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ORGANIZED CRIME IN THE PRODUCTION AND DISTRIBUTION OF FALSIFIED MEDICINES IN POLAND: OUTLINE OF THE PROBLEM*

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Abstract. Pharmaceutical crime has become a global phenomenon, an element of organized global crime, alongside drug and arms trafficking. Therefore, in order to combat this issue, there is a need of co-operation of a number of factors such as: the legal system, its proper use, cooperation of entities obliged to combat crime (not only national but also international), appropriate social campaign. This paper refers to the aforementioned issues. It presents examples of actions of the Polish police in the fight against pharmaceutical crime as a form of organized crime. The article has been prepared within the frames of realizing a research project called “Understand the Dimensions of Organized Crime and Terrorist Networks for Developing Effective and Efficient Security Solutions for First-line-practitioners and Professionals” (Project: TAKEDOWN, H2020-FCT-2015, No: 700688).

Keywords: pharmaceutical crime, organized crime, medicines

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1. Introduction

Pharmaceutical crime has become a global phenomenon, an element of organized global crime, alongside drug and arms trafficking. This results not only from the geographical scope, but also from the areas of danger, which include: 1) smuggling of counterfeit products, 2) production of counterfeit products, 3) placing counterfeit/falsified products on the market, 4) trading in prohibited products or against the required permit. Medicines or active substances are largely manufactured in China or India, and then they are sent in bulk quantities to other countries, often to other continents. The WHO data shows that about 1% of all medicinal products used in highly industrialized countries are falsified. As regards the whole world, the percentage of counterfeit medicines increases to 10%, whereas in such parts of the world as Asia, Africa and Latin America the number of falsified medicines available on the market reaches 30%. According to Secretary General of Interpol, falsified medicines are more dangerous than international terrorism which killed about 65,000 people for forty years, while in China alone, nearly 200,000 people die of using falsified and substandard drugs every year. The world "leader" in drug falsification is Nigeria (over 60 percent of all falsified medicines come from this country). Most counterfeited medicines in Nigeria include antimalarial medications, anti-inflammatory medications, analgesics and antibiotics. Inefficient antimalarial medications killed over 120,000 pre-school children in Africa in 2015. With regard to the activities of organized crime groups, international actions are taken to combat this practice. One of the examples is "He-era" operation (15 May - 17 June 2017), which involved 1150 law enforcement officers from police, customs, and regulatory authorities in seven countries - Benin, Burkina Faso, Ivory Coast, Mali, Niger, Nigeria and Togo - whose task was to liquidate illegal factories and supply chains. Raids on markets, stores, pharmacies, warehouses, vehicles and illegal factories have led to the seizure of over 41 million tablets and 13,000 boxes of illegal pharmaceutical and medical products valued at approximately \$ 21.8 million. About 150 people were arrested or prosecuted. The seized goods included health supplements, herbal products, analgesics, antibiotics, antimalarial drugs, vitamins, mineral supplements as well as printing and packaging equipment.

The article discusses the problems of organized criminal groups in the production and distribution of falsified medicines in Poland. It is addressed to specialists in combating crime, to officers of formations responsible for security and public order, as well as to students of the following faculties: internal security, law, accounting and taxes.

2. Pharmaceutical crime in Poland. Legal perspective - outline

Poland has also been affected by pharmaceutical crime in each of its forms, this is a transit country, a country where counterfeit/falsified products are placed on the market and illegally traded, as well as a country where counterfeit/falsified products are produced. That is why the Polish legal system has been adapted to European standards in the area of combating and preventing this phenomenon. The question that needs to be asked is whether we have sufficient legal, procedural and other measures to deal with organized pharmaceutical crime.

