BRAND-NAME AND GENERIC DRUGS
WHAT TO CHOOSE?

Natalia VEZIKOVA, MD, PhD, MSc
The Head of the Hospital Therapy Department
at the Petrozavodsk State University.
Chief clinical pharmacologist of the Ministry of Health and Social Development in the Republic of Karelia.

BRAND-NAME DRUG
It is the first drug that has granted marketing authorization (usually as a proprietary drug), based on the documentation confirming its effectiveness and safety and in accordance with current requirements (of the producing country, FDA, EMEA)
It also should meet GMP, GLP, GCP standards.

GENERIC DRUG
It is a drug produced by the specific manufacturer, which must be bioequivalent to the brand-name counterpart, contain the same active ingredients and have the same dosage form.

GENERIC DRUG (WHO)
Two pharmaceutical products are bioequivalent if they are pharmaceutically equivalent and their bioavailabilities (rate and extent of availability) after administration in the same molar dose are similar to such a degree that their effects, with respect to both efficacy and safety, can be expected to be essentially the same.

GENERIC DRUG (The Pharmacological Committee (PhC) of RF)
Two pharmaceutical products are bioequivalent, if they have similar bioavailability of the active ingredient (drug).
And what about drugs which are administered intravenously, or should be taken by inhalation?

BIOEQUIV ALENCE (FDA)
In rules for evaluating bioequivalence FDA pays special attention to the study design. It should be double-blind crossover method of paired comparisons AB/BA. Both the effect of a single administration and the influence of long-term treatment are studied.
Both administration and excretion of pharmaceutical products are taken into account.
The study should be held in independent laboratories.
**BIOEQUIVALENCE (PhC RF)**

Open randomized crossover scheme with single administration of pharmaceutical product. Using single administration of pharmaceutical product it is impossible to evaluate bioequivalence of drugs with the accumulation effect during long-term treatment.

There is no section “Mathematical Statistics” in the PhC RF Recommendations.

If bioequivalence was studied according to GCP standards, and all chemical (impurities), pharmaceutical and manufacturing parameters are similar to the original brand-name product, there is no need in specific evidence of therapeutic equivalence.

But if there are no such data, who should conduct the research and pay for it?

---

**FORMULARY SYSTEM**

“Formulary system” is a complex of management arrangements of the Health Service that ensure the application of rational i.e. organizational and cost-effective methods of drug supply and use of medicines; its aim is to ensure the highest quality of medical care and optimal use of available resources in terms of specific conditions.

Inclusion of generic drugs in the Formulary List of medical institution and procurement of generics can save money.

If any pharmaceutical product is registered by the Pharmacological Committee of RF, legally it meets the original drug.

- What should we do?
- How can we protect our decision in choosing generic drugs?
- Should our choice be determined only by its price?
- If we choose the cheapest generic, will we save money?

---

**Regional Formulary List of the Republic of Karelia**

- It is based on the list of essential medicines and on standards and recommendations of Russian public health experts.
- It was developed according to the principles of evidence-based medicine.
- It was discussed with leaders of working groups.
- It was approved by the Head of the Republic of Karelia Government.
Regional Formulary List of the Republic of Karelia

- International nonproprietary names.
- Drug forms.
- There is no indication of trade names and dosage.
- It is revised once a year.

Formulary Lists of medical institution

- International nonproprietary names, trade names, drug forms and dosage.

Department of Drug Supply and Clinical Pharmacology of the Republican Hospital of Karelia

What should we buy – brand-name drugs or generics?

If generics, which one to choose?

Decision on application of both original and generic drugs must be taken in accordance with the principles of evidence-based medicine, the results of pharmacological analysis (determination of impurities which may influence the bioavailability) and data on the bioequivalence of the drug according to GCP standards.

Inclusion of a generic drug into the Formulary List of the Republican Hospital:

- Data on the bioequivalence research (study design, complete protocol, setting, comparison with the original brand-name product).
- In 50% of cases manufacturer does not have any information on bioequivalence.

Formulary List of the Republican Hospital (procurement basis)

- 25% - brand-name drugs (if there are no equivalent generics, antimicrobial therapy of severe infections, drugs for oncohematology).
- 75% - generic drugs (choice is based on the bioequivalence data).

Formulary List of the Republican Hospital (procurement basis)

- Several trade names of drugs (sometimes brand names) are submitted in the Formulary List (including the application form).
- The cheapest drugs are purchased at the auction.
  For example: Ramipril (Hartil, Ampirilan, Tritace)
  There were situations when Tritace was cheaper than other drugs.
- If distributor submits a trade name that is not included in the Formulary List, he usually does not have any information on its bioequivalence.
Purchasing drugs according to the Formulary List of the Republic of Karelia (by trade names) one of the distributors lodged a complaint to the Antimonopoly Committee, because he had cheaper drug under another trade name.

We have provided the following documents: the Formulary List - basis of procurement, and bioequivalence requirements in the application form.

Antimonopoly Committee dismissed the claim, the case was not referred to court.