

identified in the group of respondents with work experience less than one year (11.9% and 9.5%, respectively). Although the use of the method of analysis of the conjunction tables for the comparison of groups showed no statistically significant differences between the frequency of use of instruments by groups of respondents with different experience in the field of CT organizing and conducting (p-level = 0,58 > 0,05; evaluation by the  $\chi^2$  criterion).

Such a general tendency for low frequency of risk-based methods use for the quality level of CT organization and conducting improvement requires further study of the causes of the present situation. Possible factors that may have led to this may be insufficient specialized training of staff on aspects of quality management, the complexity of practical perception of new methods, and lack of ease in use. In addition, the tendency indicates that utilitarian methods of CT of drugs quality control are widely used today.

It also should be emphasized that only half of the respondents (50.7%) consider that such a component of successful implementation of QMS in the practice of any organization as a systematic approach is comfortable in use. This can be one of the influential factors that cause the slow implementation of the QMS in the CT of drugs system in Ukraine as a whole, and in the work of CS, in particular, where the key CT processes are directly conducted.

**Conclusions.** A conducted survey of CT specialists has shown that routine quality control tools are often used by organizations, and risk-oriented tools are not widely used. Impact of factors “experience in CT” and “functional responsibilities performed during CT” have no statistically significant effect on the frequency of use of quality management tools.

Therefore, it is appropriate to work on development of methods for the active implementation of risk-based tools in practice, as this can also increase the assessment of ease in use of different quality management tools, including the risk-based ones.

## **APPROACHES TO STATE REGISTRATION AND CLASSIFICATION OF GENERIC MEDICINES IN UKRAINE, THE UNITED STATES OF AMERICA AND COUNTRIES OF EUROPEAN UNION**

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**Introduction.** An important element in the treatment of any disease is the use of medicines with proven efficacy and safety. Such drugs are original or innovative drugs. They go through a full cycle of clinical trials and register on a complete dossier. Therefore, by the time of entry into the pharmaceutical market of the country, these drugs have confirmed efficacy and safety in use. But there are not only original drugs, but also generic ones, which are manufactured after the end of patent protection of innovative and have the same active substance, its quantity and dosage form. So, generics would have the same efficiency and the same safety profile with the original drugs. Generic drugs take up most of the pharmaceutical market not only in Ukraine, but also in other developed countries such as the United States of America (USA) and countries of European Union (EU). For the appropriate use of generics as a replacement for the original medicines, it is necessary to have a sufficient level of evidence for the interchangeability of these drugs. The proven bioequivalence of the generic drug to the original confirms their therapeutic equivalence (identical efficacy). The use of generic drugs can reduce the cost of treatment. According to the Food and Drug Administration (FDA) the use of generics has reduced USA spending on treatment 1,67 trillion dollars from 2007 to 2016. Thus, bioequivalence studies for generic drugs not only improve treatment efficiency and safety, but also minimize treatment costs.

**Aim.** Explore features of approaches to state registration of generic drugs, compare methods of classification of such drugs in Ukraine, the USA and countries of EU.

**Materials and methods.** Literary sources placed on platforms PubMed, Wiley, Scopus, Springer have been analyzed by keywords: bioequivalence, registration of generic drugs, the classification of generic drugs and official data of FDA and European Medicines Agency (EMA).

**Results and discussions.** Registration of generic drugs, as well as the original ones, would be monitored at the legislative level. Conditionally, countries by type of control of generic drugs can be divided into three policy levels: 1) countries with minimal or nonspecific regulation, 2) countries with existing regulation, but without restrictions on replacement between different types of generics, 3) countries with specific regulation and restrictions in the absence of proven equivalence. The USA and countries of EU, namely countries with high levels of economic and social development, fall into the category of countries that strictly monitor the registration of drugs and regulate the use of drugs that have no proven effectiveness. The regulatory authorities of these countries (EMA and FDA) consider the therapeutic equivalence of a drug to be proven if pharmaceutical equivalence is substantiated and one of the studies that produces a positive result: a bioequivalence study with human involvement (comparative pharmacokinetic study); comparative pharmacodynamic study with human involvement; comparative clinical trials; in vitro solution test. Except "new" drugs in the pharmaceutical markets of these countries there are medicines with well-studied composition and long experience of use. The effectiveness of such drugs is proven on the basis of literary sources and well known experience of their use in medical practice. In the USA, there is the Orange Book, a handbook that provides information on the bioequivalence of generic drugs to the original. FDA will develop the classification of generic drugs by conducted studies of bioequivalence. According to this classification, there are two categories of medicines: category A and category B. Category A includes medicines considered FDA as therapeutically equivalent to original drugs for which bioequivalence studies have been performed or are not required. Category B is assigned to drugs that are not therapeutically equivalent, that is, the drugs do not have data to confirm their bioequivalence. In EU countries information on generic bioequivalence can be found on the organization's official website. However, there is no classification of such drugs in this territory. In Poland were conducted interviews with pharmacists, which identified the need to introduce a classification system of generics by bioequivalence. Due to the need for availability of bioequivalence data in Ukraine, the Rx Equivalence Handbook – Rx-Index was developed. It is based on a classification that represents the levels of evidence of their effectiveness and safety. According to it, drugs are divided into four categories. Category A includes original (innovative) medicines, category B – generic drugs, category C – drugs with well-studied medical use or traditional (herbal) drugs, and category D – specific types of drugs to which special requirements apply for registration in Ukraine. However, accurate data on bioequivalence are not available for all generic drugs, and there is no data on generic non-equivalence. The registration procedure for drugs in Ukraine can be done on a complete or reduced dossier in accordance with approaches to registration in the US and the EU. Specific requirements are imposed on medicines of biological origin (immunological drugs, biological drugs and biosimilars) that instigate the creation of a specific procedure for their registration.

**Conclusions.** According to the analysis of sources, it was found that classification systems were developed in Ukraine and the USA and there is no classification of drugs in countries of EU. The classification approach in Ukraine is similar to the American one. But if in the USA and countries of EU bioequivalence studies are state requirements, then in Ukraine such studies are optional. And they are mainly carried out by manufacturers of generic drugs with a high level of responsibility. Such handbook with classification of generics was developed only because of the desire of scientists. So, for Ukraine it is necessary to develop a system of state control of bioequivalence studies to manage and promote high-quality effective generics and introduce it at the state level. Such system will help provide the population of Ukraine with not only effective, but also affordable medicines and reduce treatment costs. In addition, state registration of generic and original drugs in the USA, countries of EU and Ukraine is identical and meets the requirements of current regulations.