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Reverse Drug Distribution Chain: Analysis of the Phenomenon

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Abstract:

Purpose: *The purpose of this study is to consider the mechanism of the reverse drug distribution chain as a non-code provision, introducing a type of act prohibited by the provisions of article 126b of Pharmaceutical Law. The article aims to analyse this practice, changes in the legal system and its consequences from the perspective of the economic problem and of protection of the health and life of citizens.*
Design/methodology/approach: *The article focuses on the analysis of statistical data and the legal regulations in force in Poland governing the discussed phenomenon.*
Findings: *The conducted analysis of the reverse drug distribution chain phenomenon shows that there is still a lack of effective solutions to minimise the occurring illegal practice, however, given the serious consequences for society, prosecution of this proceeding is absolutely necessary.*
Practical Implications: *An analysis of the phenomenon of the reverse drug distribution chain, carried out in this article, makes it possible to draw conclusions as to whether the solutions and methods used to deal with the discussed procedure are purposeful and justified. In the assessment of the collected material, it can be concluded that although the current shape of specific solutions raises doubts, the introduction of changes to the legal system in the discussed scope is necessary and, over time, will allow for an effective solution to the problem.*
Originality/Value: *The conducted analysis is an original scientific study presenting a detailed description of the phenomenon of the reverse drug distribution chain and methods for its eradication.*

Keywords: *Reverse drug distribution chain, pharmaceutical law, organized crime, pharmacies, pharmaceutical wholesalers, marketing of the medicinal products.*

JEL codes: *I18.*

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1. Introduction

The market for the sale of drugs based on the free movement of goods has developed significantly with the accession of new countries to the European Union. Together with the development of the pharmaceutical sector and the evolution of the drug trade, another phenomenon has emerged – the reverse drug distribution chain. When analyzing this practice, one should focus on the dangers and consequences it entails, not only from the perspective of the economic problem, but above all, from the perspective of protecting the health and life of citizens.

The marketing of medicines not only in Poland but also in other European countries is an area of economic activity subject to strict regulation and is carried out according to predetermined rules. Above all, the basis for regulating the marketing of medicines is the 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 (OJ L 311, 28.11.2001, p. 67-128).

According to this Directive: "*The essential aim of any rules governing the production, distribution and use of medicinal products must be to safeguard public health. However, this objective must be attained by means which will not hinder the development of the pharmaceutical industry or trade in medicinal products within the Community".* With regard to the phenomenon of the reverse drug distribution chain, the content of the Directive directly refers to:*"It is necessary to exercise control over the entire chain of distribution of medicinal products, from their manufacture or import into the Community through to supply to the public, so as to guarantee that such products are stored, transported and handled in suitable conditions. The requirements which must be adopted for this purpose will considerably facilitate the withdrawal of defective products from the market and allow more effective efforts against counterfeit products".*

In Poland, among the manifestations of the protection of the above, the following measures should be mentioned: licensing of entities participating in trade, strict determination of permitted sales, as well as market control by the Pharmaceutical Inspection authorities.

Licensing of entities participating in trade requires that only entities holding the appropriate authorization are present in the distribution chain. As a general rule, this may be a wholesale distribution license (WDL) for pharmaceutical wholesalers or retail distribution license (RDL) dedicated especially to pharmacies.

The permitted course of distribution means that the drug is traded only in one direction – from the marketing authorisation holder (or its representative) to the wholesaler and from the wholesaler to the pharmacy, and shortly afterwards to the pharmacy customer, i.e., the patient or the medical entity (Krakowiak, 2019).

Moreover, the legal provisions also cover the issue of prices of medicinal products, their reimbursement and the process of their production and sale. In the Polish pharmaceutical law, there are also other methods and mechanisms of combating the illegal export of drugs, however, the above requires a more extensive analysis, which will be discussed in detail later in the present article.

