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Effective Bioequivalence Research System as an important tool of affordable and good quality medicines in Ukraine

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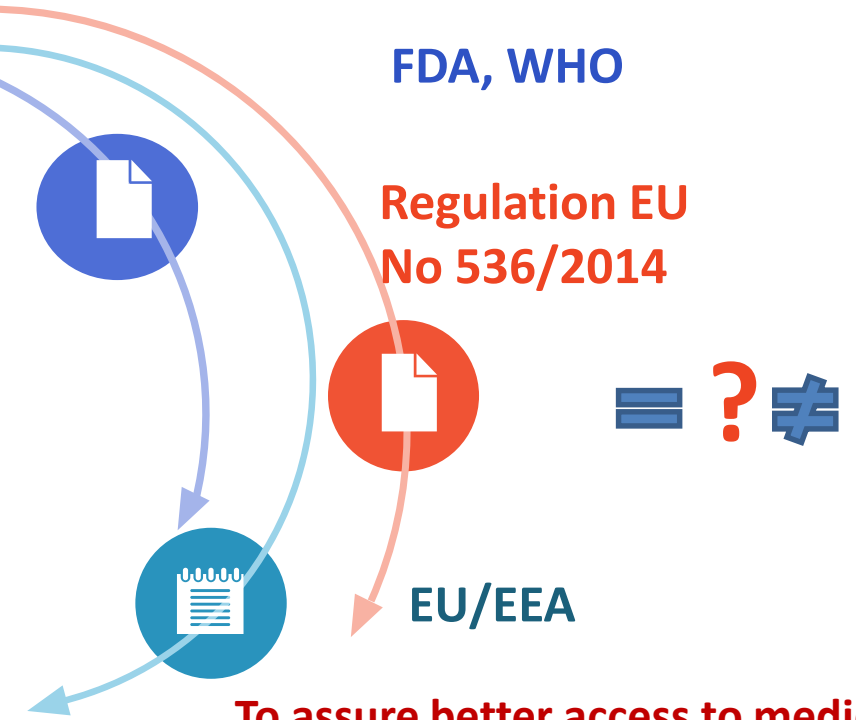
- ✓ **The topic "Bioequivalent drugs in the pharmaceutical care system of Ukraine: issues, risks, opportunities" has been discussed**
- ✓ **Bioequivalence research system improvement as the strategic goal has been chosen**

Elaboration of the strategy of the improvement of legislation concerning bioequivalence of generic medicines in Ukraine

- ✓ to provide international expertise of bioequivalence research system in Ukraine
- ✓ to develop a strategy of the improving regulations on the bioequivalence of generic medicines in compliance with European Union (EU) practices
- ✓ to develop a road map for the implementation of this strategy
- ✓ to discuss it with key stakeholders
- ✓ to organize a workgroup and arrange challenges addressed

Harmonization of the bioequivalence studies procedure in Ukraine in accordance with international requirements



The Orders of the Ministry of Health of Ukraine regulating

- state registration procedure of drugs (#426, #460)
- clinical trials and/or bioequivalence studies (#690 with addendums, #22)

The Guidelines "Good Clinical Practice", Medicinal Products. Investigation of Bioequivalence

Main tasks

- ✓ Harmonize the "Terms and Definitions"
- within the Ukrainian legislative/regulatory system
- with applicable, relevant EU provisions, and
- take into account supportive provisions from WHO and FDA
- ✓ Improve the regulations on bioequivalence in the legislative/regulatory system

To assure better access to medicinal products of good quality, proven efficacy and safety by applicable legislative/regulatory provisions

September 4th , 2018
Verkhovna Rada of Ukraine adopted

Amendments to the Law of Ukraine “On medicines”

Ministry of Heals of Ukraine must provide **free access** to **all the results of pre-clinical study and clinical trials** of medicinal products on its official website (reports on preclinical studies and clinical trials reports).

National plan of action to struggle against antimicrobial resistance of medicine

APPROVED
by Oder
the Cabinet of Ministers of Ukraine
from March 6, 2019
No 116-p

- Design & Implementation of regulations which restrict a sale of antimicrobial medicine without prescription
- Epidemiological assessment of antimicrobial resistance in Ukraine
- Study and monitoring of pharmacotherapeutical aspects of antimicrobial medicine using

Bioequivalence research of generic drugs (key examples)

The acceptance interval is 80 – 120%

Medicine	ATC	MICs - 90, mg/l	Cmax(original), mg/l	CI (generic), %	Conclusion about BE	Calculated Lower Generic Concentration, mg/l
Azithromycin 500 mg	J01F A10	***0.5*** *(H. influenza)* ***0.12*** *(S.pneumoniae)*	**0.423**	**84.1 – 116.1**	***Bioequivalent***	**0.34**
Terizidone 250 mg	J04A K03	***10-40*** *Mycobacterium tuberculosis*	**5.03**	**87.8 – 97.1**	***Bioequivalent***	**4.35** !
Protionamide 250 mg	J04A D01	***0.6-3.2*** *Mycobacterium tuberculosis*	**0.944**	**91.3 – 114.8**	***Bioequivalent***	**0.86**

