.

Furthermore, several administrative measures have been introduced into the Polish Medicines Act in order to transpose Art. 118a 2001/83 EC (Art. 51g, 51f, Art. 73f, Art. 121 and Art. 122). Worthwhile emphasising is the newly introduced Art. 121 which enables the suspension of the marketing authorisation for medicinal products, if there are reasonable grounds to suspect that a medicinal product does not comply with the requirements set for it, or that a medicinal product has been falsified.

3.22 PT – Portugal

As of 2006, Portuguese Law regulates most unlawful conduct with medicinal products, active substances and excipients according to the Decree-Law 176/2006 (DL 2006). The manufacture, placing on the market, marketing, distribution, intermediation, import, export, parallel importation, dispensing, supply or sale to the public with medicinal products, active substances and excipients without required authorisation or registration, can be sanctioned by a fine between 2,000 € and 15% of the business value of the responsible person or 180,000 € whichever is lower (article 181 paragraph 2 a) DL 2006, introduced by Law 51/2014). The same applies if the above-mentioned activities involve falsified medicinal products. Article 181-A of DL 2006 provides for additional administrative sanctions that include prohibitions to practice and suspension of licenses. The same penalties and sanctions apply to other unlawful conduct according to article 181 paragraph 2 c) onwards DL 2006. The paragraphs 2 a), b), c), d), i) and k) of article 181 DL 2006 were amended by the Portuguese legislator to transpose article 118a of Directive 2001/83 EC in 2013 and 2014, substantially raising the applicable fine (in 2012, the maximum fine was ca. 45,000 €).

Additionally, the article 282 of the Penal Code (PC) and article 23 of the Decree-Law 28/84 (DL 1984) contain criminal law provisions covering falsified substances and some provisions covering fraud with wares/goods. Inter alia, the usage, production, distribution, manufacturing, packaging, exporting, handling, or any other related activity, of falsified substances with medical purposes is punished with one to eight years imprisonment, but only if the conduct creates danger to life or the physical integrity of another person (see article 282 PC). This covers medicinal products, active substances and excipients. The element of crime “causing danger to life/health of another person” makes this offence a case of a crime of concrete endangerment, with a high burden of proof for the prosecution. According to article 23 DL 1984 the manufacture and distribution (inter alia) of falsified substances is punishable imprisonment up to a year and a 100-day fine, without requiring the causation of concrete danger. However, this criminal law provision is designed for fraudulent activities and therefore requires proof of “the intention of deceiving others in a business deal”, which reduces the scope and range of this criminal law provision. It has to be noted that article 23 paragraph 2 DL 1983 contains a criminal penalty for negligent conduct (up to six months imprisonment). Yet, if consumers intentionally buy falsified medicinal products (regularly the case in the illegal market), this provision does not apply since there is no deception/fraud.

3.23 RO – Romania

In Romanian Law, the regulation of sanctions and penalties for unlawful conduct with medicinal products, active substances and excipients remained mostly unchanged in view of article 118a of Directive 2001/83 EC. Preparing, offering or exposing for sale counterfeit³⁵ medicinal products that are harmful to health continues to be punishable with six months to five years imprisonment, art. 357 paragraph 2 Penal Code (PC). Intentionally selling counterfeit, altered or expired medicinal products can be

³⁵ This terminology does not restrict the provision to intellectual property crimes according to the expert opinion.

criminally punished with one to five years' imprisonment, if the medicinal products are harmful to health³⁶ (art. 358 paragraph 3 PC). Since these provisions require (only) the proof that the concrete medicinal products are generally dangerous, they are to be classified as abstract-concrete endangerment crimes. In case of a conviction, the Penal Code allows for banning from certain activities and revocation of licenses etc. (art. 65 onwards PC).

Additional "civil" penalties and administrative sanctions for activities involving medicinal products and active substances are found in article 36, 37, 38 of the Romanian Law on Pharmacy 2008 (LP) and article 875 of the Romanian Law on the Health Reform 2006 (LHR)³⁷, the latter being amended to transpose article 118a of Directive 2001/83. These provisions cover inter alia non-observance of the Rules of Good Practices and operating without a license (fine of up to ca. 6,500 € and closing of the pharmacy) and manufacture, distribution, export, import, supply etc. of medicinal products and/or active substances without required authorisation/registration or infringing regulatory rules (fine of up to ca. 21,800 € and suspension of licenses, closure of the unit etc.). In case of excipients, the non-compliance with Rules of Good Pharmaceutical Practice (especially manufacturing medicinal products with excipients in an unlawful way or distributing excipients in an unlawful way) can trigger a fine of up to ca. 2,200 € and in case of repeated infringement the suspension of the license and the closure of the unit (art. 36 and 37 LP).³⁸

3.24 SI – Slovenia

In Slovenia a new Medicinal Products Act (ZZdr-2) became effective as of 14 March 2014 in order to transpose Art. 118a of Directive 2001/83/EC. While the criminal law has not been amended the Medicinal Products Act set up rules for the manufacturing of medicinal products, active ingredients and excipients (Art. 90 ff.) and contains substantially new provisions of administrative law, among them "civil" penalties.

The legal criminal provisions relevant for conduct with medicinal products do not require a falsified medicinal product nor do they refer to a medicinal product produced contrary to special legal regulations. The decisive factor in Art. 183 Criminal Code-1 (CC-1: "Manufacturing and Trade in Harmful Remedies") as a crime of abstract-concrete danger is that medicines or other medical remedies have to be dangerous to health for manufacturing, selling or otherwise supplying these products to be punishable by law. Premeditated action is sanctioned with imprisonment of up to eight years and aggravating factors like the death of a person increases imprisonment up to 15 years. Furthermore, endangering of human life by means of causing public danger, or by an act capable of causing public danger is sentenced up to five years imprisonment according to Art. 314 (1) CC-1 with further aggravating factors.

Non-criminal fines, understood as "civil" penalties, on legal entities are imposed by Art. 191 Medicinal Products Act for minor offences like failing to fulfil data delivering and communication duties regarding the wholesale of medicinal products (800 EUR to 4,000 EUR) and Art. 192 Medicinal Products Act for major offences, e.g. manufacturing not in accordance with the documentation for marketing authorisation or not in accordance with good manufacturing practice or if the medicinal products has been demonstrated to be inadequate in terms of quality, safety and efficacy (8,000 to 120,000 EUR). These are also transposition measures fully initiated by Art. 118a Directive 2001/83/EC.

Administrative sanctions are stipulated in Art. 173 Medicinal Products Act and are therefore transposition measures, too. Pharmaceutical inspectors can take different measures in the field of medicinal products including prohibition of the performance of the activity due to non-compliance with the prescribed conditions, the prohibition of

³⁶ Or if they (partly) lost their therapeutic efficiency.

³⁷ The only applicable criminal penalty of the LHR is article 874, which covers failure to comply with good practices in clinical studies with medicinal products. This is of little relevance to the subject of this study.

³⁸ This is an expert opinion and not explicitly regulated in the law.

the trade, ordering the destruction of, or recalling certain batches of medicinal products if the inspectors establish that the medicinal product has been falsified (subsec. 1, lit. f). Art. 64 (1) Medicinal Products Act also includes a revocation of the marketing authorisation for medicinal products, if they are harmful or the marketing authorisation holder fails to fulfil the conditions and obligations provided by that law.

According to general rules in the Minor Offences Act-1, Art. 4 (2), the following administrative sanctions could be imposed: confiscation of objects, loss or limitation of the right to fund from the budget of the Republic of Slovenia and budgets of self-governing local communities authorities, and the exclusion from public tender procedures.

Active substances are not subject to dedicated criminal law provisions. But as far as "civil" penalties and administrative sanctions are concerned, Art. 10 Medicinal Products Act states that the provisions on manufacture and import of medicinal products also apply to active ingredients and excipients. Therefore, according to Art. 6 No. 12 in connection with Art. 91 No. 4, Art. 93, Art. 100 f. Medicinal Products Act the rules and guidelines of Good Manufacturing Practice and Good Distribution Practice have to be observed, too. "Civil" penalties of Art. 191 and Art. 192 Medicinal Products Act – both transposition measures – also apply for active substances.

With regard to administrative sanctions the competent authority, Art. 101 (8) Medicinal Product Act, can remove the manufacturer from the register of manufacturers of active substances if a pharmaceutical inspector ascertains that the manufacturer of active substances fails to comply with the requirements, e.g. if manufacturers fail to notify JAZMP and the marketing authorisation holder immediately if they obtain information that active substances are, or are suspected of being, falsified, Art. 100 (2) Medicinal Product Act.

With view to excipients, Art. 10 Medicinal Products Act states that the provisions on manufacture and import of medicinal products also apply to active ingredients and excipients.

3.25 SK – Slovakia

In the Slovak Republic, new legal provisions relevant for the conduct with medicinal products were introduced in the Criminal Code by the Act no. 397/2015 Coll., effective as of 1 January 2016 to transpose Art. 118a Directive 2001/83/EC.

According to the new key criminal provision § 170b Slovak Criminal Code (CC: "Counterfeiting of medicines and medical devices") a person who procures for himself or another person counterfeit medicinal products or who keeps, imports, exports, transfers, offers, or sells such items shall be punishable by imprisonment of up to two years (subsec. 1: crime of abstract danger). Despite the English translation "counterfeit" Slovak legal experts consider the provision applicable for falsified medicinal products. The most aggravating factors are committing the offense by causing serious injury to several persons or the death of more than one person, as a member of a dangerous grouping or to a large extent, § 170b subsec. 5 (a) to (c) CC, resulting in an imprisonment of 10 to 15 years.

Without referring to falsified or counterfeit medicinal products § 170 subsec. 1 (a) CC punishes a person with imprisonment of up to two years if he, even by negligence, causes or increases the danger of endangering the health of a human being by unduly treating medicinal products (aggravating factors similar to § 170b CC). In addition § 170a CC punishes a person for the conduct with medicinal products without authorisation and in a greater extent if he manufactures, imports, exports, transfers, transports, purchases, sells, exchanges, retains or procures medicinal products (imprisonment of one to five years; aggravating factors similar to § 170b CC).

Non-criminal fines, understood as "civil" penalties, are imposed by § 136 and § 138 of the Act on Medicinal Products and Medical Devices (MPA), no. 362/2011 Coll. as effective as of 2 January 2013, which are transposition measures, too. Pursuant to § 138 (1) ak) the holder of an authorisation for the manufacturing of medicinal products for human use commits an administrative offense, if he violates the obligation to

inform the competent authority and the holder of the registration of a medicinal product about its (suspected) falsification. The range of the "civil" penalty covers 500 to 25,000 EUR, subsec. 28. For an offense in the field of human pharmacy § 136 (2) MPA imposes a "civil" penalty in a range of 100 to 5,000 EUR or 75 to 3,000 EUR depending which variant of subsec. 1 is pertinent: unlawfully handling medicinal products (a), offering or providing human medicinal products via the internet without meeting special conditions (see § 22 MPA) (b), or offering, selling or providing medicinal products in contravention of the rules of the MPA.

Administrative sanctions are resigned in § 9 and § 10 MPA, effective (as transposition measures) as of 2 January 2013. Misconduct listed in § 9 MPA contains among others acting not in compliance with the requirements of Good Manufacturing Practice; the legal consequence is the authority suspending the activity of the holder of the authorisation for a maximum of 90 days (subsec. 1).

Misconduct concerning falsified active substances is addressed by criminal law according to Slovak legal experts, though the English translation of the referring provisions does not contain "active substances" as a technical term. Slovak legal experts consider § 170 and § 170a of the Criminal Code applicable to unauthorised "pharmaceuticals" which cause or increase the danger of endangering the health of a human being (§ 170 CC) or to an unauthorised handling of "pharmaceuticals" contrary to a generally binding legal regulation (§ 170a CC).

"Civil" sanctions are imposed for an unlawfully conduct with active substances according to § 138 MPA and § 136 MPA, e.g. § 138 (22) imposes a fine between 500 and 25,000 EUR, § 138 (33) a fine between 300 to 35,000 EUR. Misconduct applies to the manufacturing of active substances not in accordance with the requirements of Good Manufacturing Practice, § 138 (1) (t).

As far as administrative sanctions are concerned § 9 and § 10 MPA are applicable also to the unlawful conduct with active substances according to Slovak legal experts.

For excipients, criminal penalties do not apply. "Civil" penalties are again addressed by § 138 MPA, e.g. penalizing infringements of the rules of Good Manufacturing Practice, § 138 (1) (aj). For administrative sanctions, again § 9 and § 10 MPA are applicable according to Slovak legal experts.

