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Legal Regulation of Circulation of Biocidal Products and Medical Devices in the EU: Implications for the Legal System of Ukraine

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ABSTRACT
Market volumes and revenues from biocidal products and medical devices grow annually. However, due to safety concerns, many countries have tightened control over their composition and circulation. The purpose of this article is to analyze the legal regulation of the circulation of medical devices and biocidal products, in particular, the requirements for labeling, the procedure for placing on the market, import and export, as well as the procedure for obtaining a permit to introduce biocidal products to the market. In view of the chosen research topic and to achieve the set goal, the authors used general scientific and special methods of scientific knowledge. Measures to control compliance with legal requirements for the safety of medical devices and biocidal products, types of violations in this area and the responsibility of market entities are considered. The relevant legislation of the European Union and the national legislation of Austria, Lithuania, Latvia, Germany, the Netherlands, Poland and Finland are analyzed. Special attention is paid to the regulation of control over compliance with safety requirements and the procedures for obtaining permits for the introduction of biocidal products into the market. It is established that the biocidal authorization procedure is defined in the Regulation on biocidal products (EU) 528/2012 and supplemented in the national legislation of foreign countries. The principles of legislative regulation of the circulation of medical devices are defined in regulations (EU) 2027/745 and 2017/746, which are applied in EU member states and are part of national legislation. It is proved that in most countries there are rules for registration of medical devices and biocidal products, assessment of their safety and efficacy, and control over their use and distribution; databases containing information on the composition, properties, efficacy and safety for health and the environment are formed and functioning; the authorities with controlling powers in the field of circulation of medical devices and biocidal products are identified, and liability for violation of regulations related to circulation of medical devices and biocidal substances is provided. Directions for improving the legal regulation of the circulation of medical devices and biocidal products in Ukraine are proposed.

Keywords: Supervision and Control Over the Circulation of Medical Devices, Control Over the Production of Biocidal Products and Medical Devices, Patient Health and Safety, Protection of Human Health and the Environment, Consumer Protection.

INTRODUCTION

Biocidal products are products with active substances intended to destroy, deter, neutralize, inhibit their activity or otherwise control the impact on harmful or undesirable organisms, and are widely used in agriculture, chemical, pharmaceutical, cosmetic, food and woodworking industries [1]. Recently, biocidal products and active

substances contained in them have been used quite actively in the manufacture of medical devices. In this regard, the countries of the European Union (hereinafter referred to as the EU) pay considerable attention to the regulation of relations regarding the production and use of medical devices [2] [30].

It is worth noting that the market volume and revenues of biocidal products are growing rapidly. The global market for biocides in terms of revenues was estimated at USD 7.2 billion in 2010, reached USD 9.4 billion in 2016, and is projected to grow at an average annual rate of 4.3% from 2016 to 2025 [3].

At the same time, biocidal products and active substances contained in them are not always safe for humans, animals and the environment. Therefore, in many countries, there is a need to control the content and circulation of the following products on the market.

In 1998, the European Parliament signed Directive 98/8/EC on the placing of biocidal products on the market [4]. This was the first attempt to harmonize the rules and regulations for the circulation of biocidal products on the EU market. In 2012, this Directive was amended and the so-called "Regulation" (Regulation (EU) 528/2012) was approved [5], which aims to further improve the functioning of the market for biocidal products in the EU, as well as to continue to ensure a high level of protection for humans and the environment.

According to this regulatory document, starting from September 1, 2013, all manufacturers/importers of biocides in the EU must undergo the procedure for obtaining a marketing authorization for biocidal products. Also, the relevant active substances in biocidal products must be approved by the competent authorities of the EU Member States and the European Chemicals Agency (ECHA), or their equivalence to already approved active substances must be proven.

Also, on May 26, 2021, Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices amending Directive 2001/83/EC, Regulation (EC) 178/2002 and Regulation (EC) 1223/2009, which repeals Council Directives 90/385/EEC and 93/42/EEC [6] and replaces Council Directive of 20 June 1990 on the approximation of the laws of the Member States concerning active implantable medical devices (90/385/EEC) [7] and Council Directive 93/42/EEC of 14 June 1993 on medical devices [8]. These regulations establish new rules in the field of circulation of medical devices aimed at increasing transparency, accessibility of information about them and harmonization of legislation on the requirements for controlling circulation and improving the procedure for monitoring the effectiveness and safety of their use.

