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Safety of Biocidal and Medical Products: Legal Guaranteeing in EU Countries and Challenges for Ukraine

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Abstract The article provides a comparative legal analysis of the European system for regulating the circulation of biocidal products and medical devices. It argues that legal safeguards for the safety of this category of products are an important tool for protecting human health, animals and the environment. Particular attention is paid to the analysis of the regulatory framework of Regulations (EU) No. 528/2012 and No. 2017/745, as well as the practices of their national implementation in EU member states, in particular in the Netherlands, Latvia, Lithuania, Germany, Poland, Finland and Austria. The aim of the study is to identify effective mechanisms for the legal regulation of biocidal products and medical devices in EU countries and to formulate recommendations for Ukraine, taking into account European standards. Control models, authorisation procedures, labelling requirements and mechanisms of liability for violations of legislation were studied. The methodological basis of the study is systemic-analytical, comparative-legal and formal-legal methods, which made it possible to assess the degree of compliance of national regulation with EU acquis standards. Effective practices of regulatory policy based on transparency, electronic accounting and the division of powers between competent authorities were identified. The state of legal regulation in the field of circulation of biocidal products and medical devices in Ukraine, which is characterised by fragmentation and inconsistency with European standards, has been analysed. The necessity of adopting basic legislation on biocides, updating technical regulations on medical devices, creating a single electronic register and introducing effective market surveillance is substantiated. The article contains specific proposals for adapting Ukrainian legislation to the EU acquis and promoting the formation of an effective consumer protection system in the field of healthcare.

Key Words Biocidal Products and Medical Devices, Healthcare, European Union, Eu Acquis, Consumer Protection, Supervision and Control, Patient Safety

INTRODUCTION

Modern biocidal products and medical devices play an increasingly important role in ensuring adequate public health, preventing infections, disinfecting medical equipment, sterilising and ensuring the safe operation of medical facilities. Their production, use and circulation are subject to close scrutiny by governments, as even minor violations of safety requirements for such products can pose a direct threat to human life and health, the environment and wildlife.

In response to the growth of the market for biocidal products and medical devices, as well as the associated risks, the European Union has developed a complex regulatory framework covering authorisation procedures, labelling requirements, safety, traceability, liability and post-marketing control. The central acts are Regulation (EU) No 528/2012

on the making available on the market and use of biocidal products [1] and Regulation (EU) No 2017/745 on medical devices [2]. They are directly applicable in all EU Member States, but the mechanism for their transposition, adaptation and implementation in national legal systems is also important. The variety of legal models for the circulation of such products in individual EU countries (the Netherlands, Austria, Lithuania, Latvia, Germany, Poland, Finland) allows us to trace the strengths and weaknesses of regulation, particularly in the areas of manufacturer liability, market surveillance and consumer protection.

At the same time, the issue of legal safeguards for the safety of biocidal products and medical devices is still being developed in Ukraine. Despite the existence of technical regulations and general provisions of health legislation, there is still no specific law on biocides and the regulation of medical devices remains fragmented and not fully harmonised with EU acquis standards. This creates challenges for both consumers and businesses seeking to operate on an equal footing with European manufacturers.

The purpose of this article is to conduct a comparative legal analysis of the European approach to the legal regulation of the safety of biocidal products and medical devices, taking into account the national models of EU member states and to develop recommendations for improving Ukraine's legal system in this area. The study aims not only to identify the key elements of legal safeguards for safety in the EU, but also to assess the possibilities for their adaptation in the Ukrainian legal system.

Literature Review

The issue of legal regulation of the circulation of biocidal products and medical devices is mainly examined in the context of the European Union's general approach to ensuring human health, consumer safety, environmental protection and harmonization of regulatory policy within the internal market. The main act regulating the circulation of biocidal products is Regulation (EU) No. 528/2012, which establishes uniform requirements for the authorization, labelling, classification and safety control of such substances in all EU member states [1]. It provides for centralized and national authorization procedures, post-market surveillance and a system of mutual recognition of authorizations.

In the field of Medical Devices (MDR), Regulation No. 2017/745 introduces the EUDAMED system, risk classification, clinical evaluation requirements and post-market monitoring. This is confirmed by official documents of the European Commission [3] and an analytical note of the Verkhovna Rada of Ukraine on comparative legislation, which describes in detail the mechanisms for the circulation of medical devices in EU countries and individual member states [4]. The practical aspects of the transition to MDR and IVDR are also important for manufacturers-these are described in detail in the MedTech Europe Report [5], which outlines the industry's experience in implementing MDR.