3.26 FI – Finland

Directive 2011/62/EU was implemented in Finland by the Act of 1200/2013, which amended the Medicines Act of 1987 (*Lääkelaki*). The transposition act also comprised the ratification of the Council of Europe Convention on the counterfeiting of medical products and similar crimes involving threats to public health. However, the act did not provide any changes in the Finnish rules on penalties applicable to infringements of the national provisions adopted pursuant to Directive 2001/83/EC. This means that the legal provisions on unlawful behaviour and penalties which were applied before the enactment of the Act of 1200/2013 are still applicable after its entry into force.

Among them, the most significant provisions are located in Section 98 of the Finnish Medicines Act (petty medicine offence; as enacted 296/2004) and in Chapter 44 Section 5 of the Finnish Criminal Code (medicine offence; as enacted 400/2002). The offence in Chapter 44 Section 5 of the Finnish Criminal Code is a *blanco type provision* and refers – inter alia – to the substantive provisions in the Medicines Act. Both provisions provide penalties for the unlawful manufacturing, import, storage, keeping for sale and distribution of medicinal products, active substances and excipients. The penal scales for medicine offences are a fine or imprisonment of up to one year and for petty medicine offences a fine only. 'Normal' negligence is sufficient for the responsibility as to the petty medicine office. In most cases the imposed punishment has been a fine. However, the penal provision on smuggling (Chapter 46 Section 4 of the Finnish Criminal Code) is applicable for more serious cases of illegal import of medicinal products.

It is important to note that in the abovementioned provisions there is no specific reference to the term of falsified or counterfeit medicinal products and no

differentiation between medicinal products, active substances and excipients is made. However, both penal provisions are applicable irrespective of the type of falsified product and are interpreted in a way that they provide criminal penalties for the manufacturing, import, storage, keeping for sale and distribution of falsified medicinal products, falsified active substances and falsified excipients.

Civil penalties are not in use in Finland and punitive administrative sanctions are not applicable for the infringements of the Medicines Act.

3.27 SE – Sweden

Illegal conduct involving medicinal products is sanctioned through Chapter 16 § 1 of the Swedish Medicinal Products Act (*Läkemedelslag*) and Chapter 9 Section 1 of the Swedish Medicinal Products Trading Act (*Lag om handel med läkemedel*). Both offences are *blanco type provisions* and refer to several substantive provisions in the respective act. They provide penalties, inter alia, for the unlawful manufacturing, distribution, brokering, import and sale at a distance of medicinal products. The penal scales are a fine or imprisonment of up to one year.

The respective criminal offences are set up as endangerment crimes of abstract danger. As a result, the regulations can be enforced easily, for there is no need for the prosecution to prove any concrete danger or harm caused by the defendant's conduct.

It is important to note that criminal penalties are not applicable for the falsification of active substances and excipients. Such conduct is subject to a civil penalty, according to Chapter 14 Section 3 of the Swedish Medicinal Products Act. Administrative sanctions are applicable as well. Authorisations relating to the manufacture, wholesale trade and import of medicinal products may be suspended or withdrawn if the requirements for the granting of the authorisation are no longer met.

3.28 UK – United Kingdom

In the United Kingdom penalties applicable to infringements of the national provisions on medicinal products and active substances can be found in the Human Medicines Regulations 2012 that have been amended by the Human Medicines (Amendment) Regulations 2013, in order to transpose Art. 118a of Directive 2001/83/EC.

These regulations contain a large number of rules on penalties that address – inter alia – the unlawful manufacturing, distribution, brokering, import and export of medicinal products and active substances (see for example Sections 34, 45K, 45 and 255). It is important to note, that these offences do not refer to the term of falsified or counterfeit medicinal products but rather to the breach of substantive regulatory provisions. Nevertheless, conduct involving falsified medicinal products may be subject to these penalties. A person guilty of such an offence is liable on summary conviction to a fine not exceeding the statutory maximum or on conviction on indictment to a fine, to imprisonment for a term not exceeding two years, or to both.

Besides, conduct involving falsified medicinal products may be subject to criminal penalties according to Section 92 of the UK Trade Marks Act 1994. This provision refers to using the trademark associated, in the cases of interest here, with the legitimate medicinal product or something which looks deceptively like it. This offence is, however, not specific to medicinal products. Criminal trials concerning cases involving falsified medicinal products can make reference to the specific standards imposed in the field. Labelling requirements and understanding of criminality is set out in a number of statutory instruments alongside the Human Medicines Regulations 2012 as well as strategy documents of the MHRA. The maximum penalty for an offence according to Section 92 of the UK Trade Marks Act 1994 is imprisonment of up to ten years.

Civil penalties are not applicable to infringements of the national provisions on medicinal products, active substances and excipients. Administrative sanctions can be found in Sections 68 subsequent of the Human Medicines Regulations 2012. According to these provisions the licensing authority may revoke, vary or suspend a UK marketing authorization, for example if the product to which the authorisation relates

is harmful or the product's qualitative or quantitative composition is not as described in the application for the authorisation or the material supplied with it. There are also administrative sanctions for illegal conduct with active substances.

4 TRANSPOSITION AND EFFECTIVENESS – OVERVIEW OF THE MEMBER STATES

4.1 Introduction

Falsified medicinal products entering the *legal* supply chain and *illegal* medicinal products being sold via various sales channels are a Union-wide challenge. There is no Member State that is immune to this danger to public health. To assess whether Article 118a has been comprehensively transposed in all 28 MS, a synthesis across all Member States of the transposition of the Directive is presented. It covers the implementation of criminal penalties, civil penalties, and administrative sanctions. Enforcing authorities are also identified.

The presentation takes into account the following requirements of that article:

"2. The rules referred to in paragraph 1 shall address, inter alia, the following:

(a) the manufacturing, distribution, brokering, import and export of falsified medicinal products, as well as the sale of falsified medicinal products at a distance to the public by means of information society services;

(b) non-compliance with the provisions laid down in this Directive on manufacturing, distribution, import and export of active substances;

(c) non-compliance with the provisions laid down in this Directive on the use of excipients."

This transposition analysis is followed by a summary assessment by external experts of the effectiveness of different sanctions as well as the impact/success of penalties introduced by Member States with respect to both legal and illegal markets. Furthermore, the expert estimates on the share of falsified medicinal products placed on the market are summarised. Other types of measures applied by some Member States to fight falsified medicine trade are also outlined.

Finally, the results of the supplementary data collection concerning the amount of falsified medicines in European markets are reported, including a brief review of other international and national undertakings to gather such information.





4.2 Transposition of the Directive – synthesis across all Member States

4.2.1 Summary overview

The penalties for infringements of provisions that regulate the trade with medicinal products in the EU differ between Member States. A complete overview of the types of sanctions with a view to the unlawful conduct with medicinal products, active ingredients and excipients (falsified or not) is provided in the following Table 1 a) – 1 c). These tables record the type of penalty which exists in the respective country with respect to different types of conduct. Note that these tables identify only the strongest type of sanction that exists – assuming that a criminal sanction has a greater impact than a civil one, and that civil penalties are stronger than administrative sanctions. Nevertheless, where a criminal penalty is noted, this does not imply that other sanctions also exist for the same conduct. For details per country, please refer to the country reports in chapter 3.

It should be noted that bodily harm or personal injury is always covered by the general criminal law of a country. The following table only depicts the sanctions applicable to infringements related to pharmaceutical law.

Table 1: Types of sanctions/penalties implemented by Member States concerning the unlawful conduct with falsified or illegal medicines, active substances and excipients

Legend:		= Criminal penalties
		= Civil penalties
		= Administrative sanctions
		= No sanctions

a) Medicinal products

	BE	BG	CZ	DK	DE	EE	IE	EL	ES ³⁹	FR	HR	IT	CY	LV ⁴⁰	LT	LU	HU	MT	NL	AT	PL	PT ⁴¹	RO	SI	SK	FI	SE	UK
Manufacturing	◆	▲	◆	◆	◆	◆	◆	◆	◆	◆	◆	◆	◆	◆	◆	◆	◆	◆	◆	◆	◆	◆	◆	◆	◆	◆	◆	◆
Distribution	◆	▲	◆	◆	◆	◆	◆	◆	◆	◆	◆	◆	◆	◆	◆	◆	◆	◆	◆	◆	◆	◆	◆	◆	◆	◆	◆	◆
Brokering	◆	▲	◆	◆	◆	◆	◆	◆	◆	◆	◆	◆	◆	◆	◆	◆	◆	◆	◆	◆	◆	◆	◆	◆	◆	×	◆	◆
Import	◆	◆	◆	◆	◆	◆	◆	◆	◆	◆	◆	◆	◆	▲	▲	◆	◆	◆	◆	◆	◆	◆	▲	◆	◆	◆	◆	◆
Export	◆	◆	◆	◆	◆	◆	◆	◆	◆	◆	◆	◆	◆	▲	◆	◆	◆	◆	◆	◆	▲	◆	▲	◆	◆	×	▲	◆
Sale at a distance	◆	▲	◆	◆	◆	◆	◆	◆	◆	◆	◆	◆	◆	×	◆	◆	◆	◆	◆	◆	◆	◆	◆	◆	◆	◆	◆	◆

The data in Table 1 a) show that 22 Member States (BE, CZ, DK, DE, EE, ES, IE, EL, FR, HR, IT, CY, LT, LU, HU, MT, NL, AT, PT, SI, SK, UK) provide for *criminal* penalties for any type of conduct with respect to falsified medicinal products (manufacturing, distribution, brokering, import, export, and distance sales). Yet, two of these member states require a causal link of the conduct to concrete danger to health (ES, PT). Of the six Member States that do not cover all forms of conduct with criminal law, five Member States (BG, LV, PL, RO, SE) provide for either criminal or “civil” penalties depending on the conduct; e.g., four of them (LV, PL, RO, SE) have implemented only “civil” penalties for export, whereas all of them – except for BG – feature criminal penalties for manufacturing, distribution and brokering. FI is a special case insofar as it has no special penalties implemented for brokering or export, but these types of conduct may be penalised by more general legal provisions.

b) Active substances

	BE	BG	CZ	DK	DE	EE	IE	EL	ES	FR	HR	IT	CY	LV	LT	LU	HU	MT	NL	AT	PL	PT	RO	SI	SK	FI	SE	UK
Manufacturing	◆	▲	◆	◆	◆	◆	◆	◆	◆	◆	◆	◆	▲	◆	▲	◆	◆	◆	◆	◆	◆	◆	▲	▲	◆	◆	▲	◆
Distribution	◆	▲	◆	◆	◆	◆	◆	◆	◆	◆	◆	◆	▲	◆	▲	◆	◆	◆	◆	◆	◆	◆	▲	▲	◆	◆	▲	◆
Import	◆	◆	◆	◆	◆	◆	◆	◆	◆	◆	◆	◆	▲	▲	▲	◆	◆	×	◆	◆	◆	◆	▲	▲	◆	◆	▲	◆
Export	◆	◆	◆	◆	◆	◆	◆	◆	◆	◆	◆	◆	×	▲	▲	◆	◆	×	◆	◆	×	◆	▲	▲	◆	×	▲	×

³⁹ Criminal penalties for conduct involving medicinal products, active substances and excipients only apply if causation of danger to health is proven.

⁴⁰ Criminal penalties for conduct involving medicinal products, active substances and excipients only apply if causation of harm to health is proven.

⁴¹ Criminal penalties for conduct involving medicinal products, active substances and excipients only apply if causation of danger to health of a determined person is proven.

