Section I BIOMEDICAL ENGINEERING
Секція БІОМЕДИЧНА ІНЖЕНЕРІЯ

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UKRAINE'S REGULATIONS AND STANDARDS ON NANOSAFETY FOR BIOMEDICAL ENGINEERING: ALIGNING WITH THE EU GREEN DEAL

Abstract. This paper examines Europe's and Ukraine's current regulations and standards on nanosafety for biomedical engineering and their alignment with the EU Green Deal. Nanosafety is a crucial aspect of biomedical engineering as it deals with the potential risks of using nanoparticles in healthcare applications. The EU Green Deal emphasizes the importance of sustainable development and reducing the environmental impact of industries, including biomedical engineering. This study analyzes Ukraine's current regulations and standards on nanosafety and evaluates their compatibility with the EU Green Deal's objectives. The findings suggest that while Ukraine has progressed in regulating nanosafety in biomedical engineering, there is still room for improvement in aligning with the EU Green Deal. This paper analyzed recommendations for Ukraine to improve its nanosafety regulations and standards further to meet the objectives of the EU Green Deal.

Keywords: the EU Green Deal, nanosafety, biomedical engineering, nanosafety regulations and standards

Nanotechnology presents a promising potential to transform the biomedicine field, opening up many opportunities for developing new diagnostics and therapies [1]. However, several challenges need to be addressed, particularly regarding the safety of nanomaterials in biomedical applications. Nanomaterials have unique properties that make them attractive for use in medical devices, drug delivery systems, and other biomedical applications. Still, they also pose potential risks to human health and the environment. Therefore, it is essential to regulate the production and use of nanomaterials to minimize any potential risks and ensure that they are used safely and responsibly [2].

The safe use of nanomaterials in biomedical applications is a complex issue, as these materials' potential risks and benefits are not yet fully understood. Therefore, it is essential to have regulatory frameworks in place to ensure that science-based safety assessments guide the development and use of nanomaterials in medical products. These regulations also facilitate the monitoring and tracking of the use of nanomaterials in medical products, allowing for more efficient identification and mitigation of potential risks to human health and the environment. Ultimately, implementing regulations and guidelines for using nanomaterials in biomedical applications is a critical step toward ensuring the responsible and sustainable use of nanotechnology in medicine.

The regulations and guidelines that govern the use of nanomaterials in biomedical applications are in place to ensure that companies comply with safety standards and provide safety data. This helps to protect the workers involved in the production process, as well as patients who may use medical devices or drugs that contain nanomaterials, from potential harm. Moreover, these regulations serve as a preventative measure to reduce the risk of environmental contamination due to the use of nanomaterials [3].

Our study aimed to analyze the existing literature data on the regulation of nanotechnology for biomedical applications while considering the importance of developing nanosafety measures in Ukraine.

In our analytical research, we used several resources from the European Union Observatory for Nanomaterials (EUON), European Medicines Agency (EMA), U.S. Food and Drug Administration (FDA), International Council on Nanotechnology (ICON), National Institute for Occupational Safety and Health (NIOSH) and databases PubMed, Scopus, Web of Science, ScienceDirect. This study was carried out as part of the implementation of a grant project Jean Monnet Actions under ERASMUS+ Programme ERASMUS-JMO-2021-HEI-TCH-RSCH EUNanoGreen – 101047940 “Responsible development of nanosafety as the contribution to the European Green Deal” with the support of NGO CSAET.

The European Union (EU) has several regulations and guidelines in place to regulate nanosafety in biomedical engineering. One of the main regulations is the Registration, Evaluation, Authorization, and Restriction of Chemicals (REACH) regulation. REACH requires companies that manufacture, import, or use chemicals, including nanomaterials, to register those chemicals with the European Chemicals Agency (ECHA) and provide safety data. The safety data must include information on the potential hazards and risks associated with the chemicals, as well as guidance on how to handle them safely. REACH also imposes restrictions on the use of certain hazardous chemicals, including nanomaterials. Another important regulation is the Medical Device Regulation (MDR), which applies to medical devices that use nanomaterials. The MDR requires manufacturers to provide safety data on the nanomaterials used in medical devices, and to ensure that the devices comply with safety standards. The MDR also requires manufacturers to conduct post-market surveillance to monitor the safety and performance of medical devices that contain nanomaterials. In addition to these regulations, the EU has also developed guidelines for the safety assessment of nanomaterials used in food and cosmetics, as well as guidelines for the safe handling and disposal of nanomaterials. The EU’s Horizon 2020 program also funds research into the safety of nanomaterials, including their potential risks and benefits. These regulations are important because they help to ensure the safe development, production, and use of nanotechnology in biomedical applications.