2. Paralell Trade of Medicinal Products in Europe

Poland's accession to the European Union in 2004 allowed for permanent economic cooperation with other EU members, within the framework of the so-called parallel import consisting in importing medicinal drugs from countries where they are cheaper to countries where they cost more (Zimmermann and Malach, 2009). The price differences of medicinal products in individual countries are mainly due to the adjustment by pharmaceutical companies of the prices of their products to each country separately due to the strict regulation of distribution. The attractiveness of drugs export from the Republic of Poland was influenced by the low prices, mainly of the reimbursed medicines.

In 2012, the so-called Reimbursement Act entered into force, under which prices of drugs in Poland are set authoritatively and are not affected by the free market rules. In addition, the margins of pharmacists and pharmaceutical wholesalers were also tightened. Their profits were limited, and the prices of drugs in Poland, compared to other European Union countries, became exceptionally favorable. In fact, the price differences between the medicines in the individual countries of the European Union constitute the economic basis for parallel import. The restrictions imposed on exporters in the legal drug distribution chain have led to the emergence of illegal mechanisms of medicines acquisition. The export of drugs and their sale on foreign markets has become much more profitable.

In accordance with European law, parallel trade allows wholesalers to purchase medicinal products in one member state, where the prices of medicines are lower, and then sell them in other member states, where these prices are higher. Parallel import and export of medicinal products comply with the principle of the free movement of goods. However, in exceptional cases, the European Union allows restrictions if they are justified by overriding reasons of public interest, such as protection of human health and life, and there are no other less restrictive means to achieve that objective.

Parallel trade in medicinal products in the Polish legal system is defined in Article 2 (7b) of the Pharmaceutical Law (OJ L 1977, 29.10.2021), according to which parallel import is any action involving import of a medicinal product meeting all the following conditions from European Union Member States or European Free Trade Association Member States (EFTA) – parties to the Agreement on the European Economic Area:

a) the imported medicinal product has the same active substance (active substances), at least the same indications, the same strength, the same route of administration and the same or similar form,
b) the imported medicinal product and the medicinal product are concomitantly reference medicinal products or concomitantly generic medicinal products authorised in the territory of Poland.

Supplying drugs to the Polish market was to be adapted to the needs of the local population, and not to mass export outside the territory of the European Union. The first such signals regarding the phenomenon of the reverse drug distribution chain began to appear when the availability of selected groups of drugs on the market significantly decreased, despite the increased level of drug supply determined based on its current demand. Parallel import should never result in a lack of drugs on the Polish market. The above also forced the Supreme Audit Office to undertake the tasks specified in the Act of 6 September 2001 on Pharmaceutical Law (OJ L 1977, 29.10.2021) by the State Pharmaceutical Inspectorate. It was therefore initiated to monitor the state of supply by the Main Pharmaceutical Inspectorate.

3. Reverse Drug Distribution Chain in Poland

In the State Pharmaceutical Inspectorate, the term "reverse drug distribution chain" was created as a definition of illegal practice, endangering the health and life of Polish patients, used by entrepreneurs for the unlawful acquisition of medicinal products for export purposes. This is because medicines that are purchased do not go to needy patients but are sold with significant profits abroad, bypassing parallel trade requirements.

Firstly, entrepreneurs submit applications for the expiry of authorizations for running pharmacies and pharmaceutical wholesalers in order to avoid liability, and yet they still conduct their illegal activities behind closed doors. There are also situations where the area of the wholesale drug outlet was only 20 square meters.

The second approach that emerged was to lengthen the chain by opening, taking over, or recruiting additional wholesalers. Entrepreneurs artificially shift medicines between several points belonging to one owner, creating a network for collecting medicines to ultimately transfer them to a wholesale outlet which is not at the beginning of the chain. In this way, inter-warehouse transfers arise, which effectively makes it difficult to determine the distribution route. It happens that one of the entrepreneur’s pharmacies is written off, even though all pharmacies collect goods for illegal distribution through legal warehouse transfers.

