







○ Provision of medicines and public health organizations of the Republic of Belarus is carried out in accordance with **the laws of the Republic of Belarus**

**"On Healthcare"**  
**"On Medicines"**

**Law of the Republic of Belarus "On Medicines"**

○ **Chapter 1. Article 5. Availability of medicines**  
Availability of medicines is a prerequisite for timely public healthcare.

The State ensures the availability of medicines by:

- the most complete saturation of the domestic market is safe, effective and quality medicines, first included **in the list of essential medicines**;
- improving the realization system of medicines

## List of Essential Medicines

YEAR	MOH OF RB Decree	QUANTITY OF TYPES OF MEDICINES
2007	as of July 16, 2007 №65	518
2008	as of May 22, 2008 №96	496
2009	15.10.2009 №111	461
2010-2011	27.09.2010 № 128	402

## THE METHODS OF MAKING THE LIST OF ESSENTIAL MEDICINES (POLS)

- Order of the Ministry of Health (2009)**
- "On Approval of the list of essential medicines and the commission of the Ministry of Health for the establishment a list of essential medicines"

## Application

- International nonproprietary names of medicines (INN) (in Latin and Russian), in the absence of INN - common chemical name:
- Medicine/s form/s.
- The full composition of the medicine.
- Pharmacotherapeutic group, ATC code.
- Original or generic medicine.
- The manufacturer of the medicine.
- **Availability of registered generic medicines or therapeutically equivalent medicines in the Republic of Belarus, including domestic production.**

## Application

- Pharmacological effect and indications for use (*in terms of vital necessity and importance of the medicine*)
- Description of the **regular status** of medicines (the conditions of delivery in the country of origin, in other countries, in the Republic of Belarus) (*by prescription, without prescription, only for hospitals*).
- **Information confirming the importance of medicines for public healthcare (brief epidemiological analysis of the illness, for which the medicine is introduced into the list, the target groups of patients)**

## Application

- Information about the **effectiveness and efficiency** of medicines with the indication of the source (*provided copies of the clinical tests, systematic reviews and meta-analysis indicating the degree of evidence and the level of advice*).
- Information about the **therapeutic equivalence** (nonequivalence) with the medicines, available in the list.
- Information about **safety** indicating the source (*expert opinions on the pre-clinical research, or copies of works-in lag*).

## Application

- Information about research and/or use in the **pediatric practice**, during **pregnancy** and lactation
- Information on studies of bioavailability (**bioequivalent tests**) with the source (*copies of works or reports are applied*).
- **The results of pharmacoeconomic research and calculations showing reports about them** (in accordance with the type of economical assessment: cost benefit analysis, cost-minimization analysis and cost-effectiveness analysis)

## The Establishment of the List of Essential Medicines



### The Commission of the RB MOH on the establishment of the list of essential medicines

#### CLINICAL AND PHARMACOLOGICAL EXAMINATION

SPECIALISTS OF THE RB MOH (FORM WORKING GROUPS, IF NECESSARY)  
CLINICAL PHARMACOLOGIST OF THE RB MOH

#### PHARMACOECONOMIC EXAMINATION

Clinical pharmacologist of RNPC MT

#### PRIMARY EXAMINATION

RNPC MT, RUP CEIZ, RUP «Belfarmaciya»

## ЗАКЛЮЧЕНИЕ CONCLUSIONS

- ... **Therapeutic benefits** (efficiency, safety, dosage form, methods of application, clinically significant interactions, pharmacoeconomic benefits)
- ... **Pathological conditions**, for the treatment of which will the medicine will be used:
- The severity and prognosis of the disease (specify reasons: life-threatening, the tendency to chronic course, the possibility of disability, the possibility of capacity limiting)
- ... **Categories of patients** who will use the medicine

## Перечень основных лекарственных средств

- The list of essential medicines can be used to generate **clinical practice guidelines, formulary of lists of medicines of healthcare organizations**, taking into account relevant institutions, the spectrum of diseases for which medical assistance is needed, taking into account the data of pharmacoepidemiological research, as well as other regulations in healthcare.

