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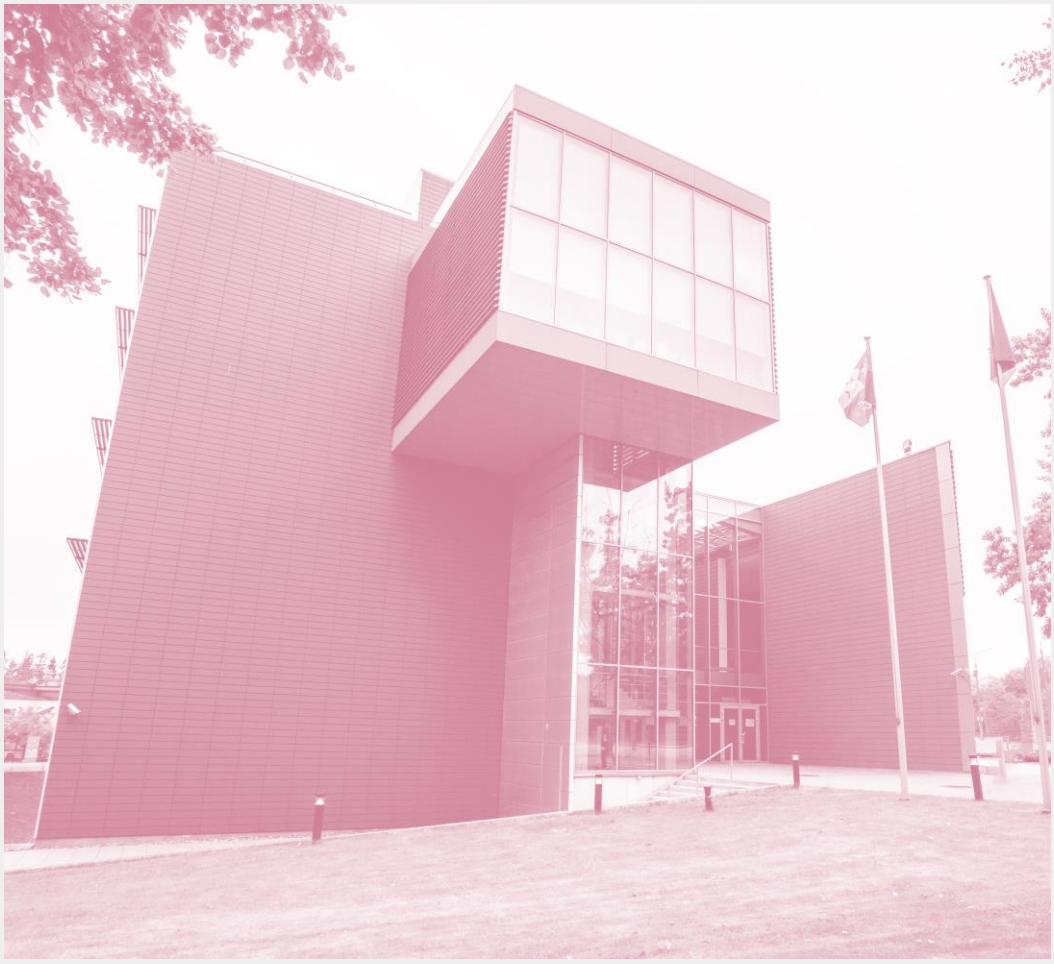

Contemporary Pharmacy: Issues, Challenges and Expectations 2024

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Problems of Medical Devices Standardization for the Ukraine Market in View of European Integration

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Background: Medical devices (MD) are an integral part of providing high-quality medical care. Their standardization problems are becoming a challenge that hinders the safety and effectiveness of their distribution and use for the Ukrainian market and for the global pharmaceutical market.

Aim(s): The main aspects of this problem are the heterogeneity of the formulations and types of medical devices, and heterogeneity of the standards that describe the requirements for those MDs. It is important for Ukraine to resolve these issues in the context of the European integration process.

Methods: An urgent issue is the adaptation of the main regulatory legislative act regarding the MD of Ukraine (Technical Regulation No. 753) to comply with the current regulation in the EU MDR (REGULATION (EU) 2017/745).

Results: When comparing the regulatory requirements of the EU and Ukraine, key differences were identified. First, the MDR changes the rules for the classification of MDs, reclassifying several devices with an increase in their risk class, separates the concepts of MDs and devices non-medical use. Second, the products that were never previously classified as "medical devices", are now subject to MDR regulation. These products include liposuction equipment, high intensity radiation equipment used for tattooing and hair removal, etc. And thirdly, the implementation of Unique Device Identification System (UDI) provides improved traceability of a product throughout its life cycle. This helps to improve the accuracy and quality of supervision and monitoring.

Conclusion: In overcoming the problems of MDs standardization for the Ukrainian market, it is important to recognize that this task can be solved through the cooperation of all departments and industries related to MDs. Shared responsibility will contribute to the creation of an effective standardization system, and as well as European integration in the development of new monographs of the Ukraine State Pharmacopoeia and legislation on MDs.

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