In the post-Soviet space, including Ukraine, scientists are increasingly raising the issue of adapting national legislation to the EU acquis. An important contextual factor is the broader legal and economic environment in which the harmonization of regulations on biocidal products and medical devices is taking place. In this regard, researchers emphasise the advisability of creating favourable legal conditions for innovation and consumer safety in regulated sectors. Thus, Loiko *et al.* [6] emphasise that building a single regulatory space requires not only technical harmonization, but also the provision of coordinated financial and institutional instruments to support innovation and risk management in various sectors.

At the same time, Ukrainian legal scholars draw attention to the complexity of adapting EU law to national legislation. Thus, Chekhovska and Moroz [7] emphasise the need to harmonise Ukrainian legislation on biocides with the provisions of European acts, in particular regarding the creation of a national system of permits, product registration and control of its circulation. Bondarets *et al.* [8] analyse approaches to the development of medical devices in accordance with Technical Regulation No. 753 of Ukraine through the prism of a risk-based methodology that takes into account risk classes, ISO requirements and certification processes.

A comparative analysis of regulatory models in EU member states demonstrates the effectiveness of the institutional approach implemented, in particular, in the Netherlands. The competent authority in this area is the independent state institution Ctgb (Board for the Authorization of Plant Protection Products and Biocides), which conducts scientific assessments of dossiers, issues permits for the circulation of biocidal products and ensures the openness and transparency of review procedures. The Ctgb's official website provides detailed information on the institution's regulatory activities, in particular the mechanisms for independent decision-making, which could serve as a model for the creation of a similar specialised body in Ukraine [9]. At the same time, the urgent task is not only to create regulatory bodies, but also to ensure the legal unity of judicial practice in the field of medical device circulation as a prerequisite for the functioning of a single medical space [10].

Thus, the literature review reveals two key trends: at the EU level-comprehensive, systematic regulation of the biocidal and medical device sectors; in Ukraine-gradual steps towards implementing EU acquis norms through regulatory acts and adaptation of technical regulations, subject to the development of institutional capacity.

METHODS

The methodological basis of the study is an interdisciplinary approach that combines legal analysis with elements of regulatory policy in the field of health care and chemical safety. In preparing this article, a systemic-structural method was used to characterise the current regulatory framework for the circulation of biocidal products and medical devices in European Union law, as well as a comparative legal method to analyse the specific features of legal regulation in

individual EU member states: The Netherlands, Poland, Germany, Lithuania, Latvia, Finland and Austria.

In order to assess the state of Ukrainian legislation in this area, a formal legal method was used, which made it possible to identify key regulatory gaps and inconsistencies with the EU acquis. A functional approach was used to establish links between the institutional capacity of market surveillance authorities and the effectiveness of regulation in EU countries and Ukraine. Doctrinal analysis, empirical observations of the application of norms and logical and normative generalization were also used, which made it possible to formulate well-founded proposals for the harmonization of Ukrainian legislation.

All sources used in the study are authentic and accessible through official European regulatory databases, national registers and publications in reputable peer-reviewed scientific journals. The study did not involve the collection of personal data or the participation of human respondents and therefore did not require separate approval from ethics committees.

RESULTS AND DISCUSSION

Biocidal Products in the EU: Legal Framework and National Implementation Models

The legal regulation of the circulation of biocidal products in the Member States of the European Union is unified at the supranational level in accordance with the provisions of Regulation (EU) No. 528/2012 [1], which replaced Directive 98/8/EC [11]. The Regulation defines the legal framework for the admission of biocidal products to the EU market through the authorization of active substances, the assessment of risks to human health, animals and the environment and the application of mechanisms for mutual recognition of decisions between Member States [1].

The Regulation also provides for two main authorization models: centralised (unified for the entire EU) and national. The former applies to innovative or high-risk products, while the latter applies to other categories with the possibility of mutual recognition of authorizations. The European Chemicals Agency (ECHA) plays a key role in coordinating authorization procedures, maintaining databases and carrying out technical supervision.

