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Pharmaceutical crime in the European Union – selected issues

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Abstract

The aim of the study is to analyse the main directions of the dynamically developing pharmaceutical crime that the European Union and all its Member States have to deal with, as well as to attempt to indicate further necessary systemic solutions to prevent this type of crime. The author presents the most common types of pharmaceutical crimes in the European Union, analyses the normative activity of its organs aimed at preventing this type of crime and the harmonisation of the laws of the Member States in this area. She also tries to identify the causes of the current problems with effectiveness in the fight against this type of crime in the European Union. In conclusion, the author presents proposals for considering the introduction of further pan-European legal regulations and formulates appropriate *de lege ferenda* conclusions in this regard.

Keywords

pharmaceutical crime, counterfeit medications, falsification of medicines, misconduct involving active substances, misconduct involving excipients, Directive 2001/83/EC, Directive 2011/62/EU

Introduction

Pharmaceutical crime includes the production, trafficking and distribution of counterfeit, stolen or illegal medicinal and medical products. Thus, pharmaceutical crime can

take many different forms. Undoubtedly, the biggest problems are counterfeit medicines and medical devices as these are the greatest threats to human life and health. For this reason, the European Union bodies are taking action to counteract this type of crime. In the normative aspect, the most important step in this direction so far has been the adoption of Directive 2011/62/EU of the European Parliament and of the Council of 8 June 2011,[1] amending Directive 2001/83/EC on the Community code relating to medicinal products for human use,[2] as regards the prevention of the entry into the legal supply chain of falsified medicinal products (hereinafter Directive 2011/62/EU). Its main aim was to harmonise the laws of the Member States in the field of appropriate counteracting pharmaceutical crime involving the counterfeiting of drugs and placing them on the market, and to oblige Member States to introduce regulations aimed at establishing appropriate penalties for violating the provisions in this area. Pursuant to Article 118a of the Directive, penalties must be effective, proportionate and dissuasive. According to the report of the European Commission of January 26, 2018, a total of 26 Member States (AT, BE, BG, CY, CZ, DE, DK, EE, EL, ES, FR, HR, IE, IT, LT, LU, LV, MT, NL, PL, PT, RO, SE, SI, SK, UK) have introduced changes to their legislation in relation to penalties for the falsification of medicines, active substances and excipients in order to transpose Article 118a of the Directive. Hungary made changes to its Criminal Code as a result of the Council of Europe 'Medicrime Convention'.[3] Finland has not changed its legislation, as penalties were already in place before the entry into force of Article 118a of the Directive.[4] A detailed analysis of changes introduced in the regulations of individual Member States, however, indicates what European Union bodies should strive to do to further harmonise the law in this area. The current, existing differences between the laws of individual Member States, primarily in terms of the nature and amount of penalties for the counterfeiting of drugs and the introduction of counterfeit drugs to the market, imply a real risk of appropriate migration of criminal groups dealing with this practice and conducting activities in these countries, in which penalties for such acts are the lowest.

1 Directive 2011/62/EU of the European Parliament and of the Council of 8 June 2011 amending Directive 2001/83/EC on the Community code relating to medicinal products for human use, as regards the prevention of the entry into the legal supply chain of falsified medicinal products [2011] OJ L 174/74.

2 Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use [2001] OJ L 311/67, as amended.

3 Council of Europe Convention on the counterfeiting of medical products and similar crimes involving threats to public health ('The Medicrime Convention') (2011), CETS 211.

4 Report from the Commission to the European Parliament and the Council on the Member States' transposition of Article 118a of Directive 2001/83/EC of the European Parliament and the Council of 6 November 2001 on the Community code relating to medicinal products for human use as amended by Directive 2011/62/EU of the European Parliament and of the Council of 8 June 2011, Brussels, 26 January 2018, COM(2018) 49 final <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52018DC0049> accessed 22 March 2022.

1. THE PHENOMENON OF FALSIFICATION OF MEDICINAL AND MEDICAL PRODUCTS

The practice of counterfeiting medicinal products, medical devices and dietary supplements and their illegal trade is a global problem. It applies to both highly developed and developing countries.[5]

In accordance with Article 1(33) of revised Directive 2001/83/EC a 'falsified medicinal product' is any medicinal product with a false representation of:

a) its identity, including its packaging and labelling, its name or its composition, as regards any of the ingredients including excipients and the strength of those ingredients;
b) its source, including its manufacturer, its country of manufacture, its country of origin or its marketing authorisation holder;
c) its history, including the records and documents relating to the distribution channels used.

