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Reporting Adverse Drug Reactions in Poland – The Legal Situation

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In Poland, the body responsible for collecting information on adverse drug reactions is a government entity called the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products, which reflects the fulfillment by public authorities of the obligation to guarantee the subjective human right to the protection of health. The office also prepares periodic reports on the safety of medicinal products and supervises the entire pharmacovigilance system. Moreover, the office evaluates periodic reports on the safety of medicinal products and exercises control over the system as a whole. In Poland there is also regional research centers which collect information on the adverse reactions observed. However, since they are not entities of the state administration, they are an optional addressee of notifications.

The principles of an adverse reaction notification are specifically defined by Polish law, including above all the Pharmaceutical Law and executive regulations of 6 September 2001. In November 2013, numerous amendments were made to this act, resulting from the Europeanization of Polish law. The regulations of Directive 2010/84/UE of the European Parliament and of the Council of 15 December 2010 amending, as regards pharmacovigilance, Directive 2001/83/EC on the Community code relating to medicinal products for human use, were implemented.

The Polish legislator modified the definition of an adverse reaction, broadening its objective scope. An adverse reaction was previously understood as every adverse effect appearing as a result of the correct use of a medicine. At present, an adverse drug reaction is every adverse and unintended effect of a drug. Hence it is necessary to notify all the reactions observed, regardless of whether the drug was used according to indications and suggested dosage or contrary to its purpose and characteristics. Notification is also obligatory for every observed reaction resulting from realized or unrealized overdosing or from a medical error.

Year	Number of spontaneous notifications
2008	904
2009	1211
2010	811
2011	1030
2012	1144

Table 1: Statement of the number of spontaneous notifications to the Polish President of the Office of Registration of Medicinal Products, Medical Devices and Biocidal Products in 2008–2012.

Notification of adverse drug reactions has become an obligation or right of people practicing a medical profession. The notification obligation applies to: physicians, pharmacists, nurses and midwives. Previously, only physicians and pharmacists were obliged by law to notify adverse drug reactions. A new right has been awarded to: laboratory diagnosticians, feldshers and pharmacy assistants.

Cases of adverse post-vaccination reactions must be notified by physicians to sanitary and epidemiological stations. The notification copies are sent to the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products.

The drug consumption in Poland is high. According to the Central Statistical Office, 71% of the population takes medications, while the number of adverse reaction notifications is small, according to the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products. The Table 1 presents a statement of the number of spontaneous notifications by physicians and pharmacists in 2008-2012 [1].

A significant change in Polish law is the introduction of a regulation granting patients a new right to notify an adverse drug reaction directly to the President of the Office of Registration of Medicinal Products, Medical Devices and Biocidal Products, the competent body or a medical professional. The notification can be submitted by post, fax or e-mail. A special website has been created with an easy-to-find notification form and the necessary information (http://dzialanianiepozadane.urpl.gov.pl).The notification process ensures full protection of the patient's personal data.

References

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