ANNOTATION

of PhD thesis of Sydykov Serikzhan Berdahovich on the topic: "Scientific and methodological justification of centralized an automated system for monitoring side effects of medicines in the Republic of Kazakhstan", presented as an application for the Doctor PhD degree on the specialty 6D110400 - "Pharmacy"

Relevance of the research topic. In accordance with EU Directive 2010/84/EC, approved on 2 July 2012, European Commission Regulation (EC) No 520/2012 provides for the establishment of a new body within the framework of pharmacovigilance - the Risk Assessment Committee - and the implementation of Good Pharmacovigilance Practice (GVP), which is a set of measures designed to facilitate the monitoring of drug safety, both for certificate holders and regulatory authorities.

The main method used by virtually all drug safety monitoring services around the world is the spontaneous message method, which can be used as the basis for regulatory measures. The importance of information from patients is underestimated.

The World Health Organisation (WHO) and the European Commission have recognised the role of consumers in spontaneous communications. Consumers, patients and their organisations are increasingly involved in pharmacovigilance, especially when it comes to risk communication.

In 2012 WHO has published recommendations for the development of a "consumer reporting system" some countries use the term "patient report", but "consumer reporting" is a broader term.

Nowadays, in an increasing number of countries such as Australia, Canada, India, the Netherlands, Sweden, the UK and the USA, patients/users are increasingly involved in pharmacovigilance, especially when it comes to the transmission of information on over-the-counter (OTC) PL.

Three studies assessed the situation where patients reported in different countries through questionnaires, interviews or telephone calls to national regulatory authorities in different countries. The results show that 44 countries allowed patients, their relatives and patient associations to directly report adverse drug reactions to their national competent health authorities. The first country to allow for the registration of patient information was Australia in 1964, and a year later New Zealand and Canada, and then the USA in 1969. In the 1990s, three countries (Colombia, Hungary and Slovenia) and in the 2000s, twelve countries (Brazil, Croatia, Czech Republic, Denmark, Italy, Malta, Morocco, Netherlands, Nigeria, Sweden, Switzerland and the UK) started implementing patient reporting, while the rest started in 2012 or 2013. In terms of reporting methods, 33 countries used online and paper reporting, 5 countries used paper forms only, 3 countries used online forms only and one country used text messages. In addition, three countries (Germany, New Zealand and Kenya) are now offering patients the opportunity to report via a downloaded mobile application.

Health authorities in 44 countries are currently highlighting spontaneous adverse reactions to drug reactions by patients and the need for a more accessible reporting system. According to the new European legislation (Directive 2010/84/EC), Member States must establish a system for reporting adverse reactions to PL for patients. Therefore, eHealth applications can be a convenient method for closer interaction with the patient, the doctor and the authorised pharmacovigilance authority. It has been demonstrated that using mobile applications to report adverse events will save time and increase the number of notifications. On average, 15 times more patient reports per month were submitted through the MedWatch® application than through traditional PD collection methods. MedWatch® is the "Safety and Adverse Analytical Reporting Program" developed by the US FDA. It communicates with the FDA or AERS system. MedWatch® is used to report an adverse event. This voluntary reporting system, established in 1993, allows such information to be communicated to the medical community or the general public. The system includes publicly available databases and online analysis tools for professionals. MedWatch® also distributes safety warnings for medical devices, such as reviews and other clinical safety messages, through its website, email list, Twitter and RSS feeds. MedWatch® collects reports on adverse reactions and quality problems in medicines and medical devices, as well as for other FDA-regulated products (such as food supplements, cosmetics, medical products and infant formulas). As of summer 2011, the programme had received over 40,000 reports of adverse events.

The current state of society and the economy is characterized by the dynamic development and introduction of new information technologies in all areas of activity. Informatization as a process of introduction of new information technologies, means of collection, transfer, storage and processing of information is a necessary condition and one of the main directions of the State program "Digital Kazakhstan".

The creation of a common information space and the provision of reliable and timely information to the authorities require a new level of organisation in this area. The nature of the relationship between technological and managerial innovations is ambiguous and cannot be directly assessed. The implementation of managerial innovations often encounters greater resistance than technological innovations.

There are practically no structures engaged in research and scientific development of managerial innovations in Kazakhstan's pharmacovigilance system. The process of actual dissemination of managerial and technological innovations, assessment of their effectiveness, and reasons for their abandonment are poorly studied. The introduction of management solutions without the involvement of all participants in the pharmacovigilance system narrows down the range of possible innovations and does not create the conditions for their independent generation and implementation. The dissertation work was carried out as part of the implementation of the state programmes "Digital Kazakhstan" for 2018-2022 and "Densaulyk" for 2016-2020.

Research objective. Develop and test the methodology of a centralized automated system for monitoring side effects of medicines in the Republic of Kazakhstan.

Research objectives:

1. Analysis of existing practices for monitoring side effects of medicines.
2. Review of the AP monitoring system in the Republic of Kazakhstan, identification of problems and areas for improvement of monitoring quality.
3. Development of a model for a centralised automated system for the medicinal product distribution system in Kazakhstan.
4. Testing of a model for an automated system for collecting PDLs.
5. Evaluation of the efficiency of the developed system for collecting medicinal products with the identification of the role of patients/consumers of medicinal products in the pharmacovigilance system.

Objects of research. System for monitoring the safety of medicines during the post-registration period at the stage of medical use.

Research methods. Marketing methods, sociological research methods.

Scientific novelty of the research. For the first time in the Republic of Kazakhstan, a centralized automated system has been created to collect adverse reactions from healthcare professionals and patients/users of medicinal products (active monitoring of medicinal products).

The system allows the authorities responsible for ensuring quality and safety of drugs used in the Republic of Kazakhstan to be informed in a timely manner.

The main provisions of the dissertation research to be submitted for protection. The introduction of the electronic automated system into the pharmacovigilance service will enable active monitoring of side effects of drugs in the Republic of Kazakhstan, continuous study of the benefit/risk balance of drug therapy, timely identification and determination of the frequency of severe and unexpected adverse reactions to drugs (especially new drugs that require increased attention), and provision of information on quality assurance and safety of drugs used in the Republic of Kazakhstan.

Use of the mobile application "MedReminder" and the web portal "MedReminder. kz" by healthcare professionals will allow timely identification of adverse reactions and timely correction of therapy, reducing the frequency of drug complications, thus preventing the development of severe clinical consequences.

The use of the mobile application "MedReminder" makes it possible to increase patients' adherence to therapy.

Research shows patients' need to be informed about the pharmacotherapy they have received and their willingness to report on their health status and adverse reactions that have occurred during treatment.

Practical significance of the study. A model of a centralized automated system for monitoring side effects of medicines in the Republic of Kazakhstan has been developed based on the MedReminder mobile application and the MedReminder web portal. kz" web-portal.

Information on publications. Based on the research results, 21 scientific papers have been published, including:

- 2 articles in international journals (International Journal of Pharmaceutical Sciences Review and Research), part of the Scopus database; Journal of Global Pharma Technology);

- 8 publications (articles) in scientific publications recommended by the Committee for Control in Education and Science of the Ministry of Education and Science of the Republic of Kazakhstan;
- 9 theses in the materials of international scientific and practical conferences;
- 2 certificates of state registration of rights to an object of copyright;
- 3 presentations at international scientific and practical conferences.

Dissertation volume and structure

The dissertation is presented on 136 pages of typewritten text in a computer set, containing 10 tables, 16 drawings, a list of literature including 89 sources and 12 annexes. The work consists of an introduction, a literature review, a section on materials and research methods, 2 sections of own research, conclusions and conclusions.