When looking at (falsified) active substances, the picture changes somewhat. The data in Table 1 b) show that 17 Member States (BE, CZ, DK, DE, EE, EL, IE, ES, FR, HR, IT, LU, HU, NL, AT, PT, SK) provide for criminal penalties for any type of illegal conduct with respect to (falsified) active substances. Yet, two of these member states require a causal link of the conduct to concrete danger to health (ES, PT). Of the remaining eleven, four (LT, RO, SI, SE) have implemented only “civil” penalties, and two Member States (BG, LV) have either criminal or “civil” penalties depending on the type of conduct (manufacturing, distribution, import or export). For the remaining five countries, three (PL, FI, UK) have implemented criminal penalties for all activities except export, one has implemented criminal penalties for manufacturing and distribution (MT) and one has implemented “civil” penalties for all activities except export (CY). But again, this may be penalised by more general legal provisions.

c) Excipients

	BE	BG	CZ	DK	DE	EE	IE	EL	ES	FR	HR	IT	CY	LV	LT	LU	HU	MT	NL	AT	PL	PT	RO	SI	SK	FI	SE	UK
Manufacturing	◆	✗	▲	◆	✗	●	◆	◆	◆	◆	◆	▲	▲	◆	●	◆	●	✗	◆	◆	◆	◆	▲	▲	▲	◆	▲	✗
Distribution	◆	✗	●	◆	✗	✗	✗	◆	◆	◆	◆	✗	▲	◆	✗	✗	●	✗	◆	◆	◆	◆	▲	▲	●	◆	▲	✗
Import	◆	✗	●	◆	✗	✗	✗	◆	◆	◆	◆	✗	▲	✗	✗	◆	✗	✗	◆	◆	✗	◆	✗	▲	●	◆	▲	✗
Export	◆	✗	●	◆	✗	✗	✗	◆	◆	◆	◆	✗	✗	✗	✗	✗	✗	✗	◆	◆	✗	◆	✗	▲	●	✗	▲	✗

Concerning misconduct with respect to excipients, the result is quite different again. The data in Table 1 c) indicate that ten Member States (BE, DK, EL, ES, FR, HR, LU, NL, AT, PT) provide for criminal penalties for any type of unlawful conduct with (falsified) excipients (manufacturing, distribution, import and export). Yet, two of these Member States require a causal link of the conduct to concrete danger to health (ES, PT). Two countries (SI, SE) have implemented “civil” penalties. Two countries (CZ, SK) have implemented “civil” penalties for violating manufacturing rules, and provide for administrative sanctions with respect to other types of misconduct. One country (FI) provides sanctions – another one (CY) provides dedicated “civil” penalties – for unlawful conduct except for export. Four countries (LV, HU, PL, RO) cover manufacturing and distribution with either criminal, “civil” or administrative sanctions while not providing any sanctions for import and export. Four countries (EE, IE, IT, LT) have only implemented sanctions for unlawful manufacture involving excipients. The remaining four countries (BG, DE, MT, UK) have no specific penalties in relation to excipients.

Concerning *administrative sanctions* in general, administrative sanctions for unlawful conduct involving medicinal products, for example in the form of suspension of licenses, are in place in all 28 MS since the legal market is strictly regulated and licenses are required for all key activities within the supply chain. These administrative sanctions are often specific to conduct involving medicinal products but sometimes stem from general statutes that regulate activities which require a license.

The situation regarding “civil” penalties is more complex. Seventeen Member States have amended their “civil” penalties applicable to medicinal products, active substances and/or excipients. However, the amount of these non-criminal fines varies greatly from Member State to Member

State. The applicability of these penalties also varies. In some Member States, “civil” penalties are treated as sanctions of different intensity (“quantity”) that apply to the same misconduct that criminal penalties apply to (e.g. IE, NL, UK). In other Member States, “civil” penalties are considered sanctions of different quality that do apply only to less severe misconduct, to which criminal penalties – covering only grave misconduct – do not apply to (mutual exclusion, e.g. DE, ES, IT, PT).

Concerning *criminal* penalties, the situation is even more complex, despite the efforts of the MEDICRIME Convention of the Council of Europe.⁴² The severity of sanctions varies greatly all across the EU. For the same misconduct, in one Member State there might be no criminal penalty, while in another the same conduct is punished by up to 10 years imprisonment.⁴³ Some countries do not criminalise conduct involving falsified or adulterated medicinal products specifically, but only the manufacture or sale etc. without a required license (e.g. LV, NL, SE). In these MSs, falsifying medicinal products is criminalised only to the extent that the medicinal products are manufactured *without a license* or considered falsified goods (e.g. NL). Many Member States do not criminalize illegal activity with medicinal products that are not falsified (e.g. manufacturing without a license, see AT and PT, e.g.). Three Member States (ES, LV, PT) require that the conduct caused danger or harm to health for criminal penalties to apply. The majority criminalise unlawful activity involving active substances, but only a few conduct involving excipients.

⁴² The "Medicrime Convention" has been the first international criminal law instrument to oblige States Parties to criminalise – inter alia – the manufacturing of falsified medical products, supplying, offering to supply and trafficking in falsified medical products, The Convention seeks to fight the dangers to public health caused by the falsification of medical products and similar crimes. It does not seek the protection of Intellectual Property rights, see <https://www.coe.int/en/web/medicrime/home>.

⁴³ See graph 3 below.

4.2.2 Changes in legislation in view of Article 118a

Most MS have introduced some changes to their legislation as a result of the entry into force of Article 118a, as detailed in Table 2~~Error! Not a valid bookmark self-reference.~~ and Table 3 below. There are only two countries (FI, HU⁴⁴) that have not modified their sanctioning system in view of the Directive 2011/62 EU. However, as shown in Table 1 above, these MSs nevertheless cover more or less all of the relevant unlawful conduct by some form of sanction already in place before 2013.

Table 2 outlines which sanctions were updated compared to the situation before Article 118a entered into force. Five countries (DE, ES, HR, CY, SK) made transposition changes to all types of sanctions.

Table 2: Changes in legislation in view of Art. 118a of the Directive 2001/83/EC (direct transpositions) | EU – TRANSPOSITION AMENDMENTS

Changes to	Member State
no provisions changed	HU, FI
criminal penalties	BE, FR, MT
“civil penalties”	LU, PT, SI
administrative sanctions	CZ, SE
criminal penalties and “civil penalties”	NL, AT, RO, UK
criminal penalties and administ. sanctions	EE, IE, PL
“civil penalties” and administ. sanctions	BG, EL, IT, LV, LT
all types of penalties/sanctions	DE, ES, HR, CY, SK

Table 3 provides an overview of changes by Member State by type of sanction. Seventeen Member States made changes to rules on civil penalties, 15 on criminal penalties, and 15 on administrative sanctions. As outlined above, two MS did not change their laws or regulations.

Table 3: Changes in legislation in view of Art. 118a of the Directive 2001/83/EC (direct transpositions) | EU – Overview of AMDENDMENTS BY TYPE OF SANCTIONS

Criminal penalties	“Civil penalties”	Administrative sanctions	None
BE, DE, EE, ES, IE, FR, HR, CY, MT, NL, AT, PL, RO, SK, UK	BG, DE, EL, ES, HR, IT, CY, LV, LT, LU, NL, AT, PT, RO, SI, SK, UK	BG, CZ, DE, EE, IE, EL, ES, HR, IT, CY, LV, LT, PL, SK, SE	HU, FI
Total n° 15	Total n° 17	Total n° 15	Total n° 2

As a first assessment of the transposition of Article 118a, the situation can be considered satisfactory in the case of falsified medicinal products for administrative sanctions and civil penalties, but could be improved regarding criminal penalties. For active substances, the situation can be considered satisfactory for all types of sanctions. However, for excipients, some countries do not provide specific sanctions

⁴⁴ However, in July 2013 the Hungarian legislator has introduced Art. 186 into the Criminal Code in order to ratify the Council of Europe Convention on the counterfeiting of medical products and similar crimes involving threats to public health.

for excipients. This will be explained in more detail below for each type of sanction (criminal, "civil", and administrative).

4.2.3 Transposition of criminal penalties

The criminal law situation regarding medicinal products in the 28 Member States is of considerable complexity and diversity. Some Member States have reacted to the profound changes of the medicinal products market since the early 2000s⁴⁵ by updating their criminal law provisions to cover the increasing importance of the illegal market and the infiltration of the legal market by falsified products, whereas others have not. Generally speaking, the most effective measure against unlawful and illegal activity is not simply the threat of severe punishment, but rather its combination with widespread enforcement. However, enforcement depends not only on resources and personnel, but also the practicability of the laws to be enforced.

When the circumstances and socio-economic structures of society change, the law has to change accordingly. With the heightened complexity and accelerating change of our societies, the way (criminal) responsibility is attributed and perceived has changed as well.⁴⁶ In long and complex causal chains, as for example in health or ecology, it is difficult to prove that a specific substance caused the development of a disease such as cancer in each individual case⁴⁷, or to prove that emissions of a particular factory caused harm to that specific environment kilometres away.⁴⁸

In an environment where proving definite causation of harm has become increasingly difficult, criminal law has been relying more and more on so-called endangerment crimes.⁴⁹ These types of crimes do not require proof of a harm caused by the criminal act. Endangerment crimes consist of an act that is, to some degree, dangerous.⁵⁰ This makes them easier to enforce, since a causal link between the act and a potential harm does not need to be proven. This is especially effective in the case of acts involving medicinal products.⁵¹ To prove that a certain illegal conduct has caused a specific harm to the victim is very difficult in the case of medicinal products.⁵² This is partly due to the complexity of the human physiology.⁵³ At least equally important is that many cases of harm due to illegal and falsified medicinal products go undetected by medical personnel, patients and/or authorities. Consequently, 26 MS apart from Bulgaria and Latvia have introduced endangerment crimes regarding manufacture and distribution of medicinal products or wares that include medicinal products.

The legal definitions of dangerousness and the types of endangerment crimes, however, vary from MS to MS. Generally, three types of endangerment crimes can be distinguished:

- concrete danger,
- abstract-concrete danger, and

⁴⁵ Cornerstone was the « DocMorris »-Case (CJEU 11 December 2003 – Rs. C-322/01). With view to the German legal situation the CJEU held that a justification of the prohibition of mail-order business of medicinal products should only work for prescription-only but not for non-prescription medicinal products

⁴⁶ See for example Prittwitz, *Strafrecht und Risiko*, 1993, from p. 114 onwards.

⁴⁷ Harrich, Daniel, Harrich-Zandberg, I.c., p. 25

⁴⁸ See for the effect of these changes to society Beck, *Risikogesellschaft*, 1986, p. 73 onwards.

⁴⁹ See for the substantive change to criminal law since the 1970s Silva Sánchez, *La Expansión del Derecho Penal*, 2001, p. 149 onwards.

⁵⁰ See Zieschang, *Die Gefährdungsdelikte*, 1998; Mendoza Buergo, *Límites dogmáticos*, 2001.

⁵¹ This was in fact one of the main reason to introduce endangerment crimes into the law regulating medicinal products in Germany in the 1970s, see Arm. Kaufmann, *JZ* 1971, p. 575 ; Sinn/Schmitz/Steinebach/Liebl/Schulte-Nölke, *ALPhA*, 2017, *passim*.

⁵² See on the difficulty to prove that the cause of death or health damage was a falsified medicinal product, Venhuis u.a. *Identification of health damage caused by Medicrime* 2013, p. 10 onwards.

⁵³ Harrich, Daniel, Harrich-Zandberg, I.c., p. 25 f.

- abstract danger.⁵⁴

In a democratic state of law, the balance has to be kept between enforceability (security) on the one side and preciseness (liberty) on the other. The wider the scope of a criminal law provision, the easier it is to enforce it. But if the scope is very wide, then enforcement becomes inflationary and imprecise. The sanctions might apply to conduct that is, in the individual case, harmless and not meant to be criminalised. This might restrict freedom and dissuade to engage in harmless, beneficial economic activities.⁵⁵

The most precise but least enforceable type of endangerment crime is the so-called crime of concrete danger.⁵⁶ These endangerment crimes require that a conduct must have caused danger (a concrete situation considered as “a danger”, in each individual case). One can find pharmaceutical criminal law that relies on crimes of concrete danger in Spain (Art. 362 CC: the criminal conduct must “*cause* danger to the life or health of persons”) and Portugal (Art. 282 CC: the criminal conducts must “*create* danger to life or the physical integrity of another person”). The advantage of this technique is that acts that do not cause danger are not criminalised, which renders the criminal law very precise. Not just any falsification of medicinal products is criminal, only a falsification that causes danger to a person. Therefore the focus is on danger to the health of patients, which is the main objective of pharmaceutical criminal law as opposed to for example intellectual property law. However, this approach renders the criminal law provision very difficult to enforce. Proving causation of danger in each individual case might be almost as difficult as proving the harm itself. It can require an exhaustive analysis of the falsified medicinal products as well as the identification of a concrete patient that was actually, *concretely* endangered by that product. If, for example, a perpetrator starts to offer falsified medicinal products online and is arrested, he might argue that no concrete danger has been caused yet. As long as the prosecution cannot prove that a specific person was put into danger by the conduct, the judge might consider that concrete danger to a concrete person has not been proven and acquit the perpetrator, in *dubio pro reo*. In our analysis, this type of endangerment crime is not ideal for falsification of medicinal products. Falsification of medicinal products is not a positive economic activity, due to its general, *abstract* dangerousness. Requiring concrete danger is an obstacle to enforcement not met by its advantages in precision.