This Regulation introduces a uniform EU-wide approach to the control of medical devices, which provides for:

- Classification of devices according to risk level (classes I–III)
- Mandatory conformity assessment involving notified bodies (for classes IIa, IIb and III)
- The use of a unique device identification (UDI) system
- The creation and maintenance of the EUDAMED database, which ensures transparency, access to information and market surveillance [12]

The Regulation also provides for enhanced post-market surveillance and legal liability for manufacturers. Manufacturers must ensure that information about medical devices (instructions, labelling) is accessible, reliable, up-to-date and provided in the language of the relevant Member State. Therefore, an important provision of the Regulation is the obligation of Member States to ensure the functioning of competent national authorities and sanction mechanisms to monitor compliance with the requirements.

Despite a unified supranational framework, the implementation of Regulation (EU) No 528/2012 into national legislation varies between EU countries depending on institutional architecture and national administrative practices.

The Netherlands has a Plant Protection Products and Biocides Act, which regulates the circulation of products, defines the powers of supervisory authorities and procedural aspects of authorization. The central authority is the Commission for the Authorization of Plant Protection Products and Biocides (Ctgb), which is responsible for granting authorizations, quality control and labelling compliance [13].

In Lithuania, regulation is carried out in accordance with the Law on Chemical Substances and Preparations. The law provides for the creation of a national register of biocidal products, a detailed procedure for dossier evaluation, labelling requirements and the definition of market participants' responsibilities [14].

In Latvia [15] the legal framework is defined by the Chemicals Act, which establishes a mandatory authorization procedure and requirements for classification and labelling in the official language. Control powers are shared between the relevant ministries of health, social protection and the environment.

Finland regulates in accordance with the Chemicals Act No. 599/2013. The Act establishes the procedure for registering biocidal products, which are classified into 22 functional groups, with mandatory assessment prior to market authorization [16].

In Austria [17] implementation is carried out through the Biocidal Product Act, which is consistent with the provisions of the BPR. The competent authority is the Federal Ministry for Climate Action, which performs the functions of evaluating applications, controlling and inspecting products and applying administrative or civil sanctions in case of violations.

Thus, the implementation of the single European Regulation (EU) No. 528/2012 in member states demonstrates the national specificity of the implementation of identical norms. Some countries, such as the Netherlands, have chosen to create specialized independent agencies to ensure transparency and effective regulation, while others have opted for a model of distributed responsibility among several ministries. The most effective model appears to be one in which powers are concentrated in a professionally independent body that carries out both product approval and post-marketing surveillance. This allows for a proper balance between the speed of procedures and the level of safety for society and the environment.

Medical Devices in the EU: Implementation of Regulation 2017/745 in National Legal Systems

The legal regulation of medical devices in European Union countries is based on Regulation (EU) No. 2017/745, which came into force on 26 May 2021 and replaced the previous Directive 93/42/EEC. The new regulation significantly tightened the requirements for safety, clinical evaluation and post-market surveillance of medical devices, in particular introducing mandatory participation of notified bodies, requirements for the manufacturer's quality management system and the creation of a unified EUDAMED database to ensure transparency of the circulation of devices in the EU [2].

Regulation 2017/745 classifies medical devices according to their risk level (classes I–III) and establishes requirements for clinical investigations, certification by conformity assessment bodies and the obligations of manufacturers, importers and distributors. Another key innovation is the institutionalization of the concept of an 'economic operator' and the creation of a Unique Device Identification (UDI) system to ensure traceability [2].

These provisions formed the basis for the development of national implementation models, which, despite a single regulatory framework, have their own characteristics depending on the administrative structure, regulatory traditions and institutional capacity of EU Member States. Let us consider some examples of the implementation of Regulation 2017/745 in different European Union countries.

In Germany, the provisions of the Regulation have been implemented through a special Law on the Implementation of EU Regulations on Medical Devices (MPDG). The document regulates in detail the registration procedures, interaction with market surveillance authorities, requirements for the language of labelling and the procedure for placing products on the market [18]. Federal health authorities are empowered to classify products, conduct technical supervision and initiate product recalls in the event of violations.

In Poland, the Medical Devices Act of 2022 sets out requirements for registration, mandatory Polish-language documentation, conditions for importing products from outside the EU and the use of an electronic reporting system for product safety. The Act also establishes penalties for violations of expiry dates, non-compliance with instructions, or lack of certificates of conformity.

In Austria, the Federal Medical Devices Act [20] details the requirements for safety, effectiveness and technical supervision. The competent authority is the Federal Ministry of Social Affairs, Health, Care and Consumer Protection, which is responsible for inspections, audits and market surveillance.

In Lithuania [21] the legal framework for the circulation of medical devices is integrated into the Law on the Health Care System, which requires the use of only devices that comply with the requirements of the Regulation. The law also allows for the temporary use of non-certified devices in cases where there is a threat to life or health and provides for the powers of authorized bodies to suspend certificates and withdraw products.