A key element of increasing transparency, ensuring traceability and facilitating the exchange of information between manufacturers and users of medical devices, authorized bodies, EU member states and the European Commission is the introduction of the EU database on medical devices EUDAMED [9]. The specified database is publicly available, combines various information and consists of six interrelated modules: registration of manufacturers; UDI/registration of medical devices; notified bodies and certificates; clinical and efficacy studies; vigilance and post-marketing surveillance; market supervision; EUDAMED public [32].

However, not all countries have formed an appropriate legal framework regulating the circulation of medical products and biocidal products, and no state bodies have been identified that would exercise control over this market. In this regard, the study of the positive experience of legal regulation of the circulation of medical devices and biocidal products in the EU countries is relevant and promising from the point of view of improving the legal regulation of the circulation of medical devices and biocidal products in Ukraine, where, at the moment, there is no special national legislation regulating the circulation of such products in the country [36].

The purpose of this article is to analyze the legal regulation of the circulation of medical devices and biocidal products, in particular, the requirements for labeling, the procedure for placing on the market, import and export, as well as the procedure for obtaining a permit to introduce biocidal products to the market [25].

MATERIALS AND METHODS

The study is based on the analysis of modern scientific literature, as well as current regulations governing legal relations in the field of circulation of biocidal products and medical devices.

The authors used general scientific and special methods of scientific cognition. Thus, using the systematic analytical method, the authors investigated the requirements for labeling, the procedure for placing on the market, importing and exporting biocidal products and medical devices; procedures for obtaining a permit to provide biocidal products on the market; measures to monitor compliance with the requirements of the legislation on the safety of medical devices and biocidal products, as well as the types of violations in this area and the responsibility of entities in the market of biocidal products and medical devices.

By applying the special legal method, the authors identified which legal acts regulate legal relations in the area under study and provided a brief description thereof. Based on the analysis of the legal acts regulating such legal relations, the authors established that the procedure for authorization of biocides is defined in the Biocidal Products Regulation (EU) 528/2012 [5]. The principles of legislative regulation of relations regarding the circulation of medical devices are defined by Regulations (EU) 2027/745 [33] and 2017/746 [40]. Their norms are applied in EU member states and are part of national legislation. Using the comparative legal method, it is proven that in most countries there are rules for registration of medical devices and biocidal products, assessment of their safety and effectiveness, control over their use and distribution; databases containing

information on the composition, properties, effectiveness and safety for health and the environment have been formed and are operating; bodies that are empowered with control powers in the field of circulation of medical products and biocidal products are defined, as well as responsibility for violations of regulatory acts related to the circulation of medical products and biocidal substances is provided for. The authors of the article also used theoretical (analysis, synthesis, generalization, systematization), empirical (observation, classification) methods, as well as comparative analysis, dialectical, extrapolation, etc[10].