The adoption by the Sejm (the lower house of the Polish Parliament) of the Act of 6 September 2001 - Pharmaceutical Law (Journal of Laws No. 126, item 1381, as amended), the Act on the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products (Journal of Laws No. 126, item 1379, as amended), the Act on medical devices (Journal of Laws No. 126, item 1380, as amended), the Act - Regulations introducing the Act - Pharmaceutical Law, the Act on Medical Devices and the Act on the Office for Registration of Medicinal

Products, Medical Devices and Biocidal Products (Journal of Laws No. 126, item 1382, as amended), initiated the adaptation of Polish legislation to the acquis of the European Union in the field of pharmaceutical issues. The content of the Act specifies: the principles and procedure for the authorization of medicinal products, in particular as regards the quality, efficacy and safety requirements for their use; conditions for conducting clinical trials on medicinal products; conditions for the manufacture of medicinal products; requirements for advertising of medicinal products; conditions for the marketing of medicinal products; requirements for pharmacies, pharmaceutical wholesalers and non-pharmacy outlets; organization and principles of operation of the pharmacovigilance system of medicinal products and monitoring the safety of their use; tasks of the Pharmaceutical Inspection and the powers of its authorities. In accordance with the content of art. 1 (2) of the aforesaid Act, the provisions of the Act are also applicable to medicinal products being narcotic drugs, psychotropic substances and precursors within the meaning of the provisions on counteracting drug addiction, to the extent not regulated by these provisions.

Changes in the Pharmaceutical Law Act resulted from the evolution of European law on medicinal products. As a result, on 20 April 2004, the Act amending the Pharmaceutical Law, the Act on the Medical Profession and the Act - Regulations introducing the Pharmaceutical Law Act, the Medical Devices Act and the Act on the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products were passed (Journal of Laws No. 92, item 882) with the aim of implementing Directive 2001/20/EC of the European Parliament and of the Council of 4 April 2001 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the implementation of the principles of good clinical practice in conducting clinical trials of medicinal products intended for human use and adaptation of the provisions of the Act - Pharmaceutical Law to the requirements of Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products intended for human use and Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to veterinary medicinal products. The changes resulted from the implementation of the provisions of the following Directives of the European Parliament and of the Council: 1) 2004/24/EC of 31 March 2004 amending Directive 2001/83/EC on the Community code relating to medicinal products intended for human use, as regards traditional herbal medicinal products, 2) 2004/27/EC of 31 March 2004 amending Directive 2001/83/EC on the Community code relating to medicinal products intended for human use, 3) 2004/28/EC of 31 March 2004 amending Directive 2001/82/EC on the Community code relating to veterinary medicinal products. In addition, a more accurate implementation of Directive 2001/20/EC has been executed. In 2015 the Pharmaceutical Law Act was amended. These changes were compelled particularly by the necessity of adapting Polish regulations to the law of the European Union in this field. The implementation of EU provisions concerns Directive 62/2011/EC of the European Parliament and of the Council. The first amendment this year was announced on 8 January (the Act of 19 December 2014 on amendment of the Pharmaceutical Law Act and some other acts). The new amendment has already been adopted by the Sejm on 9 April. Another amendment to the law was brought by the Act of 7 April 2017 amending the Pharmaceutical Law Act of 25 May 2017, item 1015.

The aim of the changes was not only to adapt the Polish law to the EU assumptions in the described scope but to shape them in such a way as to ensure the tightness and safety of the distribution chain of medicinal products and eliminate any irregularities during this process. In the discussed field, particular attention should be paid to the content of the provision of art. 124b. 1. Whoever produces a falsified medicinal product or a falsified active substance is subject to a fine, the penalty of restriction of liberty or the penalty of deprivation of liberty for up to 5 years. 2. The same penalty shall be imposed on a person who provides or makes available a falsified medicinal product or falsified active substance for payment or free of charge, or holds a falsified medicinal product or falsified active substance for this purpose.

The content of the provisions of art. 38a) and the next art. explains the concept of a falsified medicinal product, which is a medicinal product, excluding the medicinal product with an unintended quality defect, which has been

falsely presented in terms of: a) the identity of the product, including its packaging, label, name or composition with respect to any ingredients, including excipients, and the strength of these ingredients, b) its origin, including its producer, country of production, country of origin or responsible entity, or c) its history, including data and documents regarding the distribution channels used; and (38b) falsified active substance - which is the active substance, excluding the active substance containing an unintentional quality defect, which has been falsely presented in terms of: a) the identity of the product, including its packaging, label, name or composition with respect to any ingredients, including excipients, and the strength of these ingredients, b) its origin, including its producer, country of production, country of origin or responsible entity, or c) its history, including data and documents regarding the distribution channels used;

In the fight against pharmaceutical crime, other provisions apply as well:

- Criminal Code - art. 165 para. 1(2); and also art. 156, art. 157 and art. 160;
- Act of 06.09.2001 - Pharmaceutical Law - art. 124-132;
- Act of 30.06.2000 - Industrial property law - art. 304 and 305;
- Act of 25.08.2006 on food and nutrition safety - art. 96-99.

