4. COMPARATIVE ANALYSIS OF THE NATIONAL AND INTERNATIONAL LEGISLATIVE FRAMEWORK REGARDING THE STORAGE OF MEDICINAL PRODUCTS FOR HUMAN USE

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Introduction. Globally, regulating and managing medicines is vital for public health. This presentation compares how the Republic of Moldova and the European Union handle the storage and preservation of medicines. It highlights similarities and differences in authorization procedures, pharmacovigilance, GMP, GDP standards and future collaboration prospects. The analysis offers insights into ensuring optimal quality and safety for users in both jurisdictions.

Aim of study. To carry out the comparative analysis of the national and international legislative frameworks regarding the preservation of medicines of human use from different points.

Methods and materials. There have been used relevant articles and directives related to the national legislative framework in the field of medicine storage, international legislative framework in the field of medicine storage, published between 01.01.2020-01.11.2024 on search engines PubMed and ScienceDirect.

Results. In the Republic of Moldova, Order of the Ministry of Health no. 28 of 16.01.2006 regarding the storage of medicines, parapharmaceutical products and medical articles sets strict requirements for the storage and preservation of medicines, including temperature conditions, humidity and safety standards. The Medicines and medical Devices Agency monitors and regulates this field. In the European Union, Directive 2001/83/EC regulates medical products for human use, setting strict standards for authorization, distribution, storage and preservation. The European Medicines Agency (EMA) is responsible for the evaluation and supervision of medicines in the EU. The comparative analysis reveals significant similarities between the two jurisdictions highlighting the emphasis on drug safety and efficacy. Storage and preservation requirements are similar, imposing strict conditions on factors such as temperature and humidity. Both sides have specialized agencies for drug oversight and regulation. In perspective, the EU promotes the harmonization of standards and procedures in member states, ensuring cohesion in the regulation of medicines. The Republic of Moldova as an aspirant to international standards, can adopt and adapt several European Provisions to improve its regulation in the field of medicines.

Conclusion. The comparative analysis of the legislative framework regarding the storage and preservation of medicines in the Republic of Moldova and the European Union highlights significant similarities in the approach to standards and procedures. With both jurisdictions focused and drug safety and efficacy, the Republic of Moldova, in its process of alignment with EU norms, has the opportunity to adopt and adapt to the EU to further improve its drug regulation.