The middle ground is the so-called crime of abstract-concrete danger.⁵⁷ These endangerment crimes require that a conduct must be generally dangerous in the concrete case. One can find criminal law provisions of that type regarding medicinal products inter alia in the legal systems of the following MSs: France (“*likely* to pose a serious risk to human health”), Greece (*can* cause harm to health), Italy (*dangerous* to public health), Lithuania (*could* have posed a threat to human health), Luxembourg (*dangereux* ou nuisibles à la santé humaine), Romania (“*harmful* to health”) and Slovenia (“*dangerous* to health”).⁵⁸ Typically, these criminal law provisions require that a conduct or product is dangerous. This means that it is not enough to prove falsification of medicinal products by itself. The prosecution needs to prove that a concrete case of falsification was *generally* dangerous, for example by chemically analysing the respective falsified medicinal product. The difficulty of proof therefore depends on the type of medicine falsified. For example in the case of oncology medicine, it would be easy to show that an ineffective medicine is generally dangerous

⁵⁴ See, inter alia, Wohlers, Deliktstypen des Präventionsstrafrechts, 2000.

⁵⁵ See on unwanted dissuasion due to strict on the one and less strict application of the law on the other side Posner, Economic analysis of law, 2014, p. 762 onwards.

⁵⁶ See recently as an example Börgers, Studien zum Gefährurteil im Strafrecht, 2008, p. 61 onwards.

⁵⁷ See D'Avila, Ofensividade e Crimes Omissivos Próprios, 2005, p. 126 onwards; Zieschang, FS Wolter 2013, p. 557 onwards.

⁵⁸ In some of these countries, crimes of abstract endangerment apply as well, see the country reports and graph 3 below.

to cancer patients, since they would not receive proper treatment. In case of erectile dysfunction medicine however, proving that there was general danger to health is only possible if the products contained harmful substances or different (not only a lower amount of) substances than indicated on the packaging. This renders the provisions relatively effective and relatively precise, as actions that are fraudulent, but not dangerous to health, are not covered by criminal law sanctions.

The type of endangerment crimes with the widest scope are crimes of abstract danger.⁵⁹ These criminal law provisions require no proof of dangerousness. It is enough to prove the conduct has taken place, e. g., the falsification of medicinal products. This conduct is considered generally dangerous by the legislator, who criminalises it regardless of the individual circumstances found or proven by law enforcement. This type of criminal law provision for medicinal products can be found in the following legal systems in the EU: Austria, Belgium, Croatia, Cyprus, Czech Republic, Denmark, Finland, France, Germany, Hungary, Italy, Ireland, Luxembourg, Malta, Netherlands, Poland, Slovakia, Sweden and the United Kingdom. Crimes of abstract danger are easy to enforce, since only the conduct itself needs to be proven.

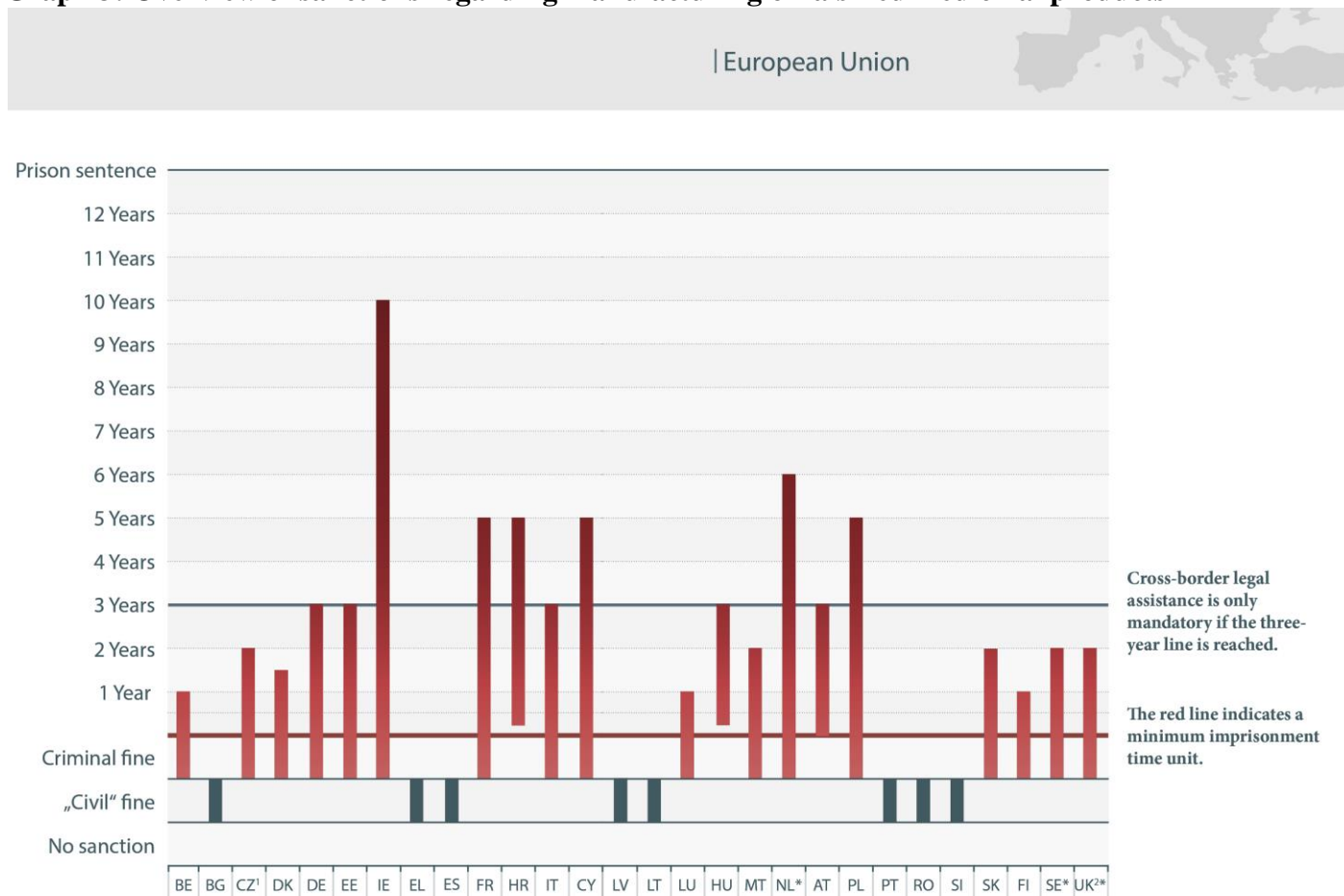
Yet these types of crimes are still controversial in the legal community, as they allow for the punishment of individual acts even if they were not dangerous in the concrete case.⁶⁰ They are also less precise in only targeting conduct that is dangerous to human health.

According to these distinctions, the study team has created four graphs that show the legal situation in all 28 Member States regarding criminal law sanctions. The *manufacture* and *sale* of falsified medicinal products have been chosen as examples.

Another important distinction regarding criminal law is between those criminal law provisions that directly address conduct that involves medicinal product and those that do not. Some Member States criminalise the manufacturing of falsified medicinal products not as such, but as the manufacturing of (any) product for which a license is required (see the country reports above). These are marked with footnotes in the following graphs.

⁵⁹ See *Mantovani*, *Principi di Diritto Penale*, 2007, p. 97 onwards.

⁶⁰ See, inter alia, *Baroke*, *Gefährdungsdelikte*, in: *Grenzen der Vorverlagerung*, 2011, p. 151 ff ; *Faria Costa*, *Noções Fundamentais de Direito Penal*, 2012, p. 161.

Graph 3: Overview of sanctions regarding manufacturing of falsified medicinal products

Graph 3 shows what (or if) criminal penalties can be applied in a Member State if the prosecution is only able to prove that the accused has manufactured falsified medicinal products (*abstract* danger), regardless of dangerousness (*abstract-concrete*) or any danger (*concrete*) or harm caused. Other aggravating factors (e.g. manufacturing in large numbers) are also not taken into account (for such aggravating circumstances, see the country reports and the annex). This ensures comparability. According to this data, the mere manufacturing of falsified medicinal products (*abstract* danger) is sanctioned in Member States in the following way:

* Act in these jurisdictions is the manufacturing of medicinal products without permission or the manufacturing contrary to legal regulations.

¹ Manufacturing is only recorded as a „business activity“ without required approval.

² Usually prosecuted as trademark infringement (10 years maximum penalty).

Most Member States (20) provide for prison sentences, but only 11 for up to or more than three years, a quantity that is important when seeking cross-border legal assistance from other countries.

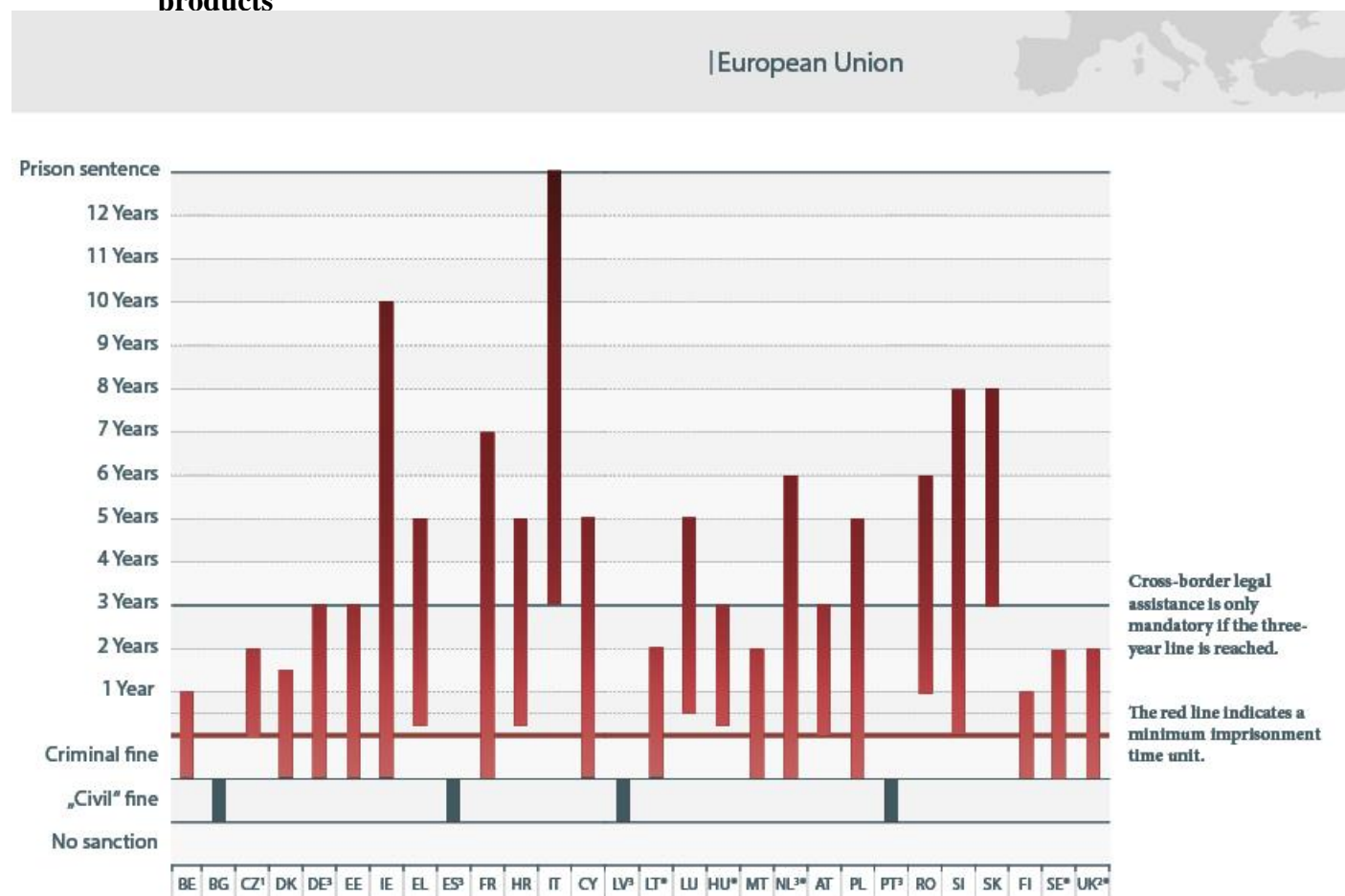
The European Investigation Order (EIO)⁶¹ aims at simplifying and facilitating the work of enforcement authorities of Member States (“issuing authorities”) when they request evidence located in other Member States from the domestic authorities (“executing authorities”). According to Art. 11 (1) (g) Directive EIO the “executing authority” can refuse the recognition or execution of an EIO if the conduct for which the EIO has been issued does not constitute an offence under the law of the executing Member State. But the rejection is inadmissible if an offence listed within Annex D of the Directive EIO is concerned⁶² and if the conduct is punishable in the issuing Member State by a custodial sentence or a detention order for a maximum period of at least three years. Since pharmaceutical crime is typically a cross-border activity, requiring cross-border legal assistance, the three-year-line is marked in the graph to highlight the importance of that threshold.