RESULTS

1. The procedure for authorization of biocides is defined in the Biocidal Products Regulation (EU) 528/2012 [5] and is applicable in all EU Member States. National legislation of the EU Member States complements the Biocides Regulation: a) in Finland, provisions on biocides are included in the Chemicals Act; b) in the Netherlands, regulations on biocides have been developed (the Plant Protection Products and Biocides Act, the Plant Protection Products and Biocides Ordinance, and the Plant Protection Products and Biocides Regulation); c) Germany has the Hazardous Substances Protection Act; d) Lithuania and Latvia have the Law on Chemicals and Mixtures; e) Romania has adopted the Law on the Placement of Biocidal Products on the Market; f) Austria has the Biocidal Products Act.
2. Many EU member states also have rules for registering biocidal products, assessing their safety and efficacy, and controlling their use and distribution. These rules establish requirements for the authorization and registration of biocides, including the submission and processing of applications, the evaluation of biocide dossiers, and the conditions for authorization, registration and labeling of biocide products. A database of biocides has also been created and is now in operation, containing information on the composition, properties, efficacy and safety for health and the environment of biocidal products.
3. In the EU Member States, the following state bodies have been identified that have control powers in the field of circulation of biocidal products: a) the Ministry of Social Protection of the Population of Latvia and its subordinate supervisory and control institutions control activities with chemicals, mixtures, chemicals in products and biocides in the production environment and monitor compliance of these activities with laws and other regulations in the field of life protection; b) the Ministry of Health of Lithuania and its subordinate institutions It controls the authorization, registration and regulation of biocidal products.
4. In all EU member states, national legislation establishes liability for violations of regulations related to the circulation of biocidal substances, including penalties for handling biocides without appropriate authorizations, for violating labeling rules, or for placing on the market products containing unauthorized biocidal components. The liability for violations varies depending on the nature of the violation and may include administrative fines for both individuals and legal entities. Administrative fines are assessed in accordance with the severity of the violation, which includes improper compliance with the requirements for labeling, classification, safe storage, transportation and circulation of chemicals and biocides. The amount of fines is set depending on the seriousness of the violation and may be significantly higher for legal entities than for individuals.
5. The principles of legislative regulation of relations regarding the circulation of medical devices are defined by Regulations (EU) 2027/745 [33] and 2017/746 [10]. Their provisions are directly applicable in the EU Member States and are part of their national legislation. Certain relations arising in the course of circulation of medical devices may be regulated at the national level, taking into account the scope of exclusive competence. The majority of EU Member States have implemented the provisions of Regulations (EU) 2027/745 and 2017/746 into national legislation by adopting separate laws on the circulation of medical devices. They provide for the procedure for registration, conformity assessment, distribution, operation, and technical supervision of medical devices, define the competencies of state authorities that supervise and control the circulation of medical devices, establish liability for ensuring the safety, quality, and efficacy of medical devices, and impose sanctions for violations of legislation on the circulation of medical devices.
6. The circulation of biocidal products and medical devices in Ukraine is regulated in accordance with the provisions of the laws of Ukraine: "Fundamentals of the Legislation of Ukraine on Health Care"; "On Technical Regulations and Conformity Assessment"; "On Consumer Protection"; "On Use of Registrars of Settlement Operations in Trade, Public Catering and Services"; "On State Market Supervision and Control of Non-Food Products"; "On the Basic Principles of State Supervision (Control) in the Field of Economic Activity"; "On Advertising". However, these legal acts are not fully adapted to the relevant EU legislation. Their provisions do not form a full understanding of the peculiarities of circulation of biocidal products and medical devices among their consumers and manufacturers. The specified problem is caused by the lack of unified legislative acts to regulate relations in the specified area. For example, the term "medical product" in some legal acts is designated as "medical product" and has several interpretations (Law of Ukraine "On the Use of Registrars of Settlement Transactions in the Field of Trade, Catering and Services" [11], Technical Regulation No. 753 [12], Technical Regulation No. 754 [13]) and does not fully comply with EU legislation. There is no national legislation on the circulation of biocidal products. Pursuant to the third subparagraph of the third subparagraph of the second paragraph of the Decree of the President of Ukraine dated March 19, 2021 No. 104 "On the decision of the

National Security and Defense Council of Ukraine dated March 19, 2021 "On measures to increase the level of chemical safety on the territory of Ukraine" [14], subparagraph 2 of paragraph 2 of the Action Plan for the Implementation of the Concept of Increasing the Level of Chemical Safety by 2026, approved by the Decree of the Cabinet of Ministers of Ukraine of April 26, 2022 No. 314-p [15], a draft Law of Ukraine "On the Supply and Use of Biocidal Products on the Market" was developed in 2023 [16]. But the said Law has not yet been considered by the Verkhovna Rada of Ukraine.

7. In Ukraine, the relations arising from the application of relevant administrative procedures in relation to products (except for products which circulation is regulated by separate laws) that are put into circulation, put into operation or are in operation are regulated by the Law of Ukraine "On Technical Regulations and Conformity Assessment" [17]. The Law defines the general legal and organizational principles for the development, adoption and application of technical regulations and the conformity assessment procedures provided for by them, as well as the implementation of voluntary conformity assessment. The specifics of regulating administrative procedures are determined by technical regulations, compliance with which is mandatory. It should be noted that technical regulations do not regulate the specifics of consumer rights in the event of adverse medical events during the use of medical devices, nor do they establish sanctions for violation of the rules set forth in the relevant technical regulations in the field of medical devices circulation. In addition, none of the above laws regulating relations in the field of medical devices in Ukraine defines the specifics of consumer protection in this area. However, EU legislation regulates these issues.

