Monitoring of adverse drug reactions – the new regulations in Poland

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ABSTRACT

The results of analyses carried out all over the world clearly indicate that drug-induced side effects are the cause of 10 to 15% of all hospital admissions. The effectiveness of pharmacovigilance in the country depends mainly on the availability of information about the risks associated with the use of drugs in patients. Collecting data on adverse drug reactions depends largely on the type of system used in the country. Continuous monitoring of suspected adverse drug reactions is very important in detecting new or investigating changing risks and then their management. That process plays an essential role in the management of risks that are already known. In view of the above, the aim of this article is to present the functioning of pharmacovigilance system in Poland, according to the latest amendment of the Pharmaceutical Law. The authors pointed out the definition of adverse drug reaction, characterised the system of pharmacovigilance in the European Union. There are also presented the rules of adverse drug reactions reporting in Poland, taking into account both existing so far, and new legislation.

Key words: medicinal product, adverse drug reaction, monitoring of adverse drug reactions