Except for IT and HU, all other countries providing for prison sentences also provide for criminal fines as an alternative option.

Concerning the case of *mere manufacturing* any falsified medicines, eight Member States (BG, EL, LV, LT, PT, RO, SI, ES) only foresee administrative fines, and no criminal penalties. Again, this might change if the medicinal products are proven to be dangerous, as can be seen in table 1 a) and the following graph 4.

⁶¹ Directive 2014/41/EU of the European Parliament and of the Council of 3 April 2014 regarding the European Investigation Order in criminal matters.

⁶² “Participation in a criminal organisation”, “swindling” and “counterfeiting and piracy of products” are especially relevant offences connected with pharmaceutical crimes.

Graph 4: Overview of sanctions regarding manufacturing of falsified health-endangering medicinal products

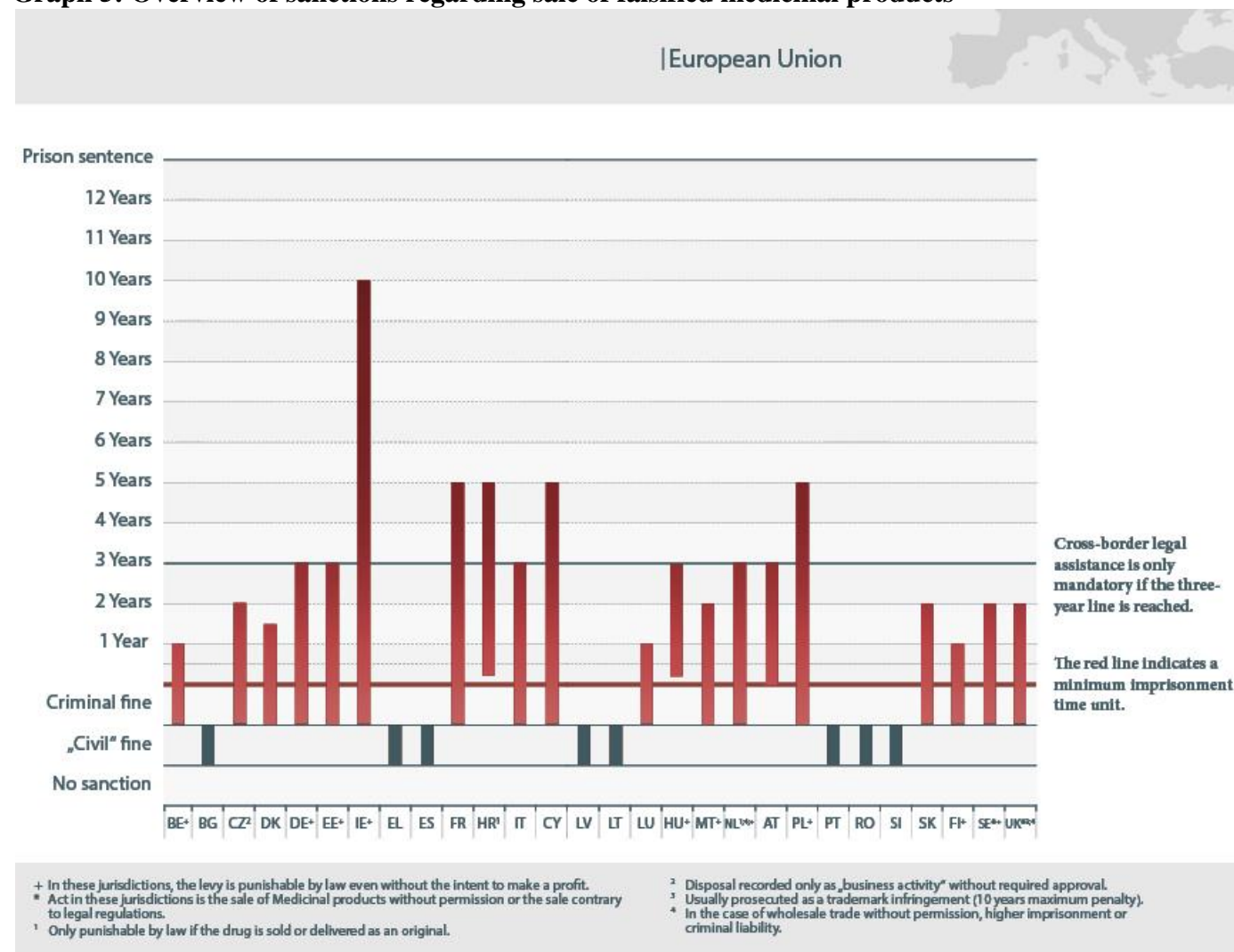
* The act of law in these jurisdictions is the manufacturing of medicinal products without permission or the manufacturing contrary to legal regulations.

¹ Manufacturing is only recorded as a „business activity“ without required approval.

² Usually prosecuted as a trademark infringement (10 years maximum penalty).

³ In these countries, higher requirements for the degree of danger (e. g. concrete offence of endangerment) or to the object of danger (majority of persons) are prerequisite for an increase in penalties or criminal liability.

As Graph 4 demonstrates the severity of sanctions increases considerably when falsified *health-endangering* medicinal products become involved. This graph describes the situation that a perpetrator (knowingly) manufactured falsified medicinal product generally dangerous in a concrete case (abstract-concrete danger). Countries such as Spain and Portugal, whose criminal laws require a concrete danger to be caused, are not listed in the graph, because concrete danger requires the causation of a concretely dangerous situation (see explanations above). If the prosecution can prove concrete endangerment, Spain and Portugal could also apply their criminal law. In that case however, other Member States (e.g. Germany) foresee even higher penalties; yet again changing the comparative overview of criminal penalties in the EU (this would require yet another graph). For manufacturing falsified dangerous medicinal products alone, the situation is as follows: All but four (BG, LV, PT, ES) countries provide for prison sentences in case of only abstract-concrete danger, and 15 of them for up to or more than three years.

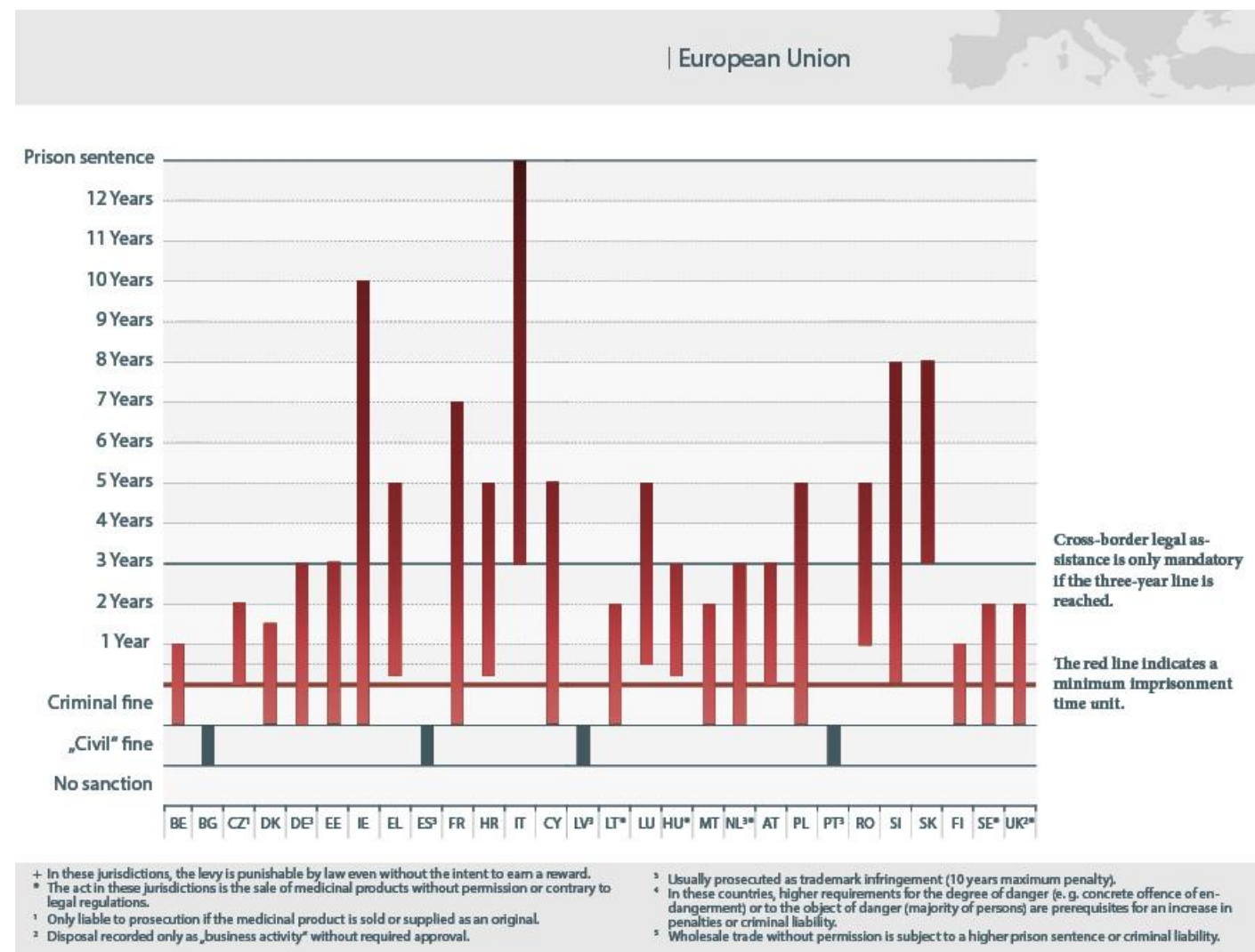
Graph 5: Overview of sanctions regarding sale of falsified medicinal products

And now in five countries, EL, HR, LU, RO, HU, this minimum imprisonment time unit is higher than the general rule in national criminal law. The number of countries also providing for criminal fines as an alternative option decreases slightly from 16 to 15.

In this case only four Member States foresee only “civil” fines, and no criminal penalties.

Graph 5 presents the situation across Member States with respect to the *sale* of falsified medicinal products. The same reasoning as to graph 3 applies (abstract endangerment). Here also the majority of Member States, 20, provides for prison sentences, but only 11 for up to or more than three years.

Except for HR, AT, and HU, the other 17 countries providing for prison sentences also provide for criminal fines as an alternative option. Concerning the sale of falsified medicines, eight Member States (BG, EL, LV, LT, PT, RO, SI, ES) only foresee “civil” fines, and no criminal penalties (for abstract endangerment).

Graph 6: Overview of sanctions regarding sale of falsified health-endangering medicinal products

Again, to compare the two different instances, graph 6 presents the situation across Member States with respect to the sale of falsified *health-endangering* medicinal products. The same reasoning as to graph 4 applies (abstract-concrete endangerment). Again, countries such as Spain and Portugal, whose criminal laws require a concrete danger, are not listed in the graph.

In this case the number of Member States providing for prison sentences increases to 23, but only 15 provide for sentences for up to or more than three years.