DISCUSSION

As the Netherlands is an EU member state, the authorization procedure for biocides is defined in the Biocidal Products Regulation (EU) 528/2012 [10] (hereinafter referred to as the Biocidal Products Regulation). The purpose of the Regulation is to improve the functioning of the markets for biocidal products in the EU and to ensure high quality protection of human health and the environment.

The Netherlands also has national legislation on the regulation of biocides. The main provisions are set out in the Plant Protection Products and Biocides Act [18] (hereinafter - the Act), the Plant Protection Products and Biocides Resolution [19] and the Regulation on Plant Protection Products and Biocides [20].

According to Article 1, paragraph 4 of the Law [11], the term biocides is used in the same meaning as specified in Article 3, paragraph 1, point a, of the Biocidal Products Regulation [10], namely "biocidal product" means (a) any substance or mixture, in the form in which it is supplied to the user, that consists of, contains or generates one or more active substances, with the intent to destroy, prevent, neutralize, prevent the action of, or otherwise exert a controlling effect on any harmful organism by any means other than mere physical or mechanical action; (b) any substance or mixture formed from substances or mixtures not by themselves falling within the description in paragraph (a), but which is used for the purpose of destroying, preventing, neutralizing, preventing the action of, or otherwise exerting a controlling influence on, any pest organism by means other than mere physical or mechanical action. A processed product that has a primary biocidal function is considered a biocidal product [10].

The Netherlands has also established the Board for the Authorisation of Plant Protection Products and Biocides (Ctgb) (hereinafter referred to as the Board), which is tasked with assessing whether biocidal products are safe for humans, animals and the environment in accordance with international agreements and criteria. Based on this assessment, the Board decides whether the products can be sold and used in the Netherlands. It is mandatory to have clear instructions for use, which must be printed - at the very least - on the product label. In order to obtain a biocide authorization, a person must compile an application file with all information about the product and its use. There are different procedures for this. The procedures and requirements that the file must meet depend on the type of authorization that is requested.

The requirements for naming authorized biocides are set out in the Decree on Approval of the Policy on Decision Making on the Naming of Biocides and Plant Protection Products [21].

An invariable part of the authorization decision for applications under the Biocidal Products Regulation is a brief product description [22]. Separate instructions and/or explanations are available for specific application forms (administrative and small application) [23]. To start the application procedure, the applicant must also pay a fee.

Persons authorized to supply biocides must ensure that biocidal products are classified, packaged and labeled in accordance with the approved biocidal product summary and in accordance with Regulation (EC) No 1272/2008 [24] and Article 69 of the Biocidal Products Regulation [10].

Chapter 7 of the Law on Plant Protection Products and Biocides [18] sets out the rules for supervision and enforcement. According to the Law, persons who violate the rules of the Law may be subject to administrative measures, such as: (1) withdrawal of the certificate of professional competence in biocidal products issued to a person to perform actions related to biocides (e.g. distribution of gaseous and aerosolized biocides, control of moles and voles, repelling or controlling pests, control of wood decay fungus) if the requirements established by the Law or in accordance with the Law for obtaining or maintaining such a certificate of professional competence are no longer met; (2) administrative compulsion to cooperate with the persons appointed in accordance with the

Law to perform functions related to the control over the implementation of the Law; (3) in case of serious danger to people, plants, animals or the environment, activities in buildings, places or objects treated with biocides are suspended, and the presence of persons in such places is prohibited (a suspension order is issued); (4) administrative fines; (5) in case of seriousness of the offense, the case may be referred to the prosecutor's office; (6) in case of necessity to manage, destroy biocides that were produced, used in violation of the Law, the authorities responsible for control have the right to apply to the court and, in accordance with the rules on unjust enrichment, to recover costs from persons who have been unjustly enriched through the management of the relevant biocides.

In Finland, biocide provisions that complement the Biocidal Products Regulation are included in the Chemicals Act. The Chemicals Act [41] establishes the procedures to be followed during the national authorization of certain types of biocidal products during the transitional period of the Biocidal Products Regulation. According to the Regulation, biocidal products are divided into four main groups: (1) disinfectants; (2) preservatives; (3) crop dusters; (4) other biocidal products. In addition, biocides are divided into 22 product groups according to their intended use [26].