However, it should be noted that the definition of a 'falsified medicinal product' does not include unintentional quality defects and is without prejudice to infringements of intellectual property rights.[6]

Therefore, a medicinal product, of which the content has been wholly or partially counterfeited or altered, and a medicinal product, of which the content is original but has been repackaged or subject to any interference in the sales process, including the documentation attached to it, is fake. Also, a full-value product, manufactured after working hours by factory employees who want to earn extra money to which illegally produced documentation is attached, is considered a counterfeit.

5 Zbigniew Fijałek, Katarzyna Sarna, 'Wybrane aspekty jakości produktów leczniczych i suplementów diety – produkty substandardowe, nielegalne i sfałszowane' (2009) 65 Rynek Farmaceutyczny 468-475; Jacek Dworzecki, Izabela Nowicka, 'Organized crime in the production and distribution of falsified medicines in Poland: outline the problem' (2019) 6 Entrepreneurship and Sustainability Issues 1762-1770 <https://doi.org/10.9770/jesi.2019.6.4(15)>; Vitalii Pashkov, Aleksey Soloviov, Andrii Olefir, 'Legal aspects of counteracting the trafficking of falsified medicines in the European Union' (2017) 70 Wiadomości Lekarskie 843-849; Robert C. Bird, *Counterfeit drugs: a global consumer perspective* (2007–2008) 8 Intellectual Property Law Journal 378-406; Rubie Mages, Thomas T. Kubic, 'Counterfeit medicines: Threat to patient health and safety' (2016) 18 Pharmaceuticals, Policy and Law 163-177 <https://doi.org/10.3233/PPL-160441>.

6 The Polish law is fully harmonised in this area with EU legislation. According to the Article 2(38a) of the Pharmaceutical Law (2001), Dz.U. (2001), No 126, item 1381 with subsequent amendments: a counterfeit medical product is a medicine that has been misrepresented in terms of: a) the identity of the product, including its packaging, label, name or composition in relation to any ingredients, including excipients, and the strength of these ingredients, b) its origin, including its manufacturer, country of manufacture, country of origin or responsible entity, or c) its history, including data and documents on the distribution channels used.

In comparison, it is worth pointing out that a much broader definition in this subject was developed by the American Food and Drug Administration (FDA), which considers a counterfeit product to be a medicine, container or label that without authorisation bears a trademark, brand name, other identifying mark, imprint or the slogan, or any similarity, to that drug manufacturer, process, packaging or distributor, other than a legal entity or persons who actually produced, processed, packaged, or distributed such a drug and that has, as a result, been misrepresented or misrepresented that product, or has been packaged or distributed by another drug manufacturer, packer, or distributor.[7]

Most often, counterfeit products are sold over the Internet. Undoubtedly, therefore, in the era of the Coronavirus, pharmaceutical crime has gained a new and, unfortunately, even worse reputation all over the world, including the European Union and all its Member States. According to the report of the European Union Intellectual Property Office from November 2020, in as many as five EU Member State the percentage of producer losses in the sale of medicinal products compared to total sales (this is an indicator that allows you to assess the number of counterfeit products, the higher the percentage, the worse the situation) was above 10 percent. This is an unprecedented aspect. Poland is in the middle of this statistic. It is much better than in Bulgaria, Romania and Hungary, but also much worse than in Germany, France or the Netherlands.[8] Counterfeit drugs pose a threat to patients and the general public, primarily because patients believe they are receiving authentic treatment, but are, instead, given potentially unsafe products that can increase resistance to the actual treatment and cause further illness, disability, and even death. The presence of these counterfeit drugs also undermines confidence in the healthcare system and results in huge financial losses. It is therefore important to raise awareness of the dangers of counterfeit medicines.[9]

Unfortunately, the phenomenon of drug counterfeiting has been gaining momentum in recent years due to the high profitability of this type of illegal activity. According to estimates by the European Commission, around 183 million packages of falsified drugs were on the market by 2020. Estimates from the WHO and the Food and Drug Administration (FDA) show that up to 1% of drugs sold in developed countries may be counterfeit. The World Medicines Organization is concerned about the rapid increase in counterfeit medicinal products purchased from the Internet. They constitute about 50% of the products offered there.[10] According to the WHO, the global market for counterfeit

7 Zbigniew Fijałek, Katarzyna Sarna, 'Fałszowanie leków i inne przestępstwa farmaceutyczne' (2009) 263 Problemy Kryminalistyki [Issues of Forensic Sciences].