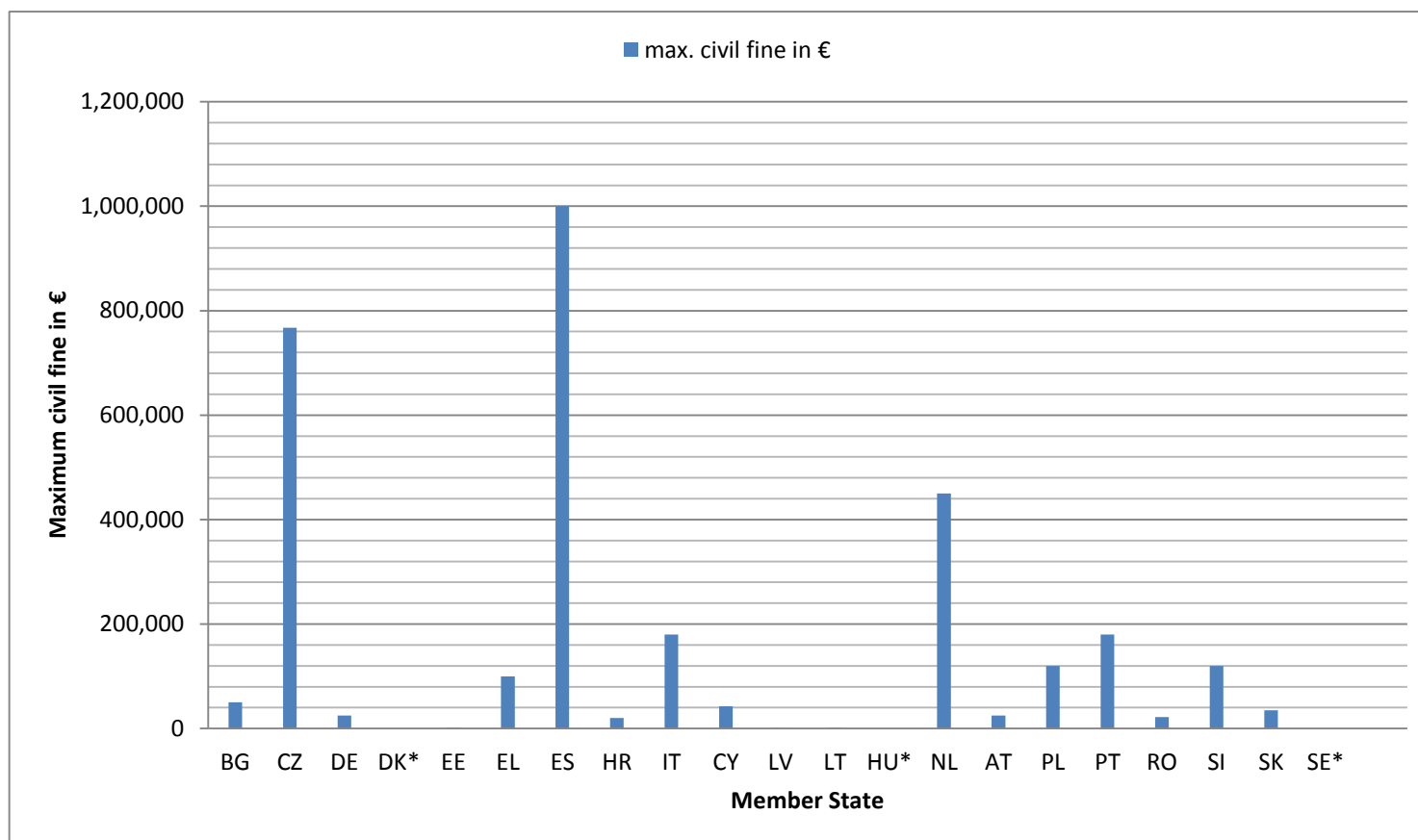
Except for EL, IT, HR, LU, AT, RO, SI, CZ and HU, the other 14 countries providing for prison sentences also provide for criminal fines as an alternative option. Only the UK foresees no criminal or administrative sanctions

In our analysis, the lack of specific criminal law penalties for the falsification of medicinal products or the need to prove concrete endangerment to convict for falsifying medicinal products in Bulgaria, Latvia, Portugal and (to some degree) Spain could be strengthened. Where no criminal law penalties apply or can be

implemented for conduct involving falsified medicinal products, we consider there are no effective, dissuasive and proportionate sanctions required by Article 118a.

4.2.4 Transposition of civil penalties

Graph 7: Maximum amount of civil penalties concerning conduct with (falsified) medicinal products in the Member States for natural persons| EU



Graph 7⁶³ shows the maximum penalties applicable to unlawful conduct with medicinal products, regardless of the type of conduct or the type of perpetrator (natural or legal person). It only depicts what maximum “civil” penalty might apply and how diverse the legal situation in the EU on this is yet again.

The “civil” penalties in most countries are tailored specifically to wrongful conduct involving medicinal products. Many countries that only provide for criminal law sanctions through their general criminal code have, in addition, special statutes for “civil” penalties applicable to pharmaceutical crimes. Other Member States treat “civil” penalties as subsidiary sanctions that can be imposed for the same conduct as criminal law sanctions in relation to falsified medicinal

⁶³ For the marked (*) countries DK, HU and SE the level is “not specified”.

products (see already above). Yet other countries codify wrongful acts with medicinal products in one statutory body, but apply criminal or civil sanctions depending on the type of conduct.

These different techniques may impact efficiency, since they require concrete and detailed knowledge by enforcement officers from different agencies of the applicable criminal or civil sanctions they may apply. Complexity may also be problematic for criminal law provisions that are based, e.g., on cross-references to other codes of criminal law and/or which are hidden in laws of lesser importance.

As with the criminal law sanctions the size of penalties varies greatly between Member States. This may not be problematic in itself considering differences in purchasing power differ and the existence of criminal law provisions.

BE, IE, LU, MT, SI, FI and the UK are not included in the graph as they do not have "civil" penalties concerning conduct with (falsified) medicinal products. In these MS only criminal fines are applied.

"Civil" sanctions are often the only sanctioning of unlawful conduct in relation to active ingredients (see Table 1: CY, LT, RO, SI, SE). In view of dangers to the health of the consumer, unlawful conduct with active ingredients can be considered a "preparatory crime"⁶⁴. Taking into account the current *modus operandi* of criminal activity with falsified medicinal products (= manufacturing takes place mostly outside of the EU), our assessment is that this form of sanctioning can, generally speaking, be considered a sufficient transposition of Article 118a of Directive 2001/83/EC.

⁶⁴ See about preparatory crimes in general (and critical) Paeffgen, FS Amelung 2009, p. 81 onwards., e. g.; Figueiredo Dias, *Direito Penal*, 2007, p. 683.

4.2.5 Transposition of administrative sanctions

Administrative sanctions, such as the revocation of a licence, were mostly in place before the Directive 2011/62 EU entered into force. A licence to manufacture and sell medicinal products was already required in all 28 MS, and provisions to revoke those licences existed accordingly. However, some countries have introduced new, special provisions in direct transposition of Article 118a Directive 2001/83 EC. These mostly concern rules on good practices. Administrative sanctions can be effective especially within the legal supply chain, where actors need a license to participate in the market. Such sanctions generally have a lower burden of proof and are therefore easier to enforce. A general lack of administrative sanctions was not found in any Member State.

However, the situation differs regarding excipients. While some Member States do provide for criminal and “civil” sanctions for unlawful conduct, some only apply administrative sanctions. Others do not dispose of specific sanctions for excipients (see table 1: Bulgaria, Germany, Malta, UK). In our analysis, the lack of sanctions in the countries above could be strengthened, especially in view of Article 46 of Directive 2001/83 EC.

4.2.6 Enforcing authorities

The competent authorities which are entitled to enforce criminal, “civil” and administrative sanctions differ according to the type of sanction. While criminal law and “civil” sanctions are typically enforced by police and prosecutors, administrative sanctions are generally enforced by the medicine agencies and health ministries. Some exceptions exist, for example the British “Medicines and Healthcare products Regulatory Agency” (MHRA) is an executive agency of the British Department of Health with law enforcement power including criminal prosecution and asset confiscation.⁶⁵

The following

⁶⁵<https://www.gov.uk/government/publications/report-a-non-compliant-medical-device-enforcement-process/how-mhra-ensures-the-safety-and-quality-of-medical-devices>;
<http://www.communityequipment.org.uk/wp-content/uploads/Enforcement-Strategy-201011.pdf>

Table 4 provides an overall view which enforcing authorities are involved in fighting the falsified medicinal products market in the Member States.

Table 4: List of national enforcing authorities for the three types of sanctions

Authorities	Criminal penalties	Civil penalties	Administrative sanctions
Ministry of health	1 (UK)	6 (BG, DK, ES, RO, SK, UK)	13 (BG, CZ, DK, FR, HR, HU, IT, LU, MT, NL, RO, SK, UK)
(Head of) Medicines agency	2 (EE, IE)	11 (BG, CY, ES, GR, IT, LT, PT, RO, SE, SI, SK)	20 (AT, BE, BG, CY, CZ, DE, EE, FI, FR, GR, HR, HU, IE, IT, LT, PL, PT, RO, SE, SI)
Police and prosecutor in general	23 (BE, BG, CZ, DE, DK, EE, ES, FI, FR, HR, HU, LT, LU, LV, MT, NL, PL, PT, RO, SE, SI, SK, UK)	4 (HR, LV, SI, SK)	4 (HU, LV, RO, SK)
Special police and/or prosecution department	9 (BG, DE, ES, FR, HR, LV, PT, RO, SK)	3 (ES, LV, SK)	6 (IT, LU, LV, PL, RO, SK)
Customs in general	7 (DE, EE, ES, FR, HU, IE, NL)	9 (BG, CY, ES, GR, LT, LV, RO, SI, SK)	12 (BG, CY, CZ, DE, EE, FR, GR, HU, LU, RO, SI, SK)
Special customs department	6 (BE, BG, DE, FR, HU, SK)	2 (BE, SK)	2 (DE, SK)
Other	3 (HR, IE, IT)	5 (EE, HR, LV, SI, SK)	8 (CY, GR, HU, IE, LU, RO, SI, SK)

4.3 Summary assessment by experts of the effectiveness and the impact of different sanctions

The national legal experts were asked to assess the effectiveness of different sanctions implemented by the respective Member State and the impact of the three types of interventions

- criminal penalties
- civil penalties
- administrative sanctions,

The answers received were validated by national government representatives.

Table 5 to Table 11 below report and summarise the answers received. They were gathered by asking the experts “to what extent have the penalties you mentioned for your country been effective to dissuade the falsification and illegal trade of medicinal products? Please use your best expert estimate and assessment as of today”, and by further, related questions. Where possible, the experts should have based their assessments on empirical data, but as was discussed earlier, reliable data are not available for almost all countries.

4.3.1 Legal distribution chain – expert assessment of effectiveness of penalties

With respect to the legal supply chain (manufacturer, wholesaler, parallel importer, pharmacist), the effectiveness estimates obtained from the experts are presented in Table 5. As a result of the lack of reliable empirical data and the short time frame for assessing the overall situation based on concrete experience, about 70% (for civil penalties 80%) of experts could not advance any estimate.

Comparing the estimates from the small number of responses received, it seems that administrative sanctions were considered by more experts to be effective with respect to the legal supply chain, followed by criminal penalties and civil penalties. However, caution should be taken when drawing conclusions considering the low number of estimates advanced.

Table 5: Effectiveness of penalties in the LEGAL distribution chain (all countries) - Summary of expert estimates

LEGAL distribution chain (manufacturer, parallel trader, broker, wholesaler) Conduct of any type (summary estimate)	Very effective (reduction by 50% or more)	Effective (reduction by 20% to 49%)	Little effect (reduction by up to 19%)	No effect at all (0% reduction, or even further increase)	No estimate
a) Criminal penalties	1 (HR)	4 (AT, IE, RO, UK)	3 (FR, HU, PT)		20 (BE, BG, CY, CZ, DE, DK, EE, ES, FI, GR, IT, LT, LU, LV, MT, NL, PL, SE, SI, SK)
b) Civil penalties	1 (ES)	3 (AT, PT, RO)	1 (UK)		23 (BE, BG, CY, CZ, DE, DK, EE, FI, FR, GR, HR, HU, IE, IT, LT, LU, LV, MT, NL, PL, SE, SI, SK)
c) Administrative sanctions	2 (BG, IE)	5 (AT, HU, PT, RO, UK)	1 (FR)		20 (BE, CY, CZ, DE, DK, EE, ES, FI, GR, HR, IT, LT, LU, LV, MT, NL, PL, SE, SI, SK)

4.3.2 Legal distribution chain –expert assessment of the overall impact (success) of penalties

Experts were also asked for an assessment of the *changes* observed since the entry into force of Directive 2011/62/EU relation to the amount of falsified medicines available.

Table 6 provides a summary of the estimated reduction in the amount of falsified medicines in the LEGAL distribution chain after transposition. Again, the vast majority (20) could not make any estimate, but of those that did two indicated a dramatic reduction by more than 75%, four a very considerable reduction by 25% to 49%, and two a reduction by less than 5%.

Table 6: Reduction in the amount of falsified medicines being available in the LEGAL distribution chain - Summary of expert estimates

Reduction in the amount of falsified medicines being available in the <i>LEGAL</i> distribution chain by	more than 75%	50% to 75%	25% to 49%	10% to 24%	5% to 9%	Less than 5%	No estimate
	2 (FR, HR)		4 (AT, BG, PT, RO)			2 (IE, SE)	20 (BE, CY, CZ, DE, DK, EE, ES, FI, GR, HU, IT, LT, LU, LV, MT, NL, PL, SI, SK, UK)

4.3.3 Illegal distribution chain – expert assessment of effectiveness of penalties

Concerning the illegal market (non-licensed vendors, illegal online sales, etc.), the majority of experts did not advance any estimates (18-24 depending on the sanction) (Table 7).

