

Issues of Inter-Agency Interaction Practice of the Republic of Belarus



Agreements (memorandums) of the Center for Expert Evaluation and Testing in Health Service (CETHS)

Cooperation between CETHS and organizations in the Republic of Belarus on issues of medicines circulation

Memorandums of understanding and cooperation between the Republican Unitary Enterprise Center for Expert Evaluation and Testing in Health Service, Republic of Belarus, and:

- Association of International Pharmaceutical Manufacturers in the Republic of Belarus, 20.01.2022.
- Belpharmprom Holding, 2020
- Educational Institution Vitebsk State Order of Peoples' Friendship Medical University, Educational Institution Gomel State Medical University, 2022

Cooperation between CETHS and organizations **in the EAEU member states** on issues of medicines circulation

1. Agreement on cooperation between the Federal State Institution "State Institute of Drugs and Good Practices" (FSI "SID & GP") and UE CETHS, Republic of Belarus, 02.12.2016.
2. Memorandum of cooperation between the Federal State Budgetary Institution Scientific Centre for Expert Evaluation of Medicinal Products of the Ministry of Health of the Russian Federation (FSBI "SCEEMP") and UE CETHS, Republic of Belarus, 28.10.2021.
3. Memorandum of cooperation between the ANCO Eurasian Academy of Good Practices and UE CETHS, Republic of Belarus, 01.03.2022.
4. Memorandum of cooperation with the Republican state enterprise on the right of economic management National Center for Expert Evaluation of Medicines and Medical Devices of the Committee of Sanitary and Epidemiological Control of the Ministry of Health of the Republic of Kazakhstan.
5. Memorandum of cooperation with the SI The Center for Pharmaceutical Products Safety under the Ministry of Health of the Republic of Uzbekistan

Cooperation between CETHS and organizations **in far-abroad countries** on issues of medicines circulation:

- Center for State Control of Medicines, Equipment and Medical Devices of the Republic of Cuba **CECMED**, 2022



Implementation of cooperation agreements:

Within the framework of the concluded cooperation agreements, the following activities are carried out:

- **Seminars for manufacturers** on current issues of registration of drug products according to the EAEU and national guidelines;

Thus, for Russian applicants, a seminar was prepared on the specifics of preparing Module 1 of the registration dossier in the Republic of Belarus when registering according to Eurasian rules, a detailed algorithm was prepared for working with CETHS when submitting a dossier.

- **Cooperation between expert organizations** on the harmonization of expert approaches to the assessment of registration dossier materials

*Approaches to the examination of a validation report and an analytical report on the bioequivalence of a drug product.
An example of interaction with expert organizations from far-abroad countries: a series of online consultations with the Cuban regulatory authority during the registration of a Cuban vaccine for the prevention of coronavirus infection.*

- **Consulting representatives of companies** representing the interests of domestic and foreign manufacturers in accordance with the list of questions provided in advance;

Training seminars on the following topics were in great demand:

Common mistakes when developing and implementing a risk management plan for a drug product.

Routine and extra risk mitigation measures in pharmacovigilance.

Handling the information about adverse drug reactions.

Preparation of Module 3 of the medicinal product dossier according to the EAEU procedures. Key notes on documents in a CTD format





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