8 Patryk Słowik, Jakub Styczyński, 'Nasze zdrowie w rękach bandytów', Dziennik Gazeta Prawna, 22 January 2021 <https://www.gazetaprawna.pl/magazyn-na-weekend/artykuly/8074698,przestepczosc-farmaceutyczna-koronawirus-falszywe-leki-wyroby-medyczne.html > accessed 22 March 2022.

9 Warszawski Uniwersytet Medyczny (WUM), Wywiad z profesorem Zbigniewem Fijałkiem na temat fałszowanych leków [Interview with professor Zbigniew Fijałek about counterfeit medicines] <https://www.wum.edu.pl/node/13622> accessed 29 April 2022.

10 Magdalena Młynarek, *Zjawiska patologiczne na rynku farmaceutycznym* (Instytut Wymiaru Sprawiedliwości 2019) 28.

drugs is worth 200 billion USD annually. In turn, according to the experts of the European Union, around 850 million Euro per year is spent on falsified medicinal products throughout Europe, and the size of the Polish market for such products was estimated by the European Commission at 62 million Euro.[11]

2. Regulatory activity of EU bodies and Member States in order to prevent the phenomenon of counterfeiting of medicinal and medical products

The necessity to fight against the constantly growing number of identified counterfeit drugs in the legal supply chain has become the basis for the introduction of the Directive 2011/62/EU. As part of the above-mentioned amendment, a delegation for the European Commission was introduced in order to develop a regulation applicable directly on the territory of all Member States. As part of the aforementioned delegation, the European Commission developed and published the Commission Delegated Regulation (EU) 2016/161 of 2 October 2015, supplementing Directive 2001/83/EC of the European Parliament and of the Council (hereinafter Commission Delegated Regulation or Regulation).[12]

According to Article 50 of the Commission Delegated Regulation, it entered into force on 9 February 2019. Article 1 of the Regulation states that it refers to:

a) the characteristics and technical specifications of the unique identifier that enables the authenticity of medicinal products to be verified and individual packs to be identified;
b) the modalities for the verification of the safety features;
c) the provisions on the establishment, management and accessibility of the repositories system where the information on the safety features shall be contained;
d) the list of medicinal products and product categories subject to prescription which shall not bear the safety features;
e) the list of medicinal products and product categories not subject to prescription which shall bear the safety features;
f) the procedures for the notification to the Commission by national competent authorities of non-prescription medicinal products judged at risk of falsification and prescription medicinal products not deemed at risk of falsification in accordance with the criteria set out in Article 54a(2)(b) of Directive 2001/83/EC;

11 Ibid, 28-29; Stowarzyszenie Leki Tylko z Apteki, raport 'Pozaapteczny obrót lekami OTC bezpieczeństwo, ekonomia i oczekiwania pacjentów' (2018) 43-44 <https://lekitylkozapteki.pl/uploads/raport.pdf> accessed 26 April 2022.

12 Commission delegated regulation (EU) 2016/161 of 2 October 2015 supplementing Directive 2001/83/EC of the European Parliament and of the Council by laying down detailed rules for the safety features appearing on the packaging of medicinal products for human use [2016] OJ L 32/1.

g) the procedures for the rapid evaluation of, and decision on, the notifications referred to in point (f) of this Article.

It is worth saying that this Regulation introduced the European Medicines Authenticity System into the territory of the European Union, which serves to verify the authenticity of potentially counterfeit medical products by comparing the data on unique identifiers entered into the system with the data applied to individual drug packages.

The data on unique identifiers are applied to the packaging in a form encoded in 2D Data Matrix ECC 200 format and in a format that can be read by the human eye. Only positive verification of the packaging in the system, and confirmation by authorised persons to deliver medicinal products to patients, that the protection against opening (the so-called ATD) has not been violated, allows, in the light of the Regulation, the issue of the medicine to the patient.