Of those that did reply, only one expert considered administrative sanctions was very effective (implying a reduction by 50% or more). With respect to *criminal* penalties, three considered them “effective” (20% to 49% reduction), and another three that they had little effect (less than 20% reduction). Four considered they had no effect at all. Concerning *civil* penalties, nobody considered that they were effective and four experts that they had little or no effect (reduction by up to 19%). With respect to *administrative* sanctions, one expert assessed them as very effective, two as having only little effect, and four as ineffective. Based on this rather uncertain evidence, it would seem that criminal penalties were more likely to be considered to deliver a benefit with respect to counteracting the illegal supply chain.

Table 7: Effectiveness of penalties in the ILLEGAL distribution chain (all countries) - Summary of expert estimates

ILLEGAL distribution chain (non-licensed vendors, illegal online sales etc.) Conduct of any type (summary estimate)	Very effective (reduction by 50% or more)	Effective (reduction by 20% to 49%)	Little effect (reduction by up to 19%)	No effect at all (0% reduction, or even further increase)	No estimate
Criminal penalties		3 (FR, HR, IE)	3 (AT, PT, UK)	4 (BE, ES, HU, RO)	18 (BG, CY, CZ, DE, DK, EE, FI, GR, IT, LT, LU, LV, MT, NL, PL, SE, SI, SK)
Civil penalties			2 (AT, PT)	2 (RO, UK)	24 (BE, BG, CY, CZ, DE, DK, EE, ES, FI, FR, GR, HR, HU, IE, IT, LT, LU, LV, MT, NL, PL, SE, SI, SK)
Administrative sanctions	1 (BG)		2 (PT, SK)	4 (AT, FR, RO, UK)	21 (BE, CY, CZ, DE, DK, EE, ES, FI, GR, HR, HU, IE, IT, LT, LU, LV, MT, NL, PL, SE, SI)

4.3.4 *Illegal distribution chain – expert assessment of the overall impact (success) of penalties*

Table 8 provides a summary of the estimated reduction in the amount of falsified medicines being available in the ILLEGAL distribution chain after transposition. Also here the majority of experts (17) do not make any estimate, but one expert assumes a dramatic reduction by more than 75%, three a very considerable reduction by 25% to 49%, one by 10% to 24% and one by 5% to 9%. Five experts estimate this change at less than 5%.

Comparing these limited results with those reported for the reduction within the legal distribution chain it seems that the experts consider a larger impact on the illegal supply chain.

In summary, whereas the majority of experts do not provide any estimate, there are a number who consider that new penalties have resulted in reductions in the overall amount of falsified medicines available in both the legal and illegal markets in their Member States.

Table 8: Reduction in the amount of falsified medicines being available in the ILLEGAL distribution chain - Summary of expert estimates

Reduction in the amount of falsified medicines being available in the <i>ILLIGAL</i> distribution chain by	more than 75%	50% to 75%	25% to 49%	10% to 24%	5% to 9%	Less than 5%	No estimate
Please tick appropriate box:	1 (HR)		3 (BG, FR, IE)	1 (PT)	1 (AT)	5 (BE, HU, SE, SK, RO)	17 (CY, CZ, DE, DK, EE, ES, FI, GR, IT, LT, LU, LV, MT, NL, PL, SI, UK)

4.3.5 Expert estimation of the share of falsified medicinal products placed on the legal and illegal markets

There is no empirical data available on the share of falsified medicinal products in the overall medicinal products market. To obtain a best estimate, the experts were also asked to "please give an evidence-based estimation (e.g. based on statistics or estimates by a competent national authority, ...) or by stakeholder associations (e.g. pharmaceutical industry, pharmacists,...) as to the share of falsified medicinal products placed on the market in your country (kindly provide such data, if available, in terms of both volume and value)."

Table 9 reports on the estimates obtained. Again, only a few concrete estimates were provided, indicating a market share of 2% or less in relation to volume. With respect to market value, this share may be slightly higher.

Table 9: Share of falsified medicinal products in the overall LEGAL national market (volume, value) – expert estimates

Share of falsified medicinal products in the overall <i>LEGAL</i> national market in terms of	more than 50%	33% to 50%	16% to 32%	11% to 15%	6% to 10%	3% to 5%	1% to 2%	Less than 1%	No estimate
VOLUME (no. of boxes ...) Please tick appropriate box:					1 (FR)		1 (PT)	5 (AT, ES, HU, IE, SE)	21 (BE, BG, CY, CZ, DE, DK, EE, FI, GR, HR, IT, LT, LU, LV, MT, NL, PL, RO, SI, SK, UK)
VALUE (Currency: _____) Please tick appropriate box:					2 (FR, RO)		1 (PT)	2 (IE, SE)	23 (AT, BE, BG, CY, CZ, DE, DK, EE, ES, FI, GR, HR, HU, IT, LT, LU, LV, MT, NL, PL, SI, SK, UK)

Table 10 provides similar data on expert estimates of falsified medicinal products in the overall national market of ILLEGAL medicinal products in terms of volume and value. With respect to volume, eight experts provided an estimate, ranging from less than 1% of the market to more than 50%. Comparing these figures with those reported for legal markets, the share of falsified medicinal products is assumed to be dramatically higher in illegal markets.

On the value of falsified products in illegal markets, only three experts provide an estimate, ranging from 6% to more than 50% of the market value.

Table 10: Share of falsified medicinal products in the overall ILLEGAL national market (volume, value) – expert estimates

Share of falsified medicinal products in the overall <i>ILLIGAL</i> national market of medicinal products in terms of	More than 50 %	33 % to 50 %	15% to 33 %	11% to 15%	6% to 10%	3% to 5%	1% to 2%	Less than 1%	No estimate
VOLUME (no. of boxes ...) Please tick appropriate box:	2 (BE, IE)	2 (FR, PT)		1 (AT)	1 (HR)	1 (ES)		1 (HU)	20 (BG, CY, CZ, DE, DK, EE, FI, GR, IT, LT, LU, LV, MT, NL, PL, RO, SE, SI, SK, UK)
VALUE (Currency: _____) Please tick appropriate box:	1 (RO)	1 (PT)			1 (HR)				25 (AT, BE, BG, CY, CZ, DE, DK, EE, ES, FI, FR, GR, HU, IE, IT, LT, LU, LV, MT, NL, PL, SE, SI, SK, UK)

4.3.6 Other types of measures to fight falsified medicine trade

The experts were also asked whether there are other measures beyond penalties in their Member State relevant to the fight against trade in falsified medicines. Out of the 28 experts consulted, seven (AT, FR, HR, HU, PT, RO, UK) identified such measures and provided estimates of the assumed effectiveness as reported in Table 11. Four different measures were noted:

- Antifraud programmes
- Training courses for inspectors
- Databases on falsified medicines
- Automated devices that recognize falsified products

All of these were assessed as relatively effective, with “automated devices that recognize falsified products” perhaps the least effective.

Table 11: Other types of measures to fight falsified medicine trade (incl. estimates of their effectiveness)

a) Specific antifraud programmes				
Very effective (reduction by 50% or more)	Effective (reduction by 20% to 49%)	Little effect (reduction by up to 19%)	No effect at all (0% reduction, or even further increase)	No estimate
1 (FR)	3 (HR, HU, UK)	3 (AT, PT, RO)		
b) Training courses for inspectors				
Very effective (reduction by 50% or more)	Effective (reduction by 20% to 49%)	Little effect (reduction by up to 19%)	No effect at all (0% reduction, or even further increase)	No estimate
2 (HR, HU)	2 (FR, UK)	1 (RO)		2 (AT, PT)
c) Databases on falsified medicines				
Very effective (reduction by 50% or more)	Effective (reduction by 20% to 49%)	Little effect (reduction by up to 19%)	No effect at all (0% reduction, or even further increase)	No estimate
1 (HR)	2 (HU, UK)	3 (FR, PT, RO)		1 (AT)
d) Automated devices that recognize falsified products				
Very effective (reduction by 50% or more)	Effective (reduction by 20% to 49%)	Little effect (reduction by up to 19%)	No effect at all (0% reduction, or even further increase)	No estimate
2 (FR, HU)	1 (UK)	1 (HR)		3 (AT, PT, RO)

4.4 Amount of falsified medicines in European markets

4.4.1 Data collected by Member State authorities

As already noted in section 1.4 above, it appears that Member States do not undertake standardised, consistent and continuous efforts to collect evidence on the share of falsified products placed on its legal market for medicinal products or on what is available in its illegal market. The few countries which do collect data do so in a way that makes them hard to compare. Data on the value of falsified medicinal products is difficult to measure, and the data on the volume or quantities is often not standardised and can apply to number of tablets, packages, dosages, "units", boxes, vials, kg.⁶⁶

As a consequence, it is not possible to provide an accurate estimate of the share of falsified products placed on the market in each Member State. It follows that this lack of evidence makes it difficult to assess the effectiveness of the specific penalties in place or introduced in the Member States.

⁶⁶ The World Customs Organisation (WCO) in its "Illicit Trade Report 2015" applies as "principles for the harmonization of units" a "conversion rate of one gram per three tablets, which allows a unified expression of all seizures in kilograms (kg), and all seizures reported in small units such as capsules, doses, packs and pieces, etc., are converted in the same way." See p. 10 there.

This difficulty is also reflected in many of the studies outlined below that have aimed to assess the illicit medicines trade worldwide or in the EU. Another significant obstacle to obtaining official estimates is disagreement over definitions of what constitutes 'illicit' and what constitutes a 'pharmaceutical product' or 'medicine'.⁶⁷

4.4.2 Studies and data collected by others

A small number of studies or globally organised efforts to fight falsified medicinal products and/or to collect relevant data have been identified. These are mostly studies of organised crime, illicit trading, smuggling, or the manufacture of falsified products in general, which may also have studied active pharmaceutical substances or medicines.

Council of Europe MediCrime Convention of 2011⁶⁸

This convention constitutes a binding international instrument in the criminal law field on counterfeiting of medical products and similar crimes involving threats to public health. The MediCrime Factsheet of 15.12.2015 provides some cursory European level data:

*"As with all clandestine criminal activities, it is impossible to gauge exactly the extent of the problem. Recent estimates suggest that global sales of counterfeit medicines are worth more than € 57 [billion], having doubled in just five years between 2005 and 2010. Numerous studies have also reported large numbers of websites supplying prescription-only medicines without a prescription and people buying medicines online despite being aware of the dangers. According to statistics from customs authorities in the European Union (EU), the number of medical products seized at the outer border of the EU (not counting patent issues) tripled between 2006 and 2009 to reach approximately 7.5 million. Medicines accounted for 8% of all seized materials in 2014. Other statistics from customs authorities in the EU appear to confirm that sales of medicines via the internet have increased. Nearly 69% of articles seized in postal traffic were medicines. However, there are no reliable statistics on the number of counterfeit medicines reaching consumers through unregulated sources such as illegal online pharmacies."*⁶⁹

Operation Volcano⁷⁰

"Operation Volcano" originated from an alert by a German parallel distributor to Italian authorities. It emerged that vials of the cancer medicine Herceptin (trastuzumab), stolen from Italian hospitals, were manipulated, falsified and re-introduced under false credentials by unauthorised wholesalers into the legal supply chain. Seizures of falsified vials were carried out by authorities in Germany, Finland and United Kingdom (UK). The distribution of the falsified vials to other EU Member States was also proved. Later, additional medicinal products were identified as stolen in Italy and, subsequently, re-introduced under false credentials by a criminal organisation connected to Italy. This had been facilitated through unauthorised wholesalers connected to an Italian criminal organisation, formally based in Cyprus, Hungary, Latvia, Romania, Slovak Republic, Slovenia and Greece issuing fake invoices to sell the stolen medicines to authorised Italian and Maltese operators. These authorised operators subsequently exported these to other EU markets.