The third popular method is the issuing of fictitious invoices to hide the actual turnover of medicinal products and the actual direction of the drugs flow. VAT invoices are partially and selectively made available, and the system data are cleaned. Moreover, hiding the actual turnover of pharmaceuticals occurs by issuing

return invoices almost at the same time as issuing a VAT invoice. Correction invoices are not presented during the inspection. In fact, medicines do not leave the wholesale borders but are only the subject of fictitious trading.

Other practices of dishonest entrepreneurs include attempts to circumvent the regulations, e.g., through donations, transfers, or advertising samples. Control activities are often hampered by the absence of individual responsible persons at the place of business, e.g., entrepreneurs, part-time warehouse managers, as well as by employing managers responsible for running pharmaceutical wholesalers only on paper to comply with the legal requirement for authorisation. Attempts were also made to simulate the need to dispose of drugs.

Due to the difficulty of proving the crime, the nationwide nature of the process requires the cooperation and coordination of many public administration bodies and services. The State Pharmaceutical Inspectorate supervises the conditions of manufacturing and importing medicinal products, as well as their quality and trading. In the case of the reverse drug distribution chain, this institution initially informed the prosecutor's office about the results of routine inspections.

4. Statistical Data

According to statistical data, in the years 2012-2015 the Department of Drug Policy and Pharmacy of the Ministry of Health received a total of 752 reports related to difficulties in access to medicines, and 126 reports were submitted to the Patient Ombudsman (Dobrowolski, 2016). However, according to the report of the Supreme Audit Office published on 9 January 2019, it was assessed that the bodies of the State Pharmaceutical Inspection did not have sufficiently effective instruments to counteract illegal practices of pharmaceutical market participants due to the lack of appropriate legal regulations or their ambiguity. The total value of medicinal products sold to EU countries is estimated to be 3.5 billion zloty, and 57% of these drugs are estimated to be exported illegally (Supreme Audit Office, 2019).

5. Measures

In December 2013, an agreement was signed between the Main Pharmaceutical Inspector and the Fiscal Control Inspector, concerning cooperation and exchange of information between fiscal control authorities and the State Pharmaceutical Inspection. It concerned the transmission of data on the marketing of medicinal products and medical devices, organization of training courses and meetings in the scope of the procedure discussed in this article (Pietryka and Kotowicz, 2020). So far, fiscal control offices in Poland could refuse to provide information to the Main Pharmaceutical Inspectorate due to fiscal secret. In addition to fiscal controls, several hundred criminal proceedings were also fought in 2014, but most of them were discontinued due to the lack of features of a prohibited act.

In order to deal with the phenomenon of the reverse drug distribution chain, which was becoming more and more extensive every month, in 2015 an amendment to the Pharmaceutical Law took place, colloquially called "anti-export law", which entered into force on July 12, 2015 (OJ L 788, 11.06.2015). Nevertheless, it has met with criticism from many circles related to the problem of the reverse drug distribution chain. This was mainly due to disapproval of the depenalisation of the then Article 127 of the Pharmaceutical Law, which was no longer a criminal provision, and also because the act in Article 126b of this Law concerned only the generally accessible pharmacies and its scope did not cover wholesale pharmacies.

An administrative fine of up to PLN 500,000 was introduced for those who run pharmaceutical wholesalers, nationwide pharmacies, or pharmacy outlets without a permit or contrary to its terms. The problem, however, was the fact that pharmaceutical inspections did not receive either the resources or the tools to be able to enforce this responsibility (Pochrzęst-Motyczyńska, 2019). Supervision over the turnover of products was carried out in an unreliable manner because the Main Pharmaceutical Inspectorate did not fulfill its obligation to check entrepreneurs in terms of compliance with the obligations arising from the Law, controls took place annually in about 10-12% of all wholesalers operating on the market (Pietryka and Kotowicz, 2020).