All the above-mentioned legal acts of EU bodies require coordinated international actions to prevent the presence of counterfeit medicinal products on the market and play a huge role in increasing the safety of treatment for all patients in the European Union. By being able to detect counterfeit medicinal products before administering them to patients, they strengthen the European pharmacovigilance system. The introduction of the Directive 2011/62/EU obligated all entities involved in the distribution of medicinal products, from manufacturers, to wholesalers, parallel importers, to public and hospital pharmacies, to modify the methods of distributing drugs in order to seal them.[13]

In result of introduction of the Directive 2001/83/EC amended by Directive 2011/62/EU, the Member States were also faced with the need to implement into their laws solutions aimed at determining proportionate, effective and dissuasive penalties for those involved in the production and distribution of falsified medicines. Article 118a(1) of Directive 2001/83/EC requires that the Member States shall lay down the rules on penalties applicable to infringements of the national provisions adopted pursuant to this Directive and shall take all necessary measures to ensure that those penalties are implemented. The penalties must be effective, proportionate and dissuasive but shall not be inferior to those applicable to infringements of national law of similar nature and importance. Article 118a(2) provides that these rules referred to Article 118a(1) shall address, inter alia:

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.

13 Krajowa Organizacja Weryfikacji Autentyczności Leków (KOWAL), 'Serializacja i Dyrektywa Antyfałszywkowa', 11 February 2019 <https://www.nmvo.pl/pl/aktualnosci/serializacja-i-dyrektywa-antyfalszywkowa/> accessed 22 March 2022.

Every year, Interpol coordinates the PANGEA operation, which is aimed at controlling the trade in drugs outside the legal distribution chain. PANGEA covers pharmaceutical markets in 153 countries. The last such operation took place in March 2020 and also included drugs for COVID-19.[14]

It should also be pointed out that several global organisations are involved in the fight against the threats caused by counterfeiting drugs, such as: the World Health Organization (WHO), or the World Customs Organization and the Working Groups of the Heads of Medicines Agencies (HMA). All these entities coordinate their activities and share information in order to stop the supply of falsified drugs.[15]

3. Analysis of changes in the law of individual Member States in connection with the obligation under Article 118a of Directive 2001/83/EC amended by Directive 2011/62/EU

An overview of the transposition of Article 118a in the Member States indicates that in all Member States at least some activities relating to the falsification of medicinal products are a criminal offence. According to the Report from the Commission to the European Parliament and the Council of January 26, 2018, in 21 UE Member States (AT, BE, CY, CZ, DE, DK, EE, GR, ES, FR, HR, HU, IE, IT, LU, MT, NL, PT, SI, SK, GB), the manufacturing, distribution, brokering, import, export and sale at a distance of falsified medicines are subject to criminal sanctions. In the remaining seven States, however, certain activities are subject to civil penalties (such as fines) rather than criminal penalties. In Bulgaria, criminal penalties apply only to the import or export of falsified medicinal products. The remaining activities are covered only by civil penalties. In Finland, there are no criminal penalties for brokering or export, but these are covered by more general provisions. In Latvia, criminal penalties cover manufacturing, distribution and brokering. Export and import are covered by civil penalties. Additionally, in Romania export and import are covered by civil penalties. In Poland and Sweden, criminal penalties do not cover export, but this is covered by civil penalties. Import covered by civil penalties also occurs in Lithuania.[16]

All 28 Member States apply criminal penalties in the form of imprisonment for the falsification of medicines. Only one Member State (LV) penalises falsification that causes physical harm or death (harm crimes). Two Member States (ES, PT) penalise falsification that causes a risk or danger to the health of a person or public health (con-

14 Interpol, 'Operation Pangea – shining a light on pharmaceutical crime', 21 November 2019 <https://www.interpol.int/News-and-Events/News/2019/Operation-Pangea-shining-a-light-on-pharmaceutical-crime> accessed 22 March 2022.

15 Europejska Akademia Pacjentów, Sfałszowane leki <https://www.eupati.eu/pl/bezpieczenstwo-stosowania-lekow/sfalszowane-leki/> accessed 22 March 2022.

16 Report (n 4) 2.

crete endangerment). Four Member States (EL, LT, RO, SI) penalise falsification that is shown to be generally dangerous, i.e. the falsified medicine contains insufficient active ingredients or harmful substances (concrete-abstract endangerment). In the remaining 21 Member States, falsification *per se* is penalised, without the need to prove that the product is dangerous to health at all. For active substances (the main component of the medicine), 23 Member States apply criminal penalties and, for excipients (auxiliary component of the medicine) only 14 Member States apply criminal penalties. Where criminal penalties apply for the falsification of medicines, the maximum prison sentence is at least three years in 20 Member States (AT, GB, CY, DE, EE, ES, FR, HR, HU, IE, IT, LT, LU, LV, NL, PL, PT, RO, SI, SK). As outlined above, all Member States apply fines for the falsification of medicines. For active substances, 26 Member States apply fines. For excipients, 20 Member States apply fines. Fines may take the form of criminal or civil penalties, although maximum levels vary across Member States. All Member States except Finland, Luxembourg and Malta have introduced additional administrative sanctions for the falsification of medicines, active substances and/or excipients.[17]

