

Section
Секція II

MEDICAL PHYSICS
МЕДИЧНА ФІЗИКА

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**DIGITIZATION AND GREEN INNOVATION IN BIOMEDICAL
ENGINEERING: UKRAINE'S POTENTIAL FOR GROWTH
AND ALIGNMENT WITH EU CONSUMER POLICY**

Abstract. This paper analyzed the potential for growth and alignment with EU consumer policy in the context of digitization and green innovation in biomedical engineering in Ukraine. The article highlighted the importance of digitalization and green innovation in the biomedical engineering industry and discussed the current state of these areas in Ukraine. The study also examined the alignment of Ukraine's policies with those of the European Union and the potential for further alignment. Finally, the paper identified critical areas for growth and development in the digitization and green innovation of biomedical engineering in Ukraine and provides recommendations for policymakers and industry stakeholders to support this growth.

Keywords: EU consumer policy, digitalization, green innovation, biomedical engineering industry.

The safety and efficacy of biomedical engineering products are of critical importance to consumers. The EU consumer policy implements strict measures to test and regulate biomedical technologies to ensure that they are both safe and effective for patients. European Union consumer protection regulations include measures for market surveillance, which involves monitoring the safety and performance of medical devices, including healthcare innovations, once they are on the market. Moreover, the EU consumer policy requires medical equipment manufacturers to implement risk management systems to identify and manage potential risks associated with these biomedical engineering products. At the same time as biomedical engineering and innovation become more digitized and greener, it is important to consider the environmental impact of these technologies. This includes not only the environmental impact of producing these technologies but also the impact of their use and disposal.

Ukraine has a growing biomedical engineering industry, with a focus on medical device manufacturing, diagnostics, and imaging technologies. There are challenges to implementing EU consumer policy in Ukraine, including limited resources and capacity for regulatory bodies and a lack of clarity and consistency in implementing regulations. Additionally, the ongoing war in Ukraine can create uncertainty and hinder progress in this area. By addressing the challenges facing the industry and promoting collaboration and innovation, Ukraine can position itself as a major player in the global biomedical engineering market.

The objective of our study was to examine the available literature on the potential benefits and difficulties of Ukraine aligning with the EU Consumer Policy in the field of biomedical engineering.

As part of our analytical research, we drew upon opened resources and databases of scientific articles, such as PubMed, ScienceDirect, Web of Science, Scopus, ACM Digital Library and Biomed Central to gather relevant information on the topic. We conducted this study as a component of the implementation of the grant project Jean Monnet Actions under ERASMUS-JMO-2021-HEI-TCH-RSCH EUGreeCon - 101047527 of "EU consumer policy in conditions of the green and digital transition" with the assistance of NGO CSAET.

EU consumer policy aims to ensure the safety and protection of consumers in the EU, including those who use biomedical engineering products. It sets standards and regulations for the

design, testing, and marketing of these products to ensure they are safe and effective for their intended use. Digitization refers to the process of converting information from a physical format to a digital format, which can be stored, processed, and transmitted electronically. The use of digital technologies, such as artificial intelligence (AI) and the Internet of Things (IoT), is becoming more prevalent in the biomedical engineering field, as it can improve efficiency, accuracy, and patient outcomes. Green innovation, on the other hand, refers to the development and adoption of environmentally friendly technologies and practices that aim to reduce negative impacts on the environment. In the biomedical engineering field, green innovation can include the use of biodegradable materials, energy-efficient medical devices, and sustainable manufacturing processes. Digitization and green innovation become more prevalent in the biomedical engineering field, and that is why it is important to assess their alignment with EU consumer policy. This involves examining how these technologies can be used to improve patient outcomes while ensuring the safety and protection of consumers. Possible areas for assessment include the regulation and testing of digital health technologies, the use of AI in medical decision-making, and the development of sustainable manufacturing processes for medical devices.

The most popular digitization and green innovation used in the field of biomedical engineering in the EU are the next: Virtual Reality (VR) and Augmented Reality (AR), Wearable Technology, 3D Printing, Artificial Intelligence (AI), Renewable Energy, Telemedicine etc.

There are some examples how EU countries have implemented digitization and green innovation in biomedical engineering. The German government has invested heavily in the development of digital healthcare solutions, such as digital patient records, telemedicine, and medical apps. They have also implemented green initiatives, such as energy-efficient hospitals and sustainable medical device manufacturing. Denmark has a strong focus on digital health solutions and has developed a national strategy for digitization in healthcare. They are also implementing green initiatives, such as sustainable hospital design and energy-efficient medical devices. The Netherlands is a leader in the development of digital health solutions and has implemented numerous projects, such as electronic health records and telehealth. They are also committed to green initiatives, such as sustainable hospital construction and green energy use in healthcare. Sweden has implemented numerous digital health initiatives, such as electronic health records and telemedicine. They also have a strong focus on sustainability and are committed to reducing their carbon footprint in healthcare through initiatives such as energy-efficient hospital design and green medical waste management.

Digitization and green innovation are two key trends that are transforming the biomedical engineering industry worldwide, and Ukraine has the potential to leverage these trends to drive growth and align with EU consumer policy. In terms of digitization, the increasing use of technology and data analytics enables greater precision and efficiency in producing and delivering medical devices. Ukraine's well-educated and highly skilled workforce, particularly in engineering and computer science, could enable it to become a center of excellence in developing digital medical devices.

In terms of green innovation, there is increasing recognition of the importance of sustainability and environmental responsibility in developing and using medical devices. Ukraine has a strong tradition of engineering and industrial manufacturing. It could leverage this expertise to become a leader in developing green medical devices that meet EU standards for environmental sustainability.

Aligning with EU consumer policy will be critical for Ukraine to realize its potential for growth in the biomedical engineering sector. This will involve implementing EU regulations and standards for medical devices, including the Medical Device Regulation (MDR) and In Vitro Diagnostic Regulation (IVDR), ensuring that devices developed and manufactured in Ukraine meet the highest safety standards and efficacy. This alignment will also enable Ukrainian companies to access the larger EU market, which will be critical for growth and success in the global marketplace.

In summary, we can note that digitization and green innovation offer significant opportunities for growth and alignment with EU consumer policy in the biomedical engineering sector in Ukraine. By leveraging its strengths in engineering and computer science, as well as aligning with EU standards and regulations, Ukraine can become a leader in proceeding with safe, effective, and sustainable medical devices that meet the needs of consumers worldwide.