Lithuanian legislation on the circulation of biocidal products is mostly harmonized with the relevant EU regulations. The main regulatory document in this area at the EU level is EU Regulation No. 528/2012 [5], which sets out the rules for placing on the market and using biocidal products. The purpose of this regulation is to ensure a high level of protection of human health and the environment.

Lithuania has the Law on Chemicals and Mixtures [27], which regulates the conditions for the safe circulation of chemicals and products based on them, including biocides. The key provisions of this law are aimed at protecting human health and the environment from potentially hazardous exposure to chemicals.

In order to implement the provisions of the EU Biocide Regulation [5] and establish specific procedures at the national level, Lithuania has developed relevant regulations and instructions. These include rules for registering biocidal products [28], assessing their safety and efficacy, and controlling their use and distribution.

In Latvia, the circulation of biocidal products is regulated by the Law "Ķīmisko vituų likums" [29]. It regulates the circulation of biocidal substances in Latvia, establishing requirements for their use, registration, labeling and provision of information on safe handling. The legislation stipulates that in order to carry out activities with biocides, it is necessary to obtain appropriate permits and maintain documentation that meets the established standards.

The Ministry of Social Protection of the Population of Latvia and its subordinate supervisory and controlling institutions control activities with chemicals, mixtures, chemicals in products and biocides in the production environment and monitor compliance of these activities with laws and other regulations in the field of protection of life and health of employees in accordance with Section II, Article 4 of the Law. Also, the Cabinet of Ministers of Latvia determines the requirements for working with biocides. Important aspects include requirements for the safety and protection of human health, as well as the protection of the environment from possible negative impacts of biocidal substances. For this purpose, rules have been established for the classification, labeling and packaging of biocides, ensuring the availability of relevant information and compliance with safe storage and transportation procedures. The labeling of biocidal products in Latvia is regulated by Article 12 of the Law "Ķīmisko vituų likums"[29], which sets out the requirements for information to be applied to the packaging of chemicals and biocidal products. According to this article, managers of chemicals or biocidal products (manufacturers, importers, distributors) are obliged to ensure that the packaging of biocidal products intended for further distribution in the country is labeled in Latvian. In addition, the labeling and packaging of biocidal products must comply with the requirements of EU Regulation 1272/2008 concerning the classification, labeling and packaging of chemicals and mixtures.

The Law "Ķīmisko vituų likums" [29] also establishes liability for violations of regulations related to the circulation of biocidal substances, including penalties for handling biocides without appropriate permits, for violating labeling rules, or for placing on the market products containing unauthorized biocidal components. The liability for violations varies depending on the nature of the violation and may include administrative fines for both individuals and legal entities.

Administrative fines are assessed in accordance with the severity of the violation, which includes improper compliance with the requirements for labeling, classification, safe storage, transportation and circulation of chemicals and biocides.

It is important to note that the legislation also establishes requirements for the competence and responsibility of state supervisory authorities for compliance with these rules, providing them with the right to conduct inspections and apply appropriate sanctions to violators.

Latvian legislation provides for detailed requirements for the competence and responsibility of state supervisory authorities in the field of circulation of biocidal products. These authorities are authorized to monitor compliance with the rules, conduct inspections, require manufacturers and distributors to provide the necessary information and documentation, and impose sanctions for violations.

The state supervisory authorities responsible for controlling the circulation of biocidal products include:

1. The Ministry of Health and its subordinate institutions control biocidal products on the market, checking their compliance with the legislative acts related to human health protection.
2. The Ministry of Social Welfare and its subordinate institutions are responsible for controlling the use of biocides in the work environment and ensuring the safety of workers.
3. The Ministry of Environmental Protection and Regional Development and its subordinate institutions control the use of biocides in production and professional activities, except for cases that fall within the competence of the Ministry of Health.

These authorities are authorized to conduct inspections of compliance with the legislation on biocidal products, require manufacturers and distributors to provide the necessary information and documentation, and impose sanctions for violations.

The Federal Ministry for Climate Action, Environment, Energy, Mobility, Innovation and Technology (BMK) is the competent authority for biocidal products in Austria. It oversees the authorization, registration and regulation of biocidal products.