The legal regulation of the circulation of medical devices in Latvia is based on a combination of subordinate and legislative levels. In particular, the relevant Resolution of the Cabinet of Ministers defines the procedure for registering medical devices, assessing their conformity, requirements for labelling in the state language, as well as technical supervision procedures. At the same time, the basic legislative act in this area is the Law 'On Treatment', which empowers the government to register market participants, control the circulation of products after their introduction to the market and ensure an adequate level of product quality and safety [22].

Thus, the implementation of Regulation (EU) 2017/745 in the national legal systems of EU member states has demonstrated a variety of approaches. Some countries have focused on creating specialised supervisory bodies (such as Germany and Austria), while others have focused on integrating the requirements into the general healthcare system (Lithuania, Latvia). The most effective jurisdictions are those where legislation not only transposes the provisions of the Regulation but is also supplemented by digital control tools, sanction mechanisms and procedural details. Such approaches ensure a higher level of transparency, safety and trust in the circulation of medical devices, which should be taken into account by Ukraine when harmonising national legislation.

Control over the Circulation of Biocidal Products and Medical Devices and Legal Liability in this Area

In European Union member states, the safety of biocidal products and medical devices is monitored both at the stage of their introduction into circulation and throughout the entire product life cycle. It is important to divide powers between different regulators, in particular health, environmental protection, social protection and market surveillance authorities.

In the Netherlands, the main regulatory authority in the field of biocides is the Commission for the Authorisation of Plant Protection Products and Biocides (Ctgb), which not only grants authorisations but also monitors compliance with the conditions of authorisation. In the event of violations, the authorisation may be suspended, the product may be recalled, or the case may be referred to the public prosecutor's office. In Finland, control functions are performed by authorities operating under the Chemicals Act. Particular attention is paid to compliance with the rules for the classification, labelling and packaging of biocidal products, as well as to the supervision of their use in professional activities [16]. In Latvia [15] the circulation of biocidal products is controlled by several authorities: the Ministry of Health at the consumer level, the Ministry of Social Security in the production environment and the Ministry of the Environment in the field of environmental safety. All these institutions have the right to check documentation, issue warnings and impose fines.

With regard to medical devices, EU countries apply the principle of shared responsibility between national competent authorities and notified conformity assessment bodies. In addition, post-market surveillance is carried out,

which allows for a rapid response to identified risks. For example, in Poland, state authorities may ban the circulation of a product if there are grounds to believe that it poses a threat to the health or life of the user. There is also an obligation to enter information about each medical device into an electronic registration system, indicating the manufacturer, importer, intended use and possible risks [19].

Legal liability in the field of circulation of biocidal products and medical devices in the European Union is administrative, civil and in exceptional cases even criminal. For example, in Latvia, the Chemical Substances Act contains specific sanctions for violations of the requirements for the circulation of biocidal substances. In particular, fines are imposed on both individuals and legal entities for unauthorized circulation, improper labelling or violation of transportation rules [15]. In Austria, liability applies for damage caused by the use of dangerous or incorrectly labelled biocidal products. In addition to administrative fines, products may be withdrawn from the market and their use restricted to specially trained professionals [24].

In the field of medical devices, in addition to penalties for violating the rules for placing products on the market (lack of certification, incorrect labelling, expired shelf life), civil liability is provided for damage caused by a defective product. In this case, the patient may file a claim for damages against the manufacturer or supplier.

Thus, the general European trend is to introduce risk-based sanctions that not only punish violations but also encourage market participants to comply with safety and transparency requirements. At the same time, the national legislation of EU countries mainly supplements European legislation, detailing the types of liability, supervisory procedures and obligations of market participants. We believe that this approach ensures a high level of consumer health and safety protection, as well as confidence in the circulation of medical and chemical products.

Challenges and Problems of Harmonising Legal Regulation in Ukraine

Despite the implementation of certain provisions of European Union law in the field of biocidal products and medical devices, Ukraine's regulatory framework remains fragmented and insufficiently adapted to the provisions of Regulations (EU) No. 528/2012 and No. 2017/745. A significant part of the regulation is based on subordinate legislation and departmental instructions, which does not ensure proper unity and transparency in law enforcement [25].

