

**PHARMACEUTICAL FORUM**

PHARMA @PATIENT IN FOCUS 2024. PHARMACOVIGILANCE

RESOLUTION

The Pharmaceutical forum PHARM@PATIENT IN FOCUS 2024. PHARMACOVIGILANCEwith international participation (Kyiv, March 07, 2024), was organized by the State Expert Center of the Ministry of Health of Ukraine in cooperation with UkrComExpo LLC, with the support of the Ministry of Health of Ukraine, participation of partners and information support of the PHARMACY Weekly, European Business Association, The Pharma Media, Pharmaceutical Journal.

Having created an effective space for dialogue, organizers of the Forum aimed to emphasize the important role and significance of pharmacovigilance in the healthcare system of Ukraine, draw attention to global safety of medicines, pharmacovigilance in times of war, highlight modern aspects, discuss topical issues in the field of pharmacovigilance in Ukraine and further harmonisation with the best European and world standards, increase international trust.

The structure of the Forum consisted of thematic sessions, panel discussions both offline and online.

A significant support for the Forum was a contribution of international partners, who accepted an invitation and took part in the event. Representatives of the World Health Organization (WHO), the European Medicines Agency (EMA) and its safety committee (PRAC), the Uppsala Monitoring Center (UMC), national regulators of Poland and Sweden shared their experience and valuable recommendations.

The Forum speakers and guests were officials of the Ministry of Health of Ukraine, the State Expert Center of MOH of Ukraine (SECMOH), the State Service of Ukraine on Medicines and Drugs Control, the Center of Public Health of the Ministry of Health of Ukraine, healthcare institutions, pharmaceutical business, as well as the the SECMOH regional representatives for pharmacovigilance, educators and scientists.

The pharmaceutical forum PHARMA@PATIENT IN FOCUS 2024. PHARMACOVIGILANCE was attended by more than 200 participants in a hybrid format.

**The key topics of the Forum were:**

* Global collaboration in pharmacovigilance;
* Importance of pharmacovigilance in healthcare system;
* Human resources for efficient pharmacovigilance system;
* International experience of pharmacovigilance system, WHO database;
* Inspection/audit of pharmacovigilance system;
* Pharmacovigilance system in Ukraine in the immediate future;
* Discussion of the challenges of effective pharmacovigilance in Ukraine and Europe.

The Forum participants had the opportunity to receive valuable information from leading industry experts and answers to the most urgent questions, as well as to join discussions and debates, and exchange views.

During the sessions and panel discussions, the European experience related to surveillance of safety of medicinal products was discussed. The participants of the discussions highlighted the importance of timely reporting quality data on adverse reactions and efficacy of medicinal products to ensure timely regulatory decision making and avoid medication errors; pharmacovigilance in special populations; new approaches to inspections/audits; further plans and prospects for the pharmacovigilance development, and many other important issues.

The pharmaceutical forum PHARMA @PATIENT IN FOCUS 2024. PHARMACOVIGILANCE noted there is a need to organize similar events in the future to discuss issues, particularly with the involvement of international representatives of the pharmaceutical and medical community, experts of global regulatory authorities, etc., to exchange experience, best practices, in order to organize a joint platform for discussion and addressing current national regulatory challenges in pharmacovigilance.

**Considering the above information the Forum proposes:**

1. To continue establishing new contacts and cooperation with regulatory authorities of European and other countries, where high quality standards complying with the WHO standards are adhered (SRA/WLA).

2. To gain full access to the European database of suspected adverse drug reactions reports to share relevant safety information.

3. To recommend to consider issues discussed at this Forum when updating the legal framework for the pharmacovigilance system in Ukraine in accordance with the provisions of the Law of Ukraine "On Medicinal Products" of July 28, 2022 No. 2469-IX (as amended) and EU legislation.

4. That the State Expert Center of MOH of Ukraine should conduct a series of workshops for applicants and their legal representatives based on results of updating the legal framework for pharmacovigilance.

5. That the State Expert Center of the Ministry of Health of Ukraine should focus on cooperation with higher medical and pharmaceutical education institutions and marketing authorization holders to implement methodical training for obtaining a state diploma. To create a platform for discussing a roadmap in order to train and develop pharmacovigilance personnel.

6. To pay attention to pharmacovigilance of dietary supplements, medical devices, cosmetics and veterinary products.

7. That the State Expert Center of MOH of Ukraine should continue the training activities in the form of workshops for applicants and their legal representatives on certain issues of pharmacovigilance, which were launched in 2023.

8. That the State Expert Center of MOH of Ukraine should carry out advisory, methodological and educational activities on the applicants’ pharmacovigilance system organization and its quality system, pharmacovigilance audit.

9. That the State Expert Center of MOH of Ukraine should strengthen measures for reporting ADR and/or lack of efficacy of medicines and AEFI in the healthcare system involving the SECMOH regional representatives for pharmacovigilance in administrative and territorial units of Ukraine.

10. In coordination with the State Expert Center of MOH of Ukraine to involve its regional representatives for pharmacovigilance in administrative and territorial units of Ukraine during visits to healthcare settings providing antiretroviral therapy and TB treatment to inform about the pharmacovigilance system and involve all healthcare professionals in conduct of pharmacovigilance.

11. To raise awareness of students of higher education institutions of medical/pharmaceutical specialties about the national system of drug safety surveillance.

12. To include in the initial training of pharmacists, when hiring them, questions related to the pharmacovigilance system, its tools, the rights and responsibilities of pharmaceutical workers.

**Unanimously approved by the Forum participants on March 7, 2024**

**The organizing committee of the pharmaceutical forum**

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