

Procedures Regarding Expired Medicinal Products – Select Legal Issues

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Abstract

This article discusses the problem of pharmaceutical waste as hazardous to both the environment and human health. Persistently low ecological awareness in society, coupled with a small number of reception places where such waste can be delivered, prevent it from adequate segregation. In effect, together with other household waste, it is sent to municipal landfills, which in most cases lack the suitable protection measures necessary to prevent negative environmental impact. Only recently have medicine manufacturers been under an obligation to include in their leaflets a notice of special precautions to be taken during the disposal of unused pharmaceuticals and their waste. At present, a selective collection of medicines constituting hazardous waste from the municipal sector is carried out to a very narrow extent. From the legal standpoint, constructing reception systems for all municipal waste is the obligation of the municipal authorities. A number of pharmacies cooperating with local governments volunteer to participate in the segregation of pharmaceutical waste, providing special containers for medicines that are past their sell-by date. The study also describes procedures for expired psychotropic medicines and narcotics, which due to social reasons present a substantial problem in terms of their disposal. Legal regulations require strict procedures while handling this type of medicine.

Keywords: environmental hazardous waste medicines, pharmaceutical waste, legislation

Introduction

Waste is one of the most significant threats to the environment. It entails problems related to prevention – i.e. stopping the generation of waste or limiting it to the maximum extent possible – and also to ensuing procedures such as disposal and recycling [1]. Hazardous waste, which is defined in art. 3, clause 2 of the Act on Waste [2], presents a considerable threat to both human health and the environment. Waste management requires the use of special precautions and control measures. This type of waste also includes expired, unused, or spoiled medicinal products, or

those excluded from trade [3]. They can be mostly generated by healthcare providers and institutions involved in research and experimentation work. These include mainly hospitals, sanatoriums, social care and other assistance institutions, health spas, detoxification centres, hospices, daycare clinics and consulting centres, as well as veterinary centres, R&D plants, a wide range of laboratories (e.g. analytical), medicine manufacturing plants, pharmacies, and households. The disposal of hazardous waste relies on eliminating hazardous and toxic components through e.g. decomposition into compounds that no longer present a threat to the natural environment.

Pharmaceutical waste may contain substances defined as toxic. The compounds present in medicines are often

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extremely durable and resilient. They penetrate into water and soils, which can effectively cause contamination [4-6]. Business people dealing with the manufacturing and sale of medicines must fulfill strict obligations regarding the proper segregation and disposal of spoiled or expired medicinal products. However, a large number of medicines that are past their sell-by date are generated by households. Persistently low ecological awareness among the general population, coupled with a small number of reception places where such waste can be delivered, prevent it from adequate segregation. In effect, together with other household waste, it is sent to municipal landfills, which in most cases lack the suitable protection measures necessary to prevent negative environmental impact. They are also burnt in house stoves or boiler rooms, causing the emission of hazardous dusts. Some of the waste is also discharged into the sewage system and then flows into surface waters or to sewage treatment plants, where the applied technology fails to remove a wide range of chemical compounds. It is worth mentioning here that only recently have medicine manufacturers been under an obligation to include in their leaflets a notice of special precautions to be taken during the disposal of unused pharmaceuticals and their waste [7].

Hazardous waste also includes medicines that have a current sell-by date but fail to meet the quality requirements to the effect that they must be excluded from trade. Pursuant to art. 67 clause 2 of the Pharmaceutical Law [8], they are subject to disposal or, under extraordinary conditions, the chief pharmaceutical inspector may give permission to use them for other purposes (e.g. for scientific research). The cost of disposal is borne by the entity where the reason for the exclusion from trade and use occurred [9].

The wholesale of medicinal products is carried out by pharmaceutical wholesale companies/warehouses, and retail sale by pharmacies, pharmaceutical outlets, and non-pharmacy stores, including herbal and medical stores, special medical supplies stores, and public-access stores [8]. Entities trading in medicinal products, upon handing over expired, spoiled or poor-quality products (e.g. improperly stored) to disposal facilities, should prepare lists of medicines giving their name, dosage, serial number, quantity, expiration date, and price. Personnel at pharmacies, pharmaceutical outlets, and warehouses are prepared to handle medicines that are past their sell-by date. What seems to be a problem is whether non-pharmacy stores selling medicines can guarantee that the required procedures regarding hazardous expired preparations are duly observed. Although the trade in medicinal products carried out at these facilities is supervised by pharmaceutical inspection, it seems that due to a large number of such stores and too few inspectors, any supervision in the form of inspections is rarely seen.