The authorization process for biocidal products in Austria includes the following steps [42]:

a. The applicant submits an application for authorization to the BMK or the designated competent authority.
b. The BMK evaluates the application, taking into account factors such as efficacy, human health, animal health and environmental risks associated with the product.
c. On the basis of the assessment, the BMK decides whether to authorize the biocidal product for placement on the market in Austria.
d. If authorized, the product may be subject to certain conditions or restrictions to ensure its safe use.

Biocidal products must be produced, distributed and used in accordance with strict regulatory requirements:

a. Compliance with GMP standards to ensure the quality and stability of biocidal products.
b. Maintaining detailed records of the production, distribution and use of biocidal products.
c. Notify regulatory authorities of new biocidal products or changes in existing products.
d. Some biocidal products may be restricted for use only by trained professionals or licensed applicators.

According to the Regulation, biocidal products must be labeled in accordance with the BPR and any additional Austrian national requirements [31]. Labeling must provide clear and complete information to users about the hazards of the product, safe handling and use [43].

Regulatory authorities in Austria, such as the Federal Ministry for Climate Action, Environment, Energy, Mobility, Innovation and Technology (BMK), monitor compliance with the labeling requirements for biocidal products. They can conduct inspections and audits to ensure that products on the market meet regulatory standards.

Manufacturers of biocidal products are primarily responsible for ensuring that their products meet the requirements set out in the BPR [5]. This includes conducting appropriate testing, providing accurate labeling and instructions for use, and ensuring that the product is safe and effective for its intended use. Manufacturers can be held liable for any harm caused by their products due to defects or non-compliance with regulatory standards.

Regulatory authorities in Austria, such as the Federal Ministry for Climate Action, Environment, Energy, Mobility, Innovation and Technology (BMK), are responsible for enforcing the BPR and other relevant regulations. They have the authority to investigate complaints, conduct inspections and impose penalties for non-compliance, including fines, product recalls and restrictions on marketing or distribution.

In terms of circulation of medical devices, the legislation of the EU member states is adapted to the requirements of the EU Regulations [33] on the principle of their transposition into national legislation. For example, the legal and organizational framework for the circulation of medical devices in Austria is established by the Federal Medical Device Act [34], which regulates the procedure for ensuring the safety, functionality and quality of medical devices during their installation, operation, use and maintenance. This Act [34] defines the acts (44 items) that result in administrative liability (e.g., a person who places a medical device on the market, puts it into operation, installs it or uses it in violation of the requirements of the Regulation [33] and the said Act is subject to an administrative penalty).

In Latvia, the issue of circulation of medical devices is regulated in detail at the level of the Cabinet of Ministers Resolution "On the Procedure for Registration, Conformity Assessment, Distribution, Operation and Technical Supervision of Medical Devices" [35]. At the level of laws, medical devices are mentioned indirectly, as Article 34 of the Law on Treatment states that “the Cabinet of Ministers determines: essential requirements for medical devices; the procedure for registering information on manufacturers of medical devices, as well as distributors of medical devices; procedures for the distribution and operation of medical devices, as well as supervision, post-sale and technical supervision” [36].

In Lithuania, the Law of the Republic of Lithuania on the Healthcare System provides for the regulations on medical devices [37]. Pursuant to Article 59-1 of the said Law, all medical devices must comply with the standards set by EU regulations. In exceptional cases, when there are no necessary equivalent or alternative medical devices that meet the requirements of the regulations, the Minister of Health may allow the placing on

the market of medical devices that have not been adapted to the conformity assessment procedures, but these medical devices are necessary to ensure health protection. The requirements for placing medical devices on the market and their supply are determined by EU regulations, laws and other regulatory legal acts of Lithuania. The authorized body of the Ministry of Health may refuse to register them if the requirements for providing information about such a product are not met, or terminate the registration if certain violations in the manufacturer's activities are committed.

State supervision over the circulation of medical devices includes regulation of the activities of medical device market participants and market surveillance of medical devices (Article 59-4) [37]. The authorized body has the right to apply enforcement measures in case of violations of the Law, regulations governing the safety, quality, operation, use, putting into circulation, supply, conformity assessment, clinical trials and efficacy studies of medical devices.