In the field of biocidal products, the main document remains Resolution No. 908 of the Cabinet of Ministers of Ukraine of 3 August 1998, which approves the Procedure for State Registration of Disinfectants [26]. At the same time, the legislation lacks provisions on a centralized database, a common unified procedure for evaluating active substances and a clear differentiation of biocide categories according to functional characteristics. The control system is based on the powers of the State Service of Ukraine for Food Safety and Consumer Protection and the Ministry of Health of Ukraine, but their ability to carry out post-marketing surveillance remains limited.

In accordance with the provisions of the Decree of the President of Ukraine No. 104/2021 of 19 March 2021 [27], the action plan for the implementation of the Concept for Improving Chemical Safety by 2026 [28] and also with the aim of implementing European Union Regulation No. 528/2012 of the European Parliament and of the Council of 22 May 2012, the Ministry of Health of Ukraine has developed a draft Law of Ukraine 'On the marketing and use of biocidal products' [29], which has not yet been adopted. If adopted, this law will harmonise Ukrainian regulations with Regulation (EU) No. 528/2012, in particular with regard to: defining the powers of competent authorities, authorisation procedures, the establishment of a register of biocidal products, labelling requirements and the responsibilities of manufacturers and distributors, etc.

With regard to medical devices, it is important to note that Ukraine does not have a single regulatory act that would integrate the provisions of Regulation (EU) 2017/745. Today, there are three technical regulations in force in Ukraine, adopted on the basis of the relevant EU directives, namely: Technical Regulation on Medical Devices [30], Technical Regulation on In Vitro Diagnostic Medical Devices [31], Technical Regulation on Active Implantable Medical Devices [32]. However, these regulations only partially comply with the provisions of Regulation (EU) 2017/745, failing to cover such important aspects as the electronic database of devices (EUDAMED), mechanisms for assessing clinical effectiveness, or the post-market surveillance system. At the same time, Ukrainian legislation uses inconsistent terminology: "medical device", "medical product", "medical equipment", which creates difficulties in law enforcement.

The lack of legal incentives for proper product registration by economic entities remains an important problem. Insufficient state control, the lack of mandatory digital traceability of products and mechanisms for recalling dangerous products pose a threat to the life and health of consumers. These risks are particularly exacerbated by the rapid development of e-commerce in medicines, where consumer rights require additional regulatory protection and harmonization with European practices [33]. There are widespread cases of products with expired shelf life, without instructions in the official language and of dubious origin [34].

Also, unlike the practice of EU member states, Ukraine does not provide for the creation of separate independent bodies for conformity assessment and licensing. This reduces the institutional capacity of the system, makes it vulnerable to corruption risks and does not ensure an adequate level of transparency of procedures.

Proposals for Improving National Regulation in the Field of Biocidal Products and Medical Devices

The results of a comparative analysis of the legal regulation of biocidal products and medical devices in European Union countries have demonstrated the existence of a

comprehensive regulatory model based on unified approaches to ensuring product safety and market compliance. At the same time, the regulatory framework in this area in Ukraine remains fragmented, which necessitates its improvement through the implementation of the main elements of European regulatory policy. Therefore, we consider it appropriate to offer a number of practical proposals that could serve as a basis for the development of relevant legislative and institutional changes in Ukraine.

First of all, the problem of the absence of a single specialised legislative act that would comprehensively regulate the circulation of biocidal products remains acute. The adoption of the Law of Ukraine 'On Biocidal Products' would allow the provisions of Regulation (EU) No. 528/2012 to be integrated into Ukrainian legislation, establish a clear classification of biocides, procedures for the evaluation of active substances, rules for labelling and packaging and provide for mechanisms of state supervision and sanctions for violations of safety requirements [1].

In the field of medical devices, the issue of unifying legal regulation is also relevant. There are two possible options: either adopting a single law or updating the existing technical regulations in accordance with the provisions of Regulation (EU) No. 2017/745 [2]. In particular, Ukraine has not yet introduced mandatory integration into the EUDAMED information system, there are no effective post-registration monitoring mechanisms and the requirements for clinical efficacy are not sufficiently detailed. Improving regulatory oversight in this area will not only help improve product quality and establish accountability for violations of norms and standards, but also strengthen consumer confidence in the healthcare system.

An important step towards institutional reform should be the creation of a single competent authority for the regulation of biocidal products and medical devices. Following the example of countries such as the Netherlands, Austria and Finland, this body should be independent and empowered to register, issue permits, supervise and impose sanctions. This approach will not only ensure effective coordination of actions, but also increase the transparency of administrative procedures.