Classification of medicines according to its equivalence:

Code A – **Original (innovative) medicine**

Code B – **Generic medicine (GM):**

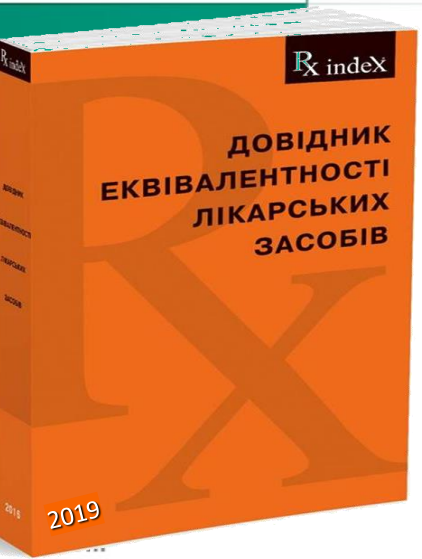
B.1 - Medicinal product, the interchangeability of which is proved by conducting in vivo study – bioequivalence

B.2 - Medicinal product, the interchangeability of which is proved by conducting in vitro study – dissolution test

B.3 - Medicinal product, the interchangeability of which is proved by conducting the comparative pharmacodynamic studies

B.4 - Medicinal product, the interchangeability of which is proved by conducting the comparative clinical studies

B.5 - Medicinal product the interchangeability of which is proved only by pharmaceutical equivalence

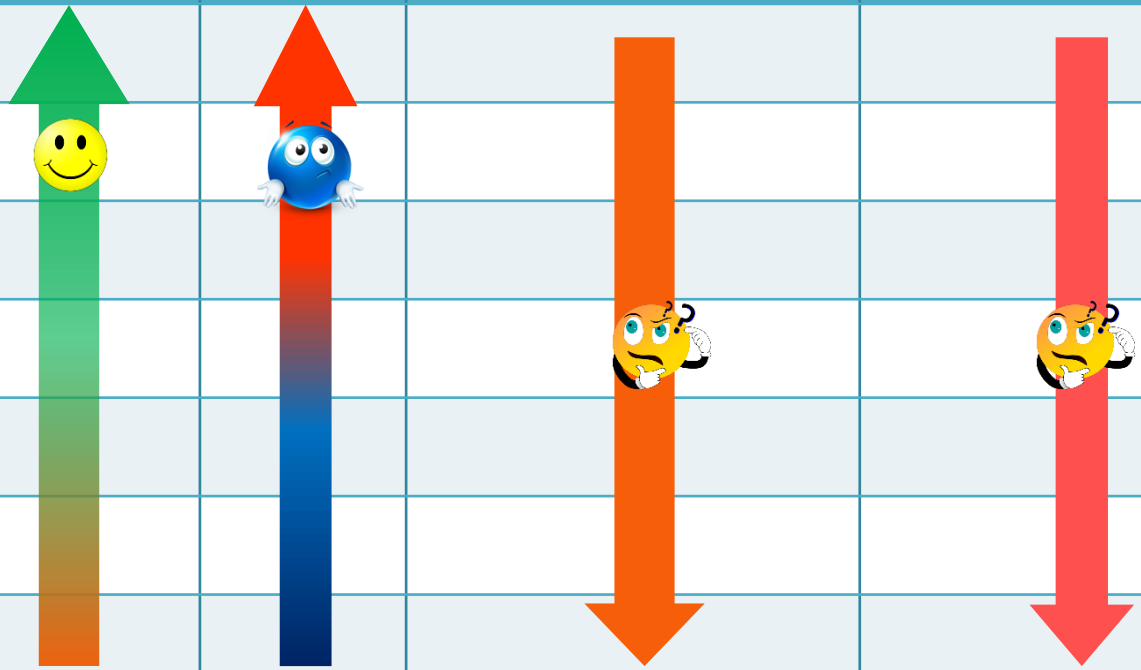


Code C – **Medicine with well-know medical use and/or traditional (herbal) medicine**

Code D – *Other medicines to which special licensing requirements are applied*

Classification of medicines according to its equivalence as a tool for HTA of generic drugs

Code	Evidence	Cost	Risks (AE/AR, low-effectiveness)	Additional Costs for Treating Risks
A				
B.1				
B.2				
B.3				
B.4				
B.5				
C				



Could be included in the government reimbursement programs

Potentially could be a subject to reimbursement if it is the best alternative available

Can't be reimbursed The cost is covered by patients

EFFECTIVE FUNCTIONING BIOEQUIVALENCE RESEARCH SYSTEM

should be considered as important tool for

- ✓ ensuring the proper selection of generics to the government reimbursement programs
- ✓ increasing the level of transparency regarding the evidence of generic's therapeutic equivalence
- ✓ availability of medicines
- ✓ raising the level of rational use of medicines
- ✓ increasing investment attractiveness of Ukrainian pharmaceutical market in the field of development and research of medicines

Thank You

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