In Germany, the Law on the Implementation of EU Regulations on Medical Devices [38] contains provisions on: proper notification of the competent authority of the start of manufacturing a medical device (Article 4); the obligation of the competent authorities to keep documentation with information about the manufacturer of the medical device (Article 5); the competence of the authorized federal bodies to place and put into operation medical devices (Article 7); the language of information about the medical device and instructions for use, etc. (Article 8). The law defines the procedure for classification of medical devices and the powers of the relevant federal authorities in classifying certain devices, class I devices (reusable surgical instruments, medical devices that enter the market in a sterile state, or devices with a measuring function).

The Regulations on Exhibiting stipulate that medical devices that do not meet the requirements of Regulation [33] (Article 13) may be exhibited at exhibitions only if they are clearly marked with a visible sign stating that they are for exhibition and demonstration purposes only. Their circulation is possible only after they are brought into compliance with EU regulations (Article 16).

Poland has adopted the Law on Medical Devices [39]. The law establishes the following: obligations of business entities, healthcare facilities, medical entities, persons engaged in medical professions and other entities regarding the circulation of medical devices; competence, powers, duties and tasks of the authorities in the implementation of state supervision; types of administrative penalties; rules and procedures for conducting clinical trials of a medical device; requirements for information about the created medical device, risks to the patient, user or third parties associated with the use of devices manufactured in state healthcare institutions (Article 11). In addition, the Law obliges to properly indicate the information about the medical device and provide instructions for use for non-professional users (Article 12) with the obligation to translate such information into Polish (Article 15). Medical devices imported by organizations and persons who use these devices for commercial or professional activities from non-EU countries must comply with the requirements of Regulation (EU) 2017/745 or Regulation (EU) 2017/746 (Article 13) [39].

The Law prohibits placing on the market, putting into operation, distribution, delivery, provision, installation, launch and use of a medical device that has expired or which certificate has been withdrawn or suspended, or if the medical device cannot be used without professional support, etc. (Article 16) [39]. Regarding the circulation of a medical device, the Law obliges the manufacturer to submit an application for a unique registration number for registration in the electronic system (Article 33), which shall include information about the device and the manufacturer/importer (Article 19). The Government is competent to prohibit or restrict the circulation of a medical device of a certain manufacturer in case of non-compliance with the law or in case of receiving information about a threat to the life, health or safety of patients during its use (Articles 50, 51) [39].

CONCLUSION

In order to improve the legal regulation of biocidal products circulation in Ukraine, the Law of Ukraine "On the Supply and Use of Biocidal Products" should be adopted, and rules for the registration of biocidal products should be developed and approved, which will set requirements for the process of authorization and registration of biocides, including the submission and processing of applications, evaluation of biocide dossiers, as well as the conditions for authorization, registration and labeling of biocidal products. It is important to form a system of government agencies with controlling powers over the circulation of biocidal products, as well as to establish liability for violation of regulations related to the circulation of biocidal substances (criminal, administrative, civil).

We believe that the implementation of the above will make it possible to form an effective mechanism for the circulation of biocidal products on the Ukrainian market.

In order to improve the legal regulation of the circulation of medical devices in Ukraine, national legislation governing relations in this area should be brought in line with the requirements of Regulations (EU) 2027/745 and 2017/746. It is also necessary to develop and adopt a unified regulatory act (similar to those existing in the EU), which should: clearly define the term "medical device"; regulate the procedure for registration, conformity assessment, distribution, operation, and technical supervision of medical devices; define the competencies of state bodies that supervise and control the circulation of medical devices; establish responsibility for ensuring the

safety, quality, and effectiveness of medical devices and sanctions for violations of legislation in the field of medical device circulation.

In order to ensure proper protection of health and safety of consumers of biocidal products and medical devices in the field of circulation of biocidal products and medical devices, it is advisable to regulate at the legislative level: the conformity assessment procedure; circulation of counterfeit products; monitoring and control of the production of biocidal products and medical devices, their post-marketing supervision; establishment of effective, proportionate and incentive sanctions for violation of circulation of biocidal products and medical devices.

We believe that a promising area for further research is the algorithm for establishing sanctions for violations in the market for biocidal products and medical devices.

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