Most European countries have implemented regulations and guidelines for the use of nanotechnology in biomedical applications. However, the specific approaches and requirements may vary depending on the country and its regulatory environment. The Swiss Agency for Therapeutic Products (Swissmedic) provides guidance on the evaluation and authorization of nanotechnology-based medical products, and has established a working group to address regulatory issues related to nanotechnology. The Norwegian Medicines Agency has issued guidance on the application of nanotechnology in medicinal products, and has also established a working group with the purpose of developing guidelines on the safe use of nanomaterials in medical products. The French National Agency for Medicines and Health Products Safety offers guidance on the assessment and approval of medical products that are based on nanotechnology. Additionally, it has formed a working group that focuses on regulatory matters pertaining to nanotechnology. The Italian Medicines Agency has developed guidance for the application of nanotechnology in medicinal products and has also created a working group that is responsible for developing guidelines on the safe use of nanomaterials in medical products.

Slovakia is taking steps to ensure the safe use of nanomaterials in biomedical applications too and is aligning its regulations and guidelines with those of the European Union. In Slovakia, the Ministry of Health is responsible for regulating the use of nanomaterials in biomedical applications. The Ministry has issued guidelines for the evaluation of the quality, safety, and efficacy of medicinal products containing nanomaterials. These guidelines are based on the EU guidelines, but are adapted to the Slovakian regulatory environment. The Slovak Republic has also adopted the Globally Harmonized System of Classification and Labeling of Chemicals (GHS), which provides guidelines for the classification and labeling of hazardous substances, including nanomaterials. In addition, Slovakia has implemented the EU’s REACH Regulation, which requires companies to

register, evaluate, and authorize the use of chemicals, including nanomaterials, before they can be placed on the market. Slovakia has also established a National Reference Laboratory for Nanotechnologies, which provides testing and analysis services for the identification and characterization of nanomaterials in various products, including medicinal products.

While the mentioned documents are specific to the European Union, Ukraine has also implemented regulations and guidelines for the use of nanomaterials in biomedical applications [4]. The Ukrainian Law "On Medicinal Products" establishes the legal framework for the regulation of medicinal products in Ukraine, including those that contain nanomaterials. The State Expert Center of the Ministry of Health of Ukraine is responsible for assessing the quality, safety, and efficacy of medicinal products before they are approved for use in Ukraine. In addition, Ukraine has adopted GHS too. The Ministry of Health of Ukraine has also issued guidelines for the use of nanomaterials in cosmetics products.

Ukraine has been taking steps towards aligning its regulations and standards on nanosafety for biomedical engineering with those of the European Union, as part of its efforts to implement the EU's Green Deal. The EU Green Deal is a comprehensive plan that aims to make the European economy more sustainable, with a focus on reducing greenhouse gas emissions, promoting sustainable growth, and ensuring a healthy environment for all [5]. As part of this initiative, the EU has been working to strengthen its regulations on nanotechnology, particularly in the field of biomedicine.

Ukraine recognizes the importance of nanosafety in the development and use of biomedical applications and is taking measures to ensure the safety of workers and consumers. The country has been working to establish a regulatory framework for nanotechnology in biomedicine, which includes the development of guidelines and standards for the use of nanomaterials in medical products. Additionally, Ukraine has been collaborating with the EU and other international organizations to share information and best practices on nanosafety regulation.

It is important to note that Ukraine is actively working to harmonize its regulations and standards with those of the European Union, in order to facilitate trade and ensure the safety of products on the Ukrainian market. Therefore, while the specific EU documents which were mentioned may not apply directly to Ukraine, their principles and recommendations may be taken into account when developing regulations and guidelines for nanotechnology in biomedical applications in Ukraine. In addition to developing regulations and guidelines for using nanomaterials in biomedical applications, Ukraine has also been working to promote public awareness and education on nanotechnology and its potential benefits and risks. The Ministry of Education and Science of Ukraine has been implementing various educational and outreach programs on nanotechnology for students, teachers, and the general public, to promote the responsible use of nanotechnology and foster innovation in the field.

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