⁶⁷ Ellis, Claire. On Tap Europe: Organised Crime and Illicit Trade in Spain: Country Report. Occasional Papers, 26 January 2017 Available from <https://rusi.org/publication/occasional-papers/tap-europe-organised-crime-and-illicit-trade-spain-country-report>

⁶⁸ Cf. www.coe.int/en/web/medicrime/home

⁶⁹ <http://rm.coe.int/CoERMPublicCommonSearchServices/DisplayDCTMContent?documentId=09000016806a966a>

⁷⁰ https://www.researchgate.net/publication/303445021_Operation_Volcano_-_The_Herceptin_Case

World Customs Organisation "Illicit Trade report 2015"⁷¹

In 2015, the World Customs Organisation (WCO) began to collect separate information on "counterfeit pharmaceutical products, as well as other types of illicit medicines that could be either smuggled, expired, transported in poor/inappropriate conditions, or lack documents such as a licence or authorisation to enter the market".⁷² Worldwide, 55 WCO member countries reported on the number of detained "pieces [quantity]". Among the top 15 reporting countries were Finland (7th place), Latvia, Romania, Poland, Sweden, Denmark (15th). When reporting by "number of cases",⁷³ Germany placed 2nd, Poland 4th, and Sweden, Czech Republic, Romania, Hungary and Denmark also were noted. In the list of "departure countries by number of pieces" Poland, Hungary and Estonia are noted in rear places.

On Tap Europe: Organised Crime and Illicit Trade in Tobacco, Alcohol and Pharmaceuticals⁷⁴

This study was undertaken by the Royal United Services Institute (RUSI) in the UK and looked at the role of organised crime groups in the illicit trade of tobacco, alcohol and pharmaceuticals across Europe (covering Greece, Italy, Poland, Romania, Spain, and the UK). It noted:

"According to Europol, commodity counterfeiting and illicit trade in substandard goods are major emerging criminal activities in the EU. The low risks and high profitability associated with illicit trade increasingly attract organised crime groups and the number of counterfeit products seized by law enforcement agencies across Europe continues to grow."

Unfortunately, the evidence collected did not allow detailed insights into the crimes and their distribution over time as they relate to falsified medicinal products.

Report of the police crime statistics in Germany 2015-2016 (Bericht zur Polizeilichen Kriminalstatistik 2016)⁷⁵

According to our research, Germany is the only Member State which has in recent years developed more detailed crime statistics on falsified medicines and related offenses. Unfortunately, these data are available only as of 2015 and report only on "cases", i.e. incidences of such offences, not on the magnitude of falsified medicines or the volume of illegal trade. Altogether, 3,269 criminal "cases" were reported for 2015, and 3,431 cases for 2016 under the Medicinal Products Act (AMG). From an earlier source⁷⁶, it can be estimated that from all crimes identified about 8% lead to condemned ("abgeurteilt"), 7% convicted ("verurteilt"), 6% to "ambulatory sanctions" like fines, and 1% to "stationary (prison) sanctions".

⁷¹ World Customs Organisation. Illicit Trade Report 2015. Brussels, Dec. 2016. There see Chapter 3 on "IPR, Health and Safety - Medicines and Pharmaceutical Products", pp. 82 ff

⁷² Their major focus is on illegal drugs like heroin, cocaine, opiates, psychotropic substances, etc.; see also on the results of the OECD Task Force on Countering Illicit Trade (TF-CIT): Sinn, Wirtschaftsmacht Organisierte Kriminalität. Illegale Märkte und illegaler Handel, Berlin 2018, p. 113

⁷³ „Cases may be composed of several seizures of various types of commodities, including different types of drugs." Ibidem, p. 11

⁷⁴ Ellis, Claire. On Tap Europe: Organised Crime and Illicit Trade in Tobacco, Alcohol and Pharmaceuticals. Whitehall Reports, 23 March 2017 Available from <https://rusi.org/publication/whitehall-reports/tap-europe-organised-crime-and-illicit-trade-tobacco-alcohol-and>

⁷⁵ Polizeiliche Kriminalstatistik (Police Criminal statistics) [Germany] 2015, p.122. Available from : https://www.bka.de/DE/AktuelleInformationen/StatistikenLagebilder/PolizeilicheKriminalstatistik/PKS2015/pks2015_node.html

⁷⁶ Sürmann, Heike: Arzneimittelkriminalität – Ein Wachstumsmarkt? Polizei + Forschung Vol. 36. Luchterhand, Köln 2007, p. 28

4.5 Summary result on transposition of Article 118a

The collection of data on the transposition of Article 118a shows that almost all Member States dispose of criminal, “civil” and administrative sanctions for falsifying medicinal products. Infringements of regulations on medicinal products are covered at least partly criminal law penalties in all EU Member States. Unlawful conduct with active substances (especially manufacturing, distribution, export and import) is covered by criminal law and “civil” penalties depending on the MS. Regarding excipients however, Bulgaria, Germany, Latvia,⁷⁷ Malta and UK do not have specific sanctions. In our view, these Member States could strengthen their transposition of the article with respect to excipients (see the overview in table 1 c)).

An additional requirement of Article 118a is that the applicable sanctions are effective, dissuasive and proportionate. Since there exists little or no data to conduct an empirical assessment of effectiveness of sanctions, this study relies on legal theory to reach the following conclusion: considering the potential dangers of falsified medicinal products and the high profitability of criminal activity in this field, only criminal penalties based on abstract or abstract-concrete endangerment can be considered effective, dissuasive and proportionate. This form of sanction facilitates enforcement by lowering the burden of proof on the prosecution. Applying this criterion, we consider that Bulgaria, Latvia, Portugal and (depending on interpretation)⁷⁸ Spain could strengthen their transposition of Article 118a (see graph 3 below).

Generally speaking, legislation on (falsified) medicinal products in the 28 Member States is still heterogeneous, despite important steps towards harmonisation that the amendment of Directive 2001/83/EC initiated. In our view, this complex legal situation complicates matters for protecting the common European market of medicinal products and its citizens. The next chapter will present some recommendations to facilitate enforcement and to heighten effectiveness of the prosecution and sanctioning of pharmaceutical crime/infringements at the European level.

⁷⁷ The theoretically applicable sanctions in Latvia (table 1c) are not specific to medicinal products and only apply in the case of injury; please see country report for LV for further details.

⁷⁸ See country report of Spain.

5 SUMMARY ASSESSMENT OF THE EFFECTIVENESS OF THE MEASURES AND RECOMMENDATIONS

The effectiveness of penalties applicable to infringements of provisions regulating conduct with respect to medicinal products, active substances and excipients depends on several factors. An important distinction has to be made between the effectiveness of sanctions on infringements within the legal market on the one hand, and the illegal market on the other. Any assessment of the effectiveness of measures should also take into account the considerable dangers that falsified medicinal products pose for patient safety and public health in legal and illegal markets.

In this final chapter, a summary assessment of the effectiveness of the measures transposed and implemented by Member States is presented, complemented by recommendations on how to improve the effectiveness of the implementation of Article 118a.

5.1 Effectiveness of measures taken

5.1.1 *Legal and illegal markets*

The lack of reliable empirical data does not allow for a quantitative assessment of the impact or trends over time of the effectiveness of the measures in place in Member States. However, some general considerations can be made from a legal perspective.

Most falsified medicinal products are discovered in the *illegal* market, which is not regulated. Therefore, administrative sanctions, for example the suspension of licenses, rarely apply as the perpetrators active in the illegal market anyhow do not hold a license. Civil penalties can be somewhat effective, but are in our analysis not proportionate when considering the high risk to public health from falsified medicinal products. In our view, compared to the very high lucrativeness of the sale of falsified medicinal products, civil penalties cannot be considered adequately dissuasive. For the illegal market, only well enforced criminal penalties are truly effective. *This requires awareness within law enforcement agencies and resources to enforce.*

The *legal* market functions mostly via licensed actors, who depend on licenses to undertake their business. In our assessment, administrative sanctions for unreliable merchants, especially wholesalers, can be dissuasive, proportionate and effective. The same holds for civil penalties.

Within the legal market the manufacturing, distribution, import and export of falsified medicinal products, at least when done with intent, shows considerable criminal disposition and are a serious threat to patient safety and public safety. Additionally, introducing falsified medicinal products into the legal supply chain abuses the trust of patients. This could be considered more dangerous than the consumption of medicinal products purchased knowingly in the illegal market, since the patient and the doctors have no reason to distrust the medicinal product acquired on the legal market and therefore usually exclude the possibility that any complications are the effect of the consumption of falsified medicinal products. *In view of this, we would strongly recommended to provide for criminal law provisions and sanctions based on the legal concept of abstract endangerment crimes for manufacturing, distributing, importing and exporting falsified medicinal products, because these are generally very dangerous and extremely lucrative endeavours.*

5.1.2 *Effect of measures and penalties on the amount of falsified medicines*

The homogeneous and fragmentary empirical data does not allow a quantitative assessment of the impact of sanctions and penalties on the amount of falsified medicinal products in either the legal or the illegal market.

Since pharmaceutical crimes are typically control-related crimes, high control pressure and effective international legal assistance and cooperation of enforcement authorities will achieve greater reduction in the amount of falsified medicinal products entering the EU than small modifications to some national law provisions.

5.2 Recommendations

Recommendations to improve the fight against the production and trade of falsified medicinal products are outlined below.

5.2.1 *Improvement of the effectiveness of penalties*

Firstly, the trade of falsified medicinal products within the legal but also illegal markets must be prosecuted consistently, particularly by applying criminal penalties, to safeguard patient safety and public health.

Criminal law provisions in the form of abstract endangerment crimes for manufacturing, distributing, importing and exporting falsified medicinal products should be introduced where absent. In our analysis, other forms of penalties or sanctions are not as effective considering the enormous dangers to patients from falsified medicinal products on the one hand, and the extremely large profits which can be gained from the falsification of medicinal products.

In our assessment, raising the applicable criminal penalty for conduct involving falsified medicinal products to *three years imprisonment across the EU* would facilitate prosecution of crimes of cross-border character, which is common for pharmaceutical crimes. A maximum penalty of at least three years imprisonment meets the requirements of the "European Investigation Order"⁷⁹ and facilitates international legal assistance.⁸⁰

However, it should also be noted that enforcement depends not only on resources and personnel, but also on the usability of the national laws to be enforced. Member States should endeavour to clarify legislation that is not sufficiently precise or proves difficult to enforce.

5.2.2 *Improvement of the effectiveness of other measures*

The most effective measure against illegal activity is not simply severe punishment, but rather widespread enforcement. We recommend prioritising pharmaceutical crimes as highly hazardous cross-border-crimes often linked to organised crime. Sufficient human and financial resources should be allocated to customs authorities and police to fight the growing illegal market, but also to authorities responsible for prosecuting infringements concerning the legal market.⁸¹ Police and customs officials would benefit from regular training in pharmaceutical criminal law and the options of international legal assistance to raise the intensity of control pressure and the quality of international cooperation between the national prosecution authorities.

Public authorities monitoring the legal market to prevent unlawful intrusion of medicinal products should forward any cases of infringements to public authorities responsible for prosecuting offences against patient safety and public health. Countering the distribution of falsified and illegal medicinal products has to move from the prevention to the prosecution phase.

⁷⁹ Directive 2014/41/EU of the European Parliament and of the Council of 3 April 2014 regarding the European Investigation Order in criminal matters

⁸⁰ Sinn. Internethandel und Arzneimittelkriminalität (Internet Commerce and Pharmaceutical Crime), Bundesgesundheitsblatt. Springer, 2017 (in print)

⁸¹ Sinn. Organisierte Kriminalität 3.0 (Organised Crime 3.0). Springer, 2016, p. 22 ; Sinn. Internethandel und Arzneimittelkriminalität (Internet Commerce and Pharmaceutical Crime), Bundesgesundheitsblatt. Springer, 2017 (in print), reporting recommendations of the ALPhA project

Additionally, preventive measures such as the upcoming end-to-end verification system should be used to strengthen criminal prosecution. Art. 80 (i) of Directive 2001/83/EC in conjunction with Art. 30 of the Delegated Regulation (EU) 2016/161 already imposes the obligation on persons who are authorised or entitled to supply medicinal products to the public to report the “case of suspected falsification” immediately to “the relevant competent authorities”. It is recommended to ensure that this mandatory information flow reaches public prosecution in the Member States involved in the supply chain of that suspicious batch. It is not enough to remove the medicinal product from circulation: penalties have to be imposed, as required by Article 118a of the Directive 2001/83/EC. As long as perpetrators are not prosecuted, incentives to infiltrate the legal market with cheap falsified medicinal products remain considerably higher than the dissuasion that comes with enforcement and punishment.

Where necessary, *awareness within enforcement agencies should be raised concerning the existence and applicability of penalties for infringements of medicinal product law.* In most Member States, there are applicable criminal penalties that do not require proving the causation of harm or concrete danger, but the enforcement and prosecution officers need to know how to apply them.

5.2.3 Collection of quantitative data

Finally it is important to provide for an evidence-based assessment of the success, the general effectiveness, and specific effects of certain measures or specific penalties on the amount (or value) of falsified medicines in the market in years to come. In order to achieve this aim, improvements to data collection and integration are necessary.

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