Furthermore, the amendment has resulted in an increased obligation to report transactions in the context of trade of medicinal products, foodstuffs intended for particular nutritional uses or reimbursed medical products. The above was to be facilitated by the Integrated System for the Monitoring of Trade in Medicinal Products (ZSMOPL).

According to the assumptions, the system would make it easier for entities such as the Ministry of Health or the Main Inspectorate to effectively implement the drug policy. The benefits of the operation of this system include: ensuring the availability of medicines to patients, expanding the knowledge of supervisory authorities on the trade in medicinal products and monitoring the ongoing availability of medicinal products in any area of Poland. The reporting obligation has fallen to traders, i.e. pharmacies, hospital pharmacy departments, and wholesalers. Unfortunately, despite the amendment in 2015, it was only from 1 April 2019 that the obligation to transfer data to the IT system discussed above came into force.

In addition, the Minister of Health was obliged to publish, at least once every two months, by way of an announcement, an updated list of the so-called drugs at risk of availability. According to the current data, based on the Notice of the Minister of Health of 29 October 2021 on the list of medicinal products, foodstuffs for particular nutritional uses and medical devices at risk of unavailability in the territory of the Republic of Poland, on 1 November 2021, the risk of unavailability concerned as many as 219 items. In July 2019, there were even 324 items missing.

According to statistical data, the most frequent lack of availability concerns anticoagulants, insulin drugs, nebuliser suspensions, antiepileptic drugs, and some drugs used in cancer patients. The list includes drugs that are missing in 5% of pharmacies in the given voivodeship (Pochrzęst-Motyczyńska, 2019).

Despite the implementation of the amendments, the measures applied did not bring the desired results. There has been no improvement in access to drugs, based on the data it can be said that the situation has worsened. In the case of ZSMOPL, the main problem was that due to the extension of the deadline for the commencement of full reporting to the ZSMOPL, not all reporting entities were connected to the system, and the reports themselves did not allow for a reliable verification and analysis of the collected data. Cooperation with law enforcement authorities has also not been very effective.

On 24 September 2020, the Ministry of Justice published the response of the Secretary of State in the Ministry of Justice, Marcin Warchol, to the interpellation no. 8043 on the effects of the amendment to the Pharmaceutical Law, which penalizes the illegal sale of drugs by pharmacies and pharmacists to entities other than patients, data on illegal export of drugs. According to the data, it is clear, that since 2015, 55 indictments have been filed for offences against Article 125 or Article 126b of the Pharmaceutical Law, including 9 indictments which have been filed after the amendment of the relevant provisions, which entered into force on 6 June 2019.

There has been no conviction in the case of these crimes. The Ministry also points out that there are 58 pending cases related to the reverse chain of distribution of medicinal products and 2 proceedings in the in-rem phase, strictly related to the illegal export of medicinal products at risk of lack of availability. 168 cases were examined and combined, and the conducted proceedings do not concern individual transactions, but the activities of organized crime groups.

With the above-mentioned amendment of 26 April 2019, which entered into force on 6 June 2019, a number of orders and bans were introduced for drug distribution chain participants. Article 126b of this Law has been amended and the administrative norm was changed from Article 86a. The prohibition was replaced by the rule of good conduct, according to which a pharmacy / pharmacy outlet may, as a rule, sell medicinal products only for the purpose of direct supply to the public and entities carrying out medical activities. If, contrary to that rule, the products are disposed of, the act shall constitute an offence under Article 126b (1).

In addition, a prohibition on the acquisition of medicines by a medicinal entity for a purpose other than the provision of healthcare in the Republic of Poland was prohibited (article 87 (1)) and finally a ban on selling drugs by a medical entity was introduced (art. 87 (5a)). Violation of these prohibitions results in the fulfillment of

the criteria – in the event of a violation of the sale prohibition – art. 126b (1) and in the event of violation of the rules related to the acquisition – art. 126b (2).