Special attention should be paid to the creation of a digital platform-an open database of biocidal products and medical devices. This platform should contain data on composition, manufacturers, authorization status, expert opinions and cases of product recalls. A similar system is already functioning effectively in the EU, in particular in the form of the ECHA register and EUDAMED and its adaptation to Ukrainian realities will significantly strengthen control over product quality and safety.

Increased transparency of state control is also possible through the institutionalization of public reporting. This involves the regular publication of information on the results of inspections, violations detected and sanctions imposed, which will contribute to the formation of an open dialogue between the regulator, business and civil society.

Finally, it is necessary to review approaches to legal liability for violations in the circulation of these products. We consider it appropriate to review the existing system of administrative and criminal sanctions by adopting appropriate rules on liability for causing harm to health through the circulation of dangerous products, as well as creating mechanisms for simplified compensation for damages to victims.

Overall, the implementation of the proposed changes will contribute to the systematic updating of Ukrainian legislation in the field of biocidal products and medical devices, as well as harmonise it with the EU acquis. This, in turn, will be an important step towards Ukraine's integration into the EU single market in the field of health and biological safety.

CONCLUSION

The study allowed for a comprehensive comparative legal analysis of the regulation of biocidal products and medical devices in European Union law and individual member states. It was established that the EU has formed a multi-level legal system based on directly applicable regulations and national models for implementing these regulations.

The authors of the study found that the legal regulation of the circulation of biocidal products and medical devices in European Union countries is based on two regulations: Regulation (EU) No. 528/2012 and Regulation (EU) 2017/745. Both documents not only unify key aspects of market access, but also provide for high standards of safety, traceability, post-marketing surveillance and the responsibility of manufacturers and suppliers. Their implementation in EU Member States, despite a common legal framework, demonstrates a variety of administrative models, institutional approaches and enforcement tools.

When writing the article, special attention was paid to the experience of countries such as the Netherlands, Austria, Latvia, Lithuania, Poland and Germany, where clear authorization procedures, product registries, effective post-marketing monitoring mechanisms and multi-level control of market participants have been introduced. The defining features of the European model are: the existence of specialized agencies with a high level of independence, transparency and expertise; a clear division of powers between the relevant authorities; electronic access to product data; and the application of liability, ranging from administrative to civil. This ensures not only timely product authorization but also comprehensive oversight of regulatory compliance at all stages of the life cycle of biocidal products and medical devices. Special attention is paid to electronic accounting systems (ECHA, EUDAMED) and the requirement to provide information in the official language of the relevant country.

In Ukraine, national legislation is currently undergoing a process of gradual alignment with the EU acquis, but this process is slow and unsystematic. For example, there is still no specific law on biocidal products and the regulation of medical devices is limited to a few technical regulations that only partially implement EU standards. This creates serious legal gaps in the areas of safety, labelling, conformity assessment and product circulation control. Therefore, it is necessary to develop new national legislation and update existing technical regulations that would

comprehensively regulate market access, accounting, labelling, conformity assessment and responsibility in the field of biocidal and medical products. In doing so, particular attention should be paid to the creation of unified electronic registers, transparent authorisation procedures and independent oversight mechanisms with clearly defined responsibilities for violations.

Thus, the implementation of European approaches to regulating the circulation of biocidal products and medical devices may become one of the key areas in the adaptation of Ukrainian legislation to EU standards. This will not only help ensure an adequate level of product safety for consumers, but also increase confidence in state regulation, create conditions for fair competition and enable Ukrainian manufacturers to enter foreign markets.

Conflicts of Interest

The authors declare no conflict of interests. All authors read and approved final version of the paper.

REFERENCES

[1] European Parliament and Council of the European Union. Regulation (EU) No. 528/2012 of 22 May 2012 concerning the making available on the market and use of biocidal products. *Official Journal of the European Union*, 22 May 2012. Eur-Lex, https: //eur-lex.europa.eu/legal-content / EN/TXT / ? uri =CELEX:32012R0528.

[2] European Parliament and Council of the European Union. Regulation (EU) 2017/745 of 5 April 2017 on medical devices. *Official Journal of the European Union*, 5 April 2017. Eur-Lex, https://eur-lex.europa.eu/legal-content/EN/TXT/?uri =CELEX:02017R0745-20200424.

[3] EC. Medical Devices Sector-MDR Regulation No. 2017/745 Overview. European Commission, n.d. Accessed 30 July 2025. https://health.ec.europa.eu/medical-devices-sector/overview_en.