The European Commission report on compliance with the requirement to introduce proportionate, effective and dissuasive penalties for those involved in the production and distribution of falsified medicines shows that the penalties vary considerably across the EU.[18] For example, the maximum prison terms for drug counterfeiting range from one year (SE, FI and GR) to fifteen years (AT, SI and SK). The maximum fines vary from 4,300 Euro (LT) to 1 million Euro (ES).[19] In Poland, pursuant to Article 124b of the Pharmaceutical Law, anyone who produces a falsified medicinal product, or a falsified active substance, is subject to a fine, restriction of liberty or imprisonment for up to five years (Section 1). The same penalty is also imposed on a person who supplies or makes available, against payment or free of charge, a falsified medicinal product or a falsified active substance, or stores, for this purpose, a falsified medicinal product or a falsified active substance (Section 2).[20]

Final remarks

Undoubtedly, the phenomenon of medicinal and medical products counterfeiting poses a significant challenge to public health. Fighting this phenomenon is a task and a challenge for the international community.

An extremely important step, aimed at minimizing the risk associated with falsified medicinal products, is the unification of the European Union's policy against falsified

17 Report (n 4) 6.

18 Polityka Zdrowotna, 'Komisja Europejska chce skuteczniejszej walki z fałszowaniem leków', 3 April 2018 <http://www.politykazdrowotna.com/30298,komisja-europejska-chce-skuteczniejszej-walki--z-falszowaniem-lekow> accessed 22 March 2022.

19 Report (n 4) 3-5.

20 Article 124b of the Pharmaceutical Law.

medicines and the harmonisation of the regulations of the Member States. However, it should be considered whether the margin of discretion currently left to the Member States in terms of establishing applicable penalties for the falsification of medicinal products is not too great. While the differences between the laws of individual Member States are not significant in terms of defining the very features of prohibited acts related to counterfeiting drugs and placing them on the market, these differences are enormous in terms of the penalties that may be imposed in particular Member States. Therefore, taking into account that the element to be protected is human health and life, the differences in the laws of individual EU Member States with regard to determining the severity of penalties for persons involved in the production and distribution of falsified drugs seem too significant. It is impossible not to pay attention to the fact that, at present, in view of the freedom of movement of people and services within the territory of the EU, there is a high risk that well-organised criminal groups dealing with drug counterfeiting will select these states in its territory, in which the sanctions for this offence are the lowest. For this reason it is necessary to further harmonise the laws of the Member States in this area, especially by proposing the introduction of uniform penalties in this respect throughout the European Union. It seems that this could be the most effective step in preventing the migration of crime from this area within the EU.[21]

There can be no doubt that the fundamental issue in the fight against counterfeiting drugs is also to raise patients' awareness of the risks that such activities pose. One should agree with Magdalena Młynarek that the fundamental role in this process is played by pharmacists working in pharmacies, who, thanks to close contact with patients and professional knowledge, can protect the health and even lives of said patients. It is important, above all, to teach patients to recognise trusted sources of drug marketing.[22] From the point of view of scientific reflection, the position that it would be desirable to conduct research in a qualitative approach, e.g. interviews with patients would broaden the knowledge of patients' perception of falsified medicinal products.[23]

It is also important to change the approach to counteracting medicinal and medical products counterfeiting itself. Perpetrators involved in this process are characterised by a high sense of impunity, due to the fact that the courts most often impose a fine or imprisonment with a conditional suspension of their execution for this type of crime, without taking into account the threat to life and health of patients resulting from counterfeiting drugs. This approach should be significantly changed so that general prevention can fulfill its function.

21 Vishv Priya Kohli, *Combatting Falsification and Counterfeiting of Medicinal Products in the European Union – A Legal Analysis* (Copenhagen Business School 2018) 282-301.

22 Młynarek (n 10) 37.

23 Damian Świeczkowski, Szymon Zdanowski, Piotr Merks, Miłosz Jarosław Jaguszewski, 'Leki sfałszowane jako wyzwanie dla zdrowia publicznego – próba definicji pojęcia i skali zjawiska na świecie oraz ujęcie prawne i socjologiczne' (2019) 75 Farmacja Polska 621 <https://doi.org/10.32383/farmpol/115755>.

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