

RESOLUTION
of the Fifth Scientific and Practical Conference with international participation “Safety and Legal Support of Medicinal Products: from Development to Medical Use” in memory of Oleksii Pavlovych Viktorov, Doctor of Medical Sciences, Professor

The Fifth Scientific and Practical Conference with international participation “Safety and Legal Support of Medicinal Products: from Development to Medical Use” in memory of Oleksii Pavlovych Viktorov, Doctor of Medical Sciences, Professor (hereinafter - the Conference) organized by the Ministry of Health of Ukraine, the National Academy of Medical Sciences of Ukraine, the State Expert Center of the Ministry of Health of Ukraine" (hereinafter - the State Expert Center of MoH) was held in Kyiv on October 22-23, 2019.

The conference was included into the Register of meetings, congresses, symposia and scientific conferences scheduled for 2019.

During the conference 1 plenary session, 16 sections and 2 round tables were run, where the current problems of pharmacovigilance in Ukraine and CIS, safety of immunoprophylaxis, bioequivalence, drug monitoring and critical regulatory aspects were highlighted. The conference also included discussions with the public and patient organizations. The safety issues of drug development, the risk and signal management systems in clinical trials of medicinal products and in post-registration period, clinical data management, including the use of electronic resources, were also addressed. The consideration was given to the items of registration dossier as a representation of the life cycle of medicinal product. The formulary system’s role in improving access to medicinal products, the national list of essential medicines and health technology assessment were also discussed.

The officials of the Ministry of Health of Ukraine, the State Expert Center of MoH, the Public Health Center of MoH of Ukraine, the State Service of Ukraine for Medicinal Products and Narcotics Control, delegates of the regulatory authorities of Ukraine and 6 CIS countries (Belarus, Moldova, Azerbaijan, Armenia, Uzbekistan, Kyrgyzstan), representative of the WHO Regional Office for Europe, pharmacovigilance researchers, speakers and experts from UK, Switzerland, the Netherlands, Germany and the USA, affiliating to the different organizations, including the International Society of Pharmacovigilance (ISOP), the Council for International Organizations of Medical Sciences (CIOMS), the Medicines and Healthcare products Regulatory Agency (MHRA), took part in the conference.

The conference attracted healthcare practitioners, pharmacists, heads of healthcare administrations and leading scientists of research institutes; lecturers of the medical and pharmaceutical higher educational institutions; experts, qualified persons for pharmacovigilance and applicants of medicinal products, as well as other professionals involved in the development, supply, prescription and use of medicinal products; delegates of pharmaceutical manufacturers associations; patient organizations: “Parents for Vaccination”, “Health Platform”, “Rare Diseases of Ukraine”, and International Renaissance Foundation, Charitable Organization “Patients of Ukraine”.

The total number of conference participants was 458.

The Fifth Scientific and Practical Conference with international participation “Safety and Legal Support of Medicinal Products: from Development to Medical Use” in memory of Oleksii Pavlovych Viktorov, Doctor of Medical Sciences, Professor, states that the State Expert Center of MoH has fulfilled the tasks declared in the Resolution of the Fourth Scientific and Practical Conference with international participation “Safety and Legal Support of Medicinal Products: from Development to Medical Use” in memory of Oleksii Pavlovych Viktorov, Doctor of Medical Sciences, Professor held on 11-12 October, 2016, namely:

- the draft article “Pharmacovigilance” was developed and submitted to the draft Law of Ukraine “On Medicines”, which was registered in the Verkhovna Rada of Ukraine;

- the draft Procedure on prohibition and/or termination of the registration certificate was developed and submitted to the Ministry of Health of Ukraine;

- the section on development, improvement and assurance of the pharmacovigilance system operation was added to the Decree of the Cabinet of Ministers of Ukraine as of 5 December, 2018 № 1022 “On approval of the State Strategy on implementing the state policy on providing the population with medicinal products for the period until 2025”;

- amendments to the Pharmacovigilance Procedure, approved by the MoH Ukraine Order of 27.12.2006 № 898, which was registered by the Ministry of Justice of Ukraine of 19.12.2016 under №1649/29779 (in wording of MOH Ukraine Order of 26.09.2016 No. 996) were made;

- the Standard “Guideline. Medicinal products. Good Pharmacovigilance Practice” (GVP) was approved by the MoH Ukraine Order of 05.04.2018 № 620.