The legal act helpful in combating counterfeiting is EC Regulation No. 1383/2003, which allows customs services to seize goods suspected of infringing intellectual property rights.

3. State administration institutions obliged by law to prevent and combat pharmaceutical crime in Poland

Various entities have been granted the right to analyze risks of the violation of pharmaceutical law from different angles. These include the Main Pharmaceutical Inspector and his subordinate units, the Chief Sanitary Inspector and his subordinate units, the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products, the Office of Competition and Consumer Protection, government institutions such as the Ministry of Justice, Customs Services, Border Guard, Office Patent, Patent Attorneys. One of the entities is also the National Medicines Institute, which was established as a result of the merger of the Institute of Medicines with its registered office in Warsaw and the Central Laboratory of Sera and Vaccines based in Warsaw and was named the National Institute of Public Health. On 8 December 2006, the Institute was named the National Medicines Institute (on the basis of the Regulation of the Minister of Health of 3 November 2006, Journal of Laws No. 210 item 1554). In 2007, the National Medicines Institute (member of the OMCL Network) prepared 226 opinions on 354 illegal products (including 44 medical devices), in 2008 - 70 opinions on 439 products (including 21 medical devices), and in the first quarter of 2009 - 27 opinions on 91 products. Particularly noteworthy are the more and more visible actions of the Team for Falsified Medicinal Products, set up at the Main Pharmaceutical Inspectorate.

This team coordinates the activities of pharmaceutical inspection, laboratory control, customs services, police and prosecution, aimed at effectively detecting and combating this problem in Poland. The team consists of representatives of the following authorities:

- Main Pharmaceutical Inspector;
- Minister of Health,
- President of the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products,
- Chief Sanitary Inspector,
- Prosecutor General,
- Commander-in-Chief of the Police,
- Head of the Customs Service,
- President of the Office of Competition and Consumer Protection,
- Head of the National Medicines Institute and
- Chief Veterinary Officer.

The main goal of the team is to:

- set directions of counteracting the phenomenon of falsification of medicinal products,
- prevent the sale of medicines in unauthorized places,
- plan and implement activities related to reporting falsified medicinal products,
- conduct educational campaigns on the risks associated with the purchase of medicines in unauthorized places.

Officers of the General Police Headquarters together with the representative of the National Medicines Institute have also developed examples of questions helpful in formulating provisions of police and prosecution, prepared to prosecute pharmaceutical crimes.

- What is the chemical composition of the products sent? Which active substances are contained in the seized products?
- Do the products in question meet the definition of a medicinal product according to ProFarm?
- Are the seized medicinal products authorized in Poland?
- Does the chemical composition of the seized medicinal products the same as of the original products available on the Polish market?
- Do the seized medicinal products meet the quality requirements specified for this type of products?
- How the seized medicinal product(s) work(s)?/ Does the self-medication (i.e., without a doctor's prescription) with the use of this product pose a risk to life or health for the person taking it?/ Does taking the medication in question expose the person to immediate danger to life or serious health detriment?

Pharmaceutical crime raises difficulties not only because of its diverse form or criminal organization. It turns out that detailed data on, for example, falsified medicines is difficult to obtain and impossible to be interpreted in a measurable format and published. Therefore, the question is whether there is any possibility of estimating the market of informal and illegal nature. An additional difficulty is the fact that the functioning of organized crime groups is based on registering non-existing production and transport companies in order to disguise their actual activity. They use falsified documents to gain access to essential pharmaceutical raw materials or devices, in order to produce fake products and packaging, and then place them on a selected market or to a legal distribution network. They take advantage of all the weaknesses of the services involved in combating and preventing crime. It is interesting that the pharmaceutical industry, despite the losses totaling billions, is reluctant to oppose illegal competition.