[4] VRU. Analytical note: Comparative legislation on the circulation of medical devices in the EU and EU member states. *Verkhovna Rada of Ukraine,* 2024. Accessed 30 July 2025. https://research.rada.gov.ua/uploads/documents/32533.pdf.

[5] MedTech Europe. Industry Status Update on Implementation of MDR and IVDR. MedTech Europe, 2022. Accessed 30 July 2025. https://www.medtecheurope.org/resource-library/mdr-ivdr-implementation-status-update-2022.

[6] Loiko, V. *et al.* "Innovative potential of the consumer sector of the economy: Financial, economic and legal aspects." *Amazonia Investiga*, vol. 11, no. 52, 2022, pp. 155–164. https://doi.org/10.34069/AI/2022.52.04.17.

[7] Chekhovska, I.V. and Y.A. Moroz. "Legal regulation of circulation of biocidal products in the member states of the European Union." *Irpin Legal Chronicle*, vol. 2, no. 15, 14 June 2024, pp. 79–94. Accessed 31 July 2025. https://ojs.dpu.edu.ua/index.php/irplegchr/article/view/233.

[8] Bondarets, I. *et al.* "Regulatory and risk-oriented approach to the design and development of medical devices in accordance with Ukraine regulations." *Pharmacia*, vol. 69, no. 2, 2022, pp. 493–500. https://doi.org/10.3897/pharmacia.69.e82316.

[9] Board for the Authorisation of Plant Protection Products and Biocides (Ctgb). *Biocidal Products.* Dutch Government, n.d. Accessed 30 July 2025. https://english.ctgb.nl/biocidal-products.

[10] Teremetskyi, V. *et al.* "Unity of case-law as an indicator for the development of single medical Space." *Brazilian Journal of Law*, vol. 19, no. 1, 2023, pp. 1–12. https://doi.org/10.18256/2238-0604.2023.v19i1.4925.

[11] European Parliament and Council of the European Union. Directive 98/8/EC of 16 February 1998 Concerning the Placing of Biocidal Products on the Market. *Official Journal of the European Union*, 16 February 1998. Eur-Lex, https://eur-lex.europa.eu/legal-content / en / ALL /? uri= CELEX % 3A 31998L0008.

[12] European Commission. European Database on Medical Devices (EUDAMED). *European Commission*, n.d. Accessed 30 July 2025. https://ec.europa.eu/tools/eudamed.

[13] Netherlands. Wet Gewasbeschermingsmiddelen en Biociden [Law on Plant Protection and Biocidal Products]. Government of the Netherlands, 1 June 2015. https://wetten.overheid.nl/BWBR0021670/2015-06-01.

[14] Lithuania. Lietuvos respublikos cheminių medžiagų ir preparatų įstatymas Nr. XIII-2802 [Law on Chemicals and Preparations]. *Seimas of the Republic of Lithuania*, n.d. https://e-seimas.lrs.lt/portal/legalAct/lt/TAD/5c2ff452428d11ea983cd4e02103c255.

[15] Latvia. Ķīmisko vielu likums [Law on Chemical Substances]. Likumi.lv, n.d. Accessed 30 July 2025. https://likumi.lv/ta/id/47839-kimisko-vielu-likums.

[16] Finland. Chemicals Act 599/2013. Ministry of Justice Finland, n.d. Accessed 30 July 2025. https://www.finlex.fi/fi/laki/kaannokset/2013/en20130599.pdf.

[17] Austria. Biocidal Product Act-biozidprodukteg. *Austrian Government*, n.d. Accessed 30 July 2025. https://www.global-regulation.com/translation/austria/2996404/biocidal-product-act---biozidprodukteg.html.

[18] Germany. Gesetz zur Durchführung Unionsrechtlicher Vorschriften Betreffend Medizinprodukte (MPDG) [Act to Implement EU Regulations on Medical Devices]. Bundesministerium der Justiz, n.d. Accessed 30 July 2025. https://www.gesetze-im-internet.de/mpdg/.

[19] Poland. Ustawa z Dnia 7 Kwietnia 2022 r. o Wyrobach Medycznych, Dz. U. 2022 Poz. 974 [Act on Medical Devices of 7 April 2022]. ISAP, 2022. Accessed 30 July 2025. https://isap.sejm.gov.pl/isap.nsf/download.xsp/WDU20220000974/T/D20220974L.pdf.

