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PHARMACOVIGILANCE IN CANADA AND BELARUS. LEGISLATIVE BASIS AND REAL CLINICAL PRACTICE

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Introduction. Pharmacovigilance, according to the world health organization is the "science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other possible drug-related problems." Adverse drug reactions (ADRs) can alter quality of life and affect the benefit–risk profile of therapy in clinical settings. It is proven that ADRs directly influence social aspects of life as well. Canada and Belarus both have respective systems and methods for dealing with, and reducing ADRs.

Aim: we define the social impacts as the effect on the society caused by an impairment of interpersonal and/or occupational (job/academic) functions, directly caused by the ADRs, for analyzing the regulatory framework of the ministry of health for both Canada and Belarus and their procedural methods for reporting adverse drug reactions. In addition, we evaluated results of pharmacovigilance at the Minsk 6th city clinical hospital from 2021 to 2023.

Materials and methods. We have obtained a Canadian pharmacovigilance form off Health Canada's official website and for the Belarusian form, we obtained it directly from the public information of the Centre for examinations and tests in health services («ЦЭИЗ»). We also have obtained 31 adverse drug reaction reports from which were reported from Minsk 6th government hospital from the 2021 – 2023 time period.

Results and discussion. In the republic of Belarus, pharmacovigilance reports are filed mainly to the Ministry of healthcare, as well as "Centre for examinations and tests in health services". Whereas in Canada, pharmacovigilance occurs through "Health Canada" (the federal ministry of health) as well as the "Canada vigilance adverse reaction online database" which then sends these reports to the federal government. ADRs can be reported by patients, health care professionals, or drug manufacturers.

In both nations, ADRs include not only prescription medications and vaccines, but also medical devices, and natural health remedies, such as supplements, sold at pharmacies and other legal vendors. In Canada however, legal cannabis products are also added to the list of preparations for ADRs. The efforts of Canada and the republic of Belarus has led each respective nation to tackle the issues of ADRs and minimize complications in treating patients with pharmaceutical products.

For both countries' pharmacovigilance reporting forms, the main focus was on who prescribed the drug, whether it be a medical worker or a doctor, and on what manufacturing company made the drug and what distributor sold the drug.For Republic of Belarus, we have analyzed 31 adverse drug reaction reports from Minsk 6th government hospital from the 2021 – 2023 time period, to better understand which reaction is most common, and which medications cause these reactions for the Belarusian public. Out of those 31 reports, the most common adverse reaction was urticaria with 23% of cases, followed by nausea with 13% of cases, then angioedema with 9% of cases, and hypotension and abdominal pain with 6% of cases each. Furthermore, out of 31 adverse drug reactions, the most common types of medications involved were antibiotics, with 12 cases (39% of all cases), followed by antivirals with 4 cases (13% of all cases), antiarrhythmics with 3 cases (9% of all cases), and anticoagulants with 2 cases (6%). The other uncommon ADRs with 1 case (3% of all) each include; diarrhea, thrombocytopenia, arterial hypotension, drug-induced hepatitis, contact dermatitis, itching, abdominal pain, anuria, and sick sinus syndrome. The other uncommon groups of drugs were amino-salicylates, calcium channel blockers, non-opioid analgesics, and medicinal plants.

Conclusion: our results demonstrate, that governmental pharmacovigilance systems both countries Canada and Belarus are guided by same principles. Regular ADR reporting improves effectiveness and safety of medical care.