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Implementation of generic drugs classification as a tool for reasonable medication choice

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Up to 85 % of the Ukrainian pharmaceutical market consists of generics. While being cheaper, generics also may pose a significant attribute – pharmaceutical equivalence, which a generic drug by definition possesses, but sometimes it isn't guaranteed. However, it is essential for healthcare providers to have reliable information sources on interchangeability of generic drugs. In Ukraine, until now, this information has been unsystematized and, thus, obscure. This, in turn, paved the way to highly subjective and possibly irrational choices of medications by healthcare providers. Implementation of our newly developed drug equivalence classification, being the first of the kind in Ukraine, is aimed to solve this problem.

Our department studied the documents of drug registration dossiers and categorized the drugs according to the provided efficacy and safety evidence. Here we present a short version of the classification, expanding subcategories only of the generic drug category.

Category A – Original drug

Category B – Generic drug

B.1 Interchangeability is proven by in vivo bioequivalence studies

B.2 Interchangeability is proven by in vitro solubility studies

B.3 Interchangeability is proven by comparative pharmacodynamic studies

B.4 Interchangeability is proven by comparative clinical studies

B.5 Interchangeability does not need any proof

Category C – Drug with a well-studied medical use and/or traditional (herbal) drug

Category D – Drugs which are the subjects of special requirements for registration in Ukraine

This classification became the basis for the drug equivalence reference book – Ukrainian analogue of the American «Orange book». Such systematization helps healthcare providers to success in therapeutic choices, benefiting from lower cost of high-quality generics while avoiding unreliable ones.

Biography:

Nataliya Bezugla – PhD, associate professor of Clinical Pharmacology and Clinical Pharmacy Department of the National University of Pharmacy. She conducts researchers in clinical pharmacology. Her research interests are related to clinical trials, mostly with healthy volunteers. She teaches the disciplines "Clinical Pharmacology", "Clinical pharmacy and pharmaceutical care" for the senior undergraduate students." She has published more than 55 research articles, co-author of 6 books (Pharmacology, Clinical pharmacology, Clinical Pharmacy, Pharmaceutical care), monographs, patents, etc. She has been serving as an editorial board member of Clinical Pharmacy.