[20] Austria. Gesamte Rechtsvorschrift für Medizinproduktegesetz 2021 [Medical Devices Act 2021]. Bundeskanzleramt, n.d. Accessed 30 July 2025. https://www.ris.bka.gv.at/Geltende.

[21] Lithuania. Lietuvos Respublikos Sveikatos Sistemos Įstatymas [Law on the Health System of the Republic of Lithuania]. Seimas of the Republic of Lithuania, n.d. Accessed 30 July 2025. https://e-seimas.lrs.lt/portal/legalAct/lt/TAD/TAIS.5905.

[22] *Latvia. Ārstniecības Likums [Medical Treatment Law].* Likumi.lv, n.d. Accessed 30 July 2025. https://likumi.lv/ta/id/44108-arstniecibas-likums.

[23] Ctgb-Board for the Authorisation of Plant Protection Products and Biocides. Registration Manual. *Ctgb*, n.d. Accessed 30 July 2025. https://english.ctgb.nl/biocidal-products / assessment-framework/registration-manual.

[24] Swedish Chemicals Agency (KEMI). Labelling of biocidal products. *KEMI*, n.d. Accessed 30 July 2025. https://www.kemi.se/en/pesticides-and -biocides/biocidal-products/rules-for-biocidal-products/labelling -of-biocidal-products.

[25] Ukraine. Law on technical regulations and conformity assessment No. 124-VIII of 15 January 2015. *Verkhovna Rada of Ukraine*, 2015. Accessed 30 July 2025. https://zakon.rada.gov.ua/laws/show/124-19#Text.

[26] Cabinet of Ministers of Ukraine. Resolution No. 908 of 3 August 1998 on approval of the procedure for state registration of disinfectants. *Verkhovna Rada of Ukraine*, 1998. Accessed 30 July 2025. https://zakon.rada.gov.ua/laws/show/908-2006-%D0%BF#Text.

[27] President of Ukraine. Decree No. 104/2021 of 19 March 2021 on the decision of the national security and defense council "On Measures to Improve Chemical Safety in Ukraine." *President of Ukraine*, 2021. Accessed 30 July 2025. https://www.president.gov.ua/documents/1042021-37417.

[28] Cabinet of Ministers of Ukraine. Order No. 314-p of 26 April 2022 on the action plan for implementation of the concept for improving the level of chemical safety until 2026. *Verkhovna Rada of Ukraine*, 2022. Accessed 30 July 2025. https://zakon.rada.gov.ua/laws/show/314-2022-%D1%80#Text.

[29] Ukraine, Ministry of Health. Draft law of Ukraine "On Placing on the Market and Use of Biocidal Products." *Ministry of Health of Ukraine*, 2023. Accessed 30 July 2025. https://moz.gov.ua/uk/povidomlennja -pro-opriljudnennja-proektu-zakonu-ukraini--pro-nadannja -na-rinku-ta-vikoristannja-biocidnih-produktiv.

[30] Ukraine, Cabinet of Ministers. Resolution No. 753 of 2 October 2013 on approval of the technical regulation on medical devices. *Verkhovna Rada of Ukraine*, 2 October 2013. Accessed 30 July 2025. https://zakon.rada.gov.ua/laws/show/753-2013-% D0 % BF#Text.

[31] Ukraine, Cabinet of Ministers. Resolution No. 754 of 2 October 2013 on approval of the technical regulation on in vitro diagnostic medical devices. *Verkhovna Rada of Ukraine*, 2 October 2013. Accessed 30 July 2025. https://zakon.rada.gov.ua/laws/show/754-2013-%D0%BF.

[32] Ukraine, Cabinet of Ministers. Resolution No. 755 of 2 October 2013 on approval of the technical regulation on active implantable medical devices. *Verkhovna Rada of Ukraine*, 2 October 2013. Accessed 30 July 2025. https://zakon.rada.gov.ua/laws/show/755-2013-% D0% BF # Text.

[33] Teremetskyi, V. *et al.* "Consumers rights in the field of electronic trade in medicinal products: Legal challenges and global harmonization trends." *Journal of Pioneering Medical Sciences*, vol. 14, no. 4, 2025, pp. 113–119.

[34] The Accounting Chamber. Audit report on the effectiveness of control over circulation of medical devices in Ukraine. *The Accounting Chamber,* 2021. Accessed 30 July 2025. https://rp.gov.ua/upload-files/Activity/Reports/2021/ med _ vyroby/Med_vyroby.pdf.