Moreover, the obligation for pharmaceutical wholesalers to supply medicinal products only and exclusively from the responsible entity, an entrepreneur holding a license to manufacture or import medicinal products or an entrepreneur conducting business activity consisting in conducting wholesale trade has also been introduced (art. 78b). The amendment introduced the penalisation of intentional quasi-trafficking, which consisted in the further purchase or sale, export outside the territory of the Republic of Poland, transport, and storage of a medicinal product against the orders and prohibitions (art. 126b (3)).

It is punishable by imprisonment from 3 months to 5 years. A new provision was also added to the Act, introducing a new type of crime, consisting in the export or sale of drugs outside the territory of the Republic of Poland without reporting this fact to the Main Pharmaceutical Inspector, against the objection of this authority or before the expiry of the objection period.

The amended act provides for the introduction of two qualified types – when the subject of execution is property of considerable value (exceeding 200,000 zloty), the penalty of deprivation of liberty is from 6 months to 8 years, and when medicinal products are threatened by a lack of availability, the risk of imprisonment varies from one year to 10 years. Increasing the range for the threat of imprisonment may facilitate the application of preventive measures against suspects in connection with the reverse drug distribution chain.

Noteworthy is also the fact of extending the subjective side of a prohibited act to all entities participating in the illegal chain. To date, only pharmacies and pharmacy outlets had been responsible.

6. Reverse Drug Distribution Chain in Other Countries

It should be noted that the phenomenon of the reverse chain of distribution of medicinal products and their illegal export to other Member States in the form in which it occurs in Poland, does not exist in other OECD/EU countries. The specificity of the Polish situation results primarily from the medicinal product reimbursement system adopted in our country, as well as the model of pharmaceutical distribution and non-legal factors, i.e., the size of the market and the general national drug policy.

Legal regulations in other Member States therefore regulate the general problem of deficiencies in the availability of medicinal products and not the activities of organised groups involved in illegal export of medicinal products outside the country.

Some of the Member States, e.g., Portugal, Spain, Bulgaria or France, have introduced solutions in their legal systems according to which, lists are published of medicinal products whose export at a specific time is illegal. Selling medicinal products with limited availability to a foreign entity is subject to a financial penalty.

For example, in Bulgaria, on the basis of the current Medicinal Products in Human Medicine Act, a person who has permission to distribute drugs, must inform the Bulgarian drug market regulatory authority – Bulgarian Drug Agency (BDA) of each planned export of drugs.

Those who fail to inform about the export of drugs from Bulgaria are subject to an administrative fine from 50,000 to 100,000 BGN (about 107–213 thousand zloty), and in the case of recidivism – from 100 to 200 thousand BGN (about 213–426 thousand zloty).

In Australia, on the basis of the current National Health Act 1953, a person who illegally exports reimbursed drugs is subject to a penalty of up to 2 years in prison or a fine of AUD 5,000 (about 13.5 thousand zloty) or both.

7. Conclusions

The changes in the provisions in the Polish legal system discussed in this article, despite their drawbacks, can definitely contribute to the fight against the phenomenon of the reverse supply chain. It must be acknowledged that the procedure under discussion takes on even more complicated forms over the years, while the legislator tries to reduce and limit the discussed activities. Prosecution of these proceedings is absolutely necessary, as it carries with it serious consequences for society.

The lack of availability of drugs for patients in pharmacies carries a risk to their health and even life. The inability to buy medicines necessary for human life harms the sense of security and has a negative impact on the trust in the state that guarantees the fundamental rights of the citizen.

Moreover, taking into account the economic turnover, which is not fully controlled with such an important product as a medicinal product, it carries the risk that a Polish patient, once he/she receives his/her drug, risks receiving a counterfeit drug, for example with smaller or bigger amount of substances, or the drug which will not have them at all.

However, despite the existing substantive and evidentiary difficulties in the conduct of proceedings related to the illegal drug distribution chain, the fight and prosecution of the discussed practice are necessary and, more precisely because of the dynamic evolution of the problem, it requires the full mobilisation of the relevant services and institutions together with the legislator.

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