Responsibility for the management of pharmaceutical waste generated by households lies with the municipalities. They are bound by the Act on Maintaining Cleanliness and Order on the one hand [10] and by the Act on Waste (art. 16a clause 2 it. b) on the other, to provide suitable conditions for the separation of hazardous waste from the stream of municipal waste. Pursuant to art. 3 clause 2 it. 4 of the

Act on Waste [2], municipal waste shall be construed as waste generated by households, excluding vehicles withdrawn from operation, and also as waste not containing hazardous waste received from other waste generators, which due to its nature or composition remain similar to household-generated waste.

The role of the municipality is to guarantee the possibility of separating hazardous waste, while the regional authority has the obligation to build, maintain and operate systems and facilities for recycling and disposal of hazardous waste separated from municipal waste (art. 16b of the Act on waste). This corresponds to the guideline that municipal waste is the responsibility of the municipal authorities, and hazardous waste – of the regional authorities [11].

According to art. 3 [10], maintaining order and cleanliness in the municipality is the obligatory task of the municipal authorities, which reflects the special importance of those tasks assigned by the legislators. This entails that the municipality, which in this range of organisational activities and on its own territory holds the status of a monopolist [12], cannot abandon their implementation. Otherwise, everyone whose legal interest or rights have been infringed upon by the municipal authority as a result of failure to take the action required by the law, can file a complaint against such inaction on the part of the municipality with the administrative court [13]. Additionally, it should be noted that pursuant to art. 4 clause 1 of the aforementioned act, the municipal council adopts rules and regulations for maintaining cleanliness and order in the municipality, which constitutes a local legal act and requires publication in a regional official journal [14-16]. However, it transpires that many municipalities have failed to adopt the relevant rules and regulations despite the legal requirement [17]. The rules and regulations stipulate in detail the principles of maintaining cleanliness and order in the municipality, including the requirements related to the selective collection and reception of municipal waste to a specified extent, and also refers to household-generated hazardous waste, including medicines.

It should be stressed that failure to perform the obligations stated in the rules and regulations is deemed an offence subject to a fine. The rules and regulations are correlated with the obligations of property owners. Pursuant to art. 5 clause 1 [10], they should guarantee cleanliness and order, providing the property with municipal waste reception facilities and keeping these facilities in proper sanitary, technical, and orderly condition. In the case of a failure to fulfill the above obligation, a village leader or a town mayor can make a decision ordering the completion of the obligation, subject to enforcement according to the provisions of the 1966 act on enforcement procedures in administration [18]. Proprietors are also obliged to collect municipal waste generated on the premises of a property in line with the requirements set forth in the rules and regulations, to dispose of municipal and liquid waste collected on the premises of a property in compliance with the provisions of the act and separate regulations, and finally to perform other obligations specified in the aforementioned rules and regulations.

At present, a selective collection of medicines as hazardous waste from the municipal sector is carried out to a very narrow extent. Unused or expired medicines should be disposed of in containers, the so-called confiscators, that are placed in municipal offices, healthcare institutions, or in pharmacies. They are collected and disposed of in suitable conditions by dedicated companies. The cost of such services is borne by the municipality. This is aimed to minimize the threat to the environment and to human life and health, preventing possible poisoning.

Pharmacies are the right places for educational campaigns encouraging the segregation of pharmaceutical waste. However, they should not be the only ones who bear the considerable cost of the reception and disposal of expired medicinal products coming from home medicine cabinets. Therefore, the pharmacies that do not have confiscators refuse to accept expired medicines from patients.

The Act on Waste [2] has introduced the obligation to provide waste management plans. The 2010 national waste management plan [19] indicates that it is necessary to build a more extensive and robust system of collecting expired medicines from society. It should be demanded that the role of pharmacies in the segregation system of pharmaceutical waste be better acknowledged and used in a more efficient manner.

Procedures Regarding Narcotics and Psychotropic Substances

Due to social reasons, the disposal of narcotics and psychotropic substances presents a substantial problem. The legal regulations, which require strict procedures while handling expired or spoiled narcotics and psychotropic substances, enforce specific obligations onto business people dealing in this type of product.

The trade in narcotics and psychotropic substances is rationed and described in detail by the Act on Preventing Drug Addiction [20]. Wholesale can only be carried out by pharmaceutical warehouses upon permission granted by the chief pharmaceutical inspector. Retail sale can take place only in pharmacies and pharmaceutical outlets operating on the basis of permission granted by a regional pharmaceutical inspector. The trade in and disposal of narcotics and psychotropic substances is supervised by the pharmaceutical inspection authority.

Entities that in the course of their business activity are in possession of fake, spoiled, falsified, or expired narcotics and psychotropic substances are required to dispose of them at their own expense. Medicinal products that fail to meet the specified quality standards are excluded from market circulation and then disposed of. The provisions of the pharmaceutical law [8] describe procedures for the suspension and withdrawal of such medicines from trade circulation.