Since 2016, as part of the operations conducted by the Central Police Bureau of Investigation, 6 939 (6 829) persons, operating in 874 (812) organized criminal groups, including 739 (725) Polish groups, 126 (83) international groups, 3 (2) Russian-language groups, 6 (2) groups of foreigners, have been kept under observation. Number of criminal groups (by nationality) remaining under observation of the Central Police Bureau of Investigation in 2015 and 2016, Polish criminal groups were directed by 730 (731) identified leaders, international groups by 97 (92), Russian-speaking groups by 3 (3), and foreigners by 3 (6). As at 31 December 2016, the total number of leaders under observation of the Central Police Investigation Bureau was 833 (832). During the reporting period in question, 143 (190) criminal groups operating in the area of criminal offenses and 290 (237) criminal groups involved in drug-related crime remained under observation. 341 (320) groups were involved in economic activity and 100 (65) groups were active in the area of multi crime activity.

It is almost impossible to distinguish a falsified drug from the original without a special equipment, and criminals are more and more accurate in counterfeiting of packaging and holograms, they also shift to a more cost-effective production of complex medicines containing many active substances. Criminal groups change their activities from drug-related to pharmaceutical crime.

As regards Poland, despite the appropriate legal structure, cooperation of many entities and the fact that in Europe we are classified as a high-risk country in terms of organized crime and counterfeiting of various products, there

is still no official data on the scale of the phenomenon of pharmaceutical crime. It is due to the difficulty of estimating this market value, because the average for the EU is given, which is EUR 350 million. In the case of Poland, the error in these calculations is large and it can range from EUR 100 to 150 million per year. The market of falsified medicines purchased in Poland is calculated at EUR 65 million. The fact that we are neighbors with the countries of the former USSR, known for easy access to falsified medicines and dietary supplements, translates into easy expansion of the products through illegal channels to the Polish market and further to other EU countries. When analyzing orders sent to the National Medicines Institute by police headquarters, prosecutors' offices or customs services, we can divide illegal and falsified products reaching Poland into seven groups:

- Illegal and falsified medicinal products and dietary supplements, recommended for erectile dysfunction - containing sildenafil, tadalafil, vardenafil or their derivatives,
- Falsified herbal dietary supplements for weight loss - containing sibutramine, monomethyl sibutramine or dimethyl sibutramine,
- Illegal and falsified steroid and anabolic hormones,
- Illegal herbal raw materials and products of Traditional and Chinese Medicine,
- Illegal and falsified dietary supplements and cosmetics available in sex shops - containing cantardine, yohimbine, benzocaine or lidocaine,
- Some of them bear the markings typical for homeopathic medicines, e.g. Cantharis D6 or Yohimbinum D4,
- Various dietary supplements working "wonderfully" and healing all diseases,
- „Designer Drugs"- containing BZP (N-benzylpiperazine), a psychoactive substance with a stimulating effect. The effect of BZP in combination with TFMPP (3-trifluoromethylphenylpiperazine) may resemble the effect of using Extasy tablets (MDMA).

According to the Report of the World Health Organization (WHO), Poles spend about PLN 100 million annually on counterfeit medicines. Poles buy them in different ways. They usually purchase such medicines by means of the Internet and still on bazaars. Of course original medicines are available in the Internet as well, however these usually are products of a theft. Demand for a product is a determinant of specific criminal activities.

According to official statistics, in 2016, the Main Pharmaceutical Inspectorate received 58 reports on illegal trade in medicinal products and 18 notifications in the international WGEO Rapid Alert System regarding the detection of illegal pharmaceuticals. In turn, the Customs Service has detained over 18.6 thousand counterfeit medicinal products with a value exceeding PLN 830 thousand.

Examples of police actions:

1. „14 people are detained, 48 different types of machines used to produce falsified medicines, 430 thousand steroids in ampoules and tablets and 100,000 potency tablets with a total black market value of over PLN 17 million are seized - this is the effect of several months of work by the Central Police Bureau of Investigation in Poznań (2016). Thus, the police officers liquidated the first in the world and the world's largest illegal pharmaceutical factory, and disbanded the organized criminal group involved in the production and large-scale trading of steroids and potency drugs. The arrests took place in the following voivodships: Kujawsko-Pomorskie, Śląskie, Pomorskie and Wielkopolskie. 3 persons faced charges of directing the group, and the remaining ones were accused of being its members. They were also accused of violating pharmaceutical law and endangering the life and health of many people. Police officers from the Central Police Bureau of Investigation worked several months to determine who is responsible for the production and large-scale trade of falsified pharmaceuticals. They determined that an illegal factory of medicinal products, counterfeiting medicines of four well-known pharmaceutical concerns, was set up near Bydgoszcz. They also identified persons involved in various stages of the procedure, starting from the production process through distribution. At the same time, policemen entered several places in four voivodships: Wielkopolskie, Kujawsko-Pomorskie, Pomorskie and Śląskie, and detained 14 people involved in illegal activities. The factory was located near Bydgoszcz. On the spot, the police arrested a