The Pharmacovigilance Automated Information System (PAIS) was implemented in Ukraine for improving collection, analysis and evaluation of reports on ADR and/or lack of efficacy of medicinal products, vaccines, tuberculin received from health care professionals, patients, and applicants of medicinal products. The the State Expert Center of MoH Pharmacovigilance Department and representatives for pharmacovigilance in the Ukraine’s administrative and territorial units provided the health care settings with the methodological and organizational support.

The development of the applicant's pharmacovigilance systems in compliance with international standards is in progress.

The State Expert Center of MoH conducted a number of practical workshops and trainings on pharmacovigilance for applicants. The practical workshops and trainings, telephone and Skype conferences were organized for the Center’s representatives for pharmacovigilance in the administrative and territorial units of Ukraine, including 25 Skype conferences on AEFI Investigation Protocols for members of regional groups of quick response to AEFI.

To comply with the WHO requirements, the active pharmacovigilance of new medicinal products used for the first time in Ukraine for treating socially dangerous diseases is being conducted.

According to the MoH Ukraine Order the Center also conducts enhanced pharmacovigilance of medicinal products that require additional safety monitoring during their use.

The international relations, including with the WHO Collaborating Centre for International Drug Monitoring were established. The role of pharmacovigilance in the procedural processes, which regulate the circulation (use) of medicinal products in Ukraine has significantly increased.

However, given the current achievements in the organization and implementation of pharmacovigilance in Ukraine, here are still some outstanding issues to resolve.

Hence, participants of the Conference decided:

1. To consider it necessary to hold the Sixth Scientific and Practical Conference with international participation “Safety and Legal Support of Medicinal Products: from Development to Medical Use” in memory of Oleksii Pavlovych Viktorov, Doctor of Medical Sciences, Professor in 2022, and to submit a proposal to include it in the Register of meetings, congresses, symposia, scientific and practical conferences of the Ministry of Health of Ukraine and the National Academy of Medical Sciences of Ukraine scheduled for 2022.
2. To continue the development of pharmacovigilance system in Ukraine according to the requirements of the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH), using the EU approaches and international recommendations, with technical, organizational and methodological support of WHO, EMA and other partners through:
 - organization of drug safety and pharmacovigilance training for PV experts, representatives of NGOs and patient organizations, healthcare professionals and applicants;
 - harmonization of the approaches to the processes of pharmacovigilance and regulation of medicinal products with those applied in EU;
 - optimization of exchange of drug safety information with EU and CIS countries, WHO and EMA;
3. With the purpose to benefit from international positive experience of rational pharmacotherapy and pharmacovigilance to draft relevant regulatory documents and submit them to the Ministry of Health of Ukraine for approval, namely:
 - to develop and submit a draft Procedure for non-interventional studies of medicinal products to MoH Ukraine;
 - to draft amendments to the MoH Ukraine Order of 22.11.2011 № 809 "On Approval of Procedure to Impose a Ban (Temporary Ban) on and to Restore Circulation of Medicinal Product in the Territory of Ukraine” in respect of the grounds for ban (temporary ban) of the circulation of medicinal products in the territory of Ukraine jointly with the State Service of Ukraine for Medicinal Products and Narcotics Control;
 - to improve existing legislation governing the processes of circulation of medicinal products and pharmacovigilance taking into consideration recent changes in the European legislation and international standards.
4. To promote communication with all stakeholders regarding safety of medicinal products through:
 - development of a communication plan in response to vaccine safety issues;

- development of an algorithm for interaction and exchange of AEFI information between the State Expert Center of MoH and the Public Health Center of MoH of Ukraine;

- effective interaction with the media and making objective the media perception of safety of medicinal products, use of the media potential in education of the medical community and the public on safety of medicinal products and vaccines;

- interaction with governmental, public and international organizations contributing to the safe use of medicinal products;

- active involvement of patients in the process of reporting ADR and a lack of efficacy of medicinal product;

- holding the working group meetings, workshops, trainings, etc. to discuss pharmacovigilance issues and improve the legislative framework.

5. To recommend the Ministry of Health of Ukraine and the State Expert Center of MoH to improve the methods of enhanced/active pharmacovigilance and signal management.

6. To publish the conference resolution in the publications “Pharmacology and Drug Toxicology”, “Ukrainian Medical Journal”, “Rational Pharmacotherapy”, “PHARMACY Weekly”, “Medicine and Pharmacy News”, “Health of Ukraine”, and other specialized medical publications, and place it on the official website of the Ministry of Health of Ukraine and the State Expert Center of MoH.