If an entity running a pharmacy or pharmaceutical warehouse discovers out that they are in possession of fake, spoiled, falsified, or expired narcotics and psychotropic substances, they must report it in writing to a regional pharmaceutical inspector. The preparations should then be duly secured and placed in sealed bulk containers wrapped in a

band stating "FOR NEUTRALIZATION!" The actions aimed at securing medicinal products intended for neutralization are carried out in the presence of a regional inspector or his representative, and a person in charge of providing a control system and securing psychotropic substances and narcotics on the premises owned by a particular entrepreneur running a pharmacy or a warehouse. Inspectors of the pharmaceutical inspection authority provide security measures by way of sealing a bulk container. The performed actions are set forth in a report giving, among other details, the deadline by which medicinal products should be handed over for disposal.

The disposal of narcotics and psychotropic medicines can only be done by companies carrying out their business activity in the field of waste recycling and neutralization on the basis of relevant permission to conduct such activity. Neutralization is carried out immediately upon the delivery of the medicines in the presence of a person in charge employed at a pharmacy or pharmaceutical warehouse and an employee of a disposal company [20]. According to the opinion of the chief pharmaceutical inspector (25 September 2009), the disposal company conducting business on the basis of a relevant permission must ensure the disposal of psychotropic substances and narcotics according to the law. Therefore, the presence of a person in charge (e.g. a pharmacy or warehouse manager) during the process of burning the preparations is not required [21]. This opinion differs from the verbatim wording of the provision and seems to diverge from the special regime in handling narcotics as intended by the legislature.

A person in charge sends notification of the planned neutralization of narcotics and psychotropic medicines to a regional inspector no later than 7 days prior to its execution. A report of the performed disposal is made up in two identical copies, one of which is sent by a person in charge to a regional pharmaceutical inspector. The report gives the details regarding the disposal company and the place of neutralization. It also includes the package delivery date to the place of neutralization, the package's condition at delivery, and the date of neutralization. The number of neutralized medicinal products should also be taken into consideration, with a note whether the neutralization was preceded by the opening of bulk containers. The report describes the course of the neutralization procedure, especially those cases when the opening of bulk containers was necessary. Additionally, the name, surname, and position of each person attending the neutralization is provided [22].

Patients are given narcotics and psychotropic substances in hospitals – therefore each hospital must have a control system over the medicines kept in the wards. This is effected through a periodic inspection of their storage conditions, use and expiration date, and also by verifying the conformity of their quantity with the dispensation records. Hospitals must develop and strictly observe their disposal procedures, especially the disposal of unused medicines.

Unfortunately, there is no legal framework for pharmacies to collect expired, unused or spoiled narcotics and psychotropic medicines from patients. Pharmacies cannot accept medicines returned by patients even if those medi-

cines have a valid sell-by date and their packaging is intact. This is forbidden pursuant to art. 96 clause 5 of the Act on Pharmaceutical Law. There are only two exceptions: products failing to meet the quality standards, and returns due to improper dispensation. This solution was prompted by the necessity of preventing a patient from the purchase of a medicinal product outside of the distribution network controlled by the qualified personnel supervising the storage and handling conditions of medicinal products in pharmacies and pharmaceutical warehouses, thus beyond the control of the state pharmaceutical inspection authority. In the case of improper dispensation of a medicine by a pharmacist, the preparation is received back from a patient, but the law fails to provide any guidelines regarding the next steps to be taken about such a medicine. If, for safety reasons, medicines brought back by patients should not be accepted, medicines received in such circumstances cannot be re-entered into circulation and should be disposed of, even if they remain intact.

Conclusions

Since medicines are hazardous waste, entities dealing with pharmaceuticals are required by law to ensure proper disposal of damaged or expired medicines. Alas, pharmaceutical waste from households is not properly segregated and it ends up in regular landfill sights. From the legal point of view, the obligation of constructing reception systems for all types of municipal waste lies with the municipal authorities. Therefore, municipalities should ensure the disposal of expired medicines. The reason for the inadequate segregation of pharmaceutical waste lies in the lack of strict legal regulations and failure to observe the obligation of selective waste collection by municipalities. A number of pharmacies cooperating with local governments volunteer to participate in collecting this type of medicine and provide special containers for expired medicines. These containers are structured in the way that once the medicinal products have been placed in a container by a patient, it is impossible to take them out again. Amendment of the current laws and more restrictive regulations should be implemented in order for the municipality to increase its involvement in the selective collection of pharmaceutical waste. There should be a definite obligation for municipalities to provide pharmacies with special containers for collecting expired medicines. Municipalities should also be obliged to receive and dispose of the contents of those containers every six months. Additionally, regulations should be adopted to enforce a definite obligation on municipalities to provide such containers in municipal offices.

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