man who was involved in the production of falsified medicines. In storage rooms there were special passages, hidden behind the doors of wardrobes, leading into further production rooms equipped with various types of machines. The policemen also seized ready-made products as well as their semi-finished products. In total, the officers have seized 48 machines: blanking dies, screen printing machine, pad printing machine, image setter, tablet press, blistering machines, coating machines, ampoule machines, storage reservoirs, packing machines, mixers and other. There were also 377 stamps for production, 23 printing screens, 28 printing matrices. The total value of the equipment amounted to over PLN 4 million. In addition to production components, police officers have seized finished products: anabolic steroids in ampoules, vials and tablets, as well as 100,000 potency tablets. As policemen determined, some of the finished products, as well as semi-finished products were imported from China through the transfer channel via Greece, as well as Great Britain and Romania. The distribution took place mostly by means of the Internet. These products threatened the life and health of buyers due to conditions of their production as well as differences in composition. It is estimated that the group launched falsified products worth at least several million PLN. In addition to charges of directing or participating in an organized criminal group, detainees were accused of endangering life or health of many people by the production, storage and making available in return for payment of falsified medicinal products, as well as the import of finished medicinal products and active substances, and the marketing of medicinal products.”

2. „As a result of the actions of police officers from the Central Police Bureau of Investigation in Rzeszów, officers from the Bieszczady Border Guard Division and authorities from the Czech Republic, Slovakia, Ukraine and Europol, 44 people were detained, three methamphetamine laboratories and a marijuana plantation were liquidated. Drugs were being sent to the laboratories. The criminal practice started in Podkarpacie, where drugs containing pseudoephedrine were obtained. - The medicines were taken from pharmacies and pharmacy points. Each receipt contained a sale transaction for one medicine packaging. In reality, however, these drugs were received in bulk by "couriers", and such situations could have involved even several tens of thousands of packages at one time. The tablets were then removed from blisters, i.e. separated from the packaging and delivered directly to several methamphetamine laboratories. 23 people were detained in Poland, out of which 19 were temporarily arrested on the basis of collected evidence by the District Court in Rzeszów. As a result of the activities of officers, over 200,000 packages of medicines and about 100 kg of tablets were seized. In addition, officers seized PLN 1.2 million in cash and cars with a value of approx. PLN 400,000. According to the decision of the prosecutor, bank accounts for the amount of about PLN 5 million were blocked. Police officers from the Central Police Bureau of Investigation in Warsaw and Katowice, the Voivodship Police Headquarter in Rzeszów, anti-terrorists, officers of the Internal Affairs Office and officers from the Delegation of the Internal Security Agency from Rzeszów also took part in the operation conducted in Poland. Another 8 people have been detained in the Czech Republic, they are suspected of organizing criminal activities and the production of narcotic drugs. Several hundred thousand euros have been secured against future fines. The Czech and Slovak authorities dismantled two methamphetamine factories and a marijuana plantation in the Czech Republic. Additionally, seven people suspected of participation in an organized criminal group, trading in precursors and drugs were detained in Slovakia. There, the Slovak police also seized chemical agents used for the production of methamphetamine and a few dozen kilos of tablets removed from blisters. "The case is in progress. In Ukraine, the officers of the local services, basing on the information received from the Central Police Bureau of Investigation in Przemyśl, dismantled a methamphetamine laboratory and detained 6 people.”

Conclusions

Money rules the world, which is why organized crime groups will not hesitate to take any opportunity to make easy money. As it turns out, the need for medications, as well as the aforesaid difficulties provide them enormous opportunities in this area. The fight against the broadly understood pharmaceutical crime requires not only the

involvement of a functioning legal system and cooperating legitimate entities, but also social campaigns that should be joined by the media which, so far, fuel the pseudo-demand for drugs through advertising.

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