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The Surveillance of the Adverse Drug Reaction in Romania: Pharmacovigilance in Romania

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Brief History

For over 50 years, the present Agency has represented the drug regulatory authority in Romania. Known as the Institute for Medicinal Product Control and Pharmaceutical Research on its setup in 1956, the name of the institution was further changed in 1960 to become the Institute for the State Control of Medicinal Products and Pharmaceutical Research (ICSMCF). Between 1999-2010, by reorganisation of the former ICSMCF, the institution operated as the National Medicines Agency. The activity related to medical devices was set up 50 years ago as well.

As early as 1958, the technical directorate of the Ministry of Health set up its own laboratory for technical testing of medical equipment, which became a distinct entity in 1973 within the Station for Verification and Maintenance of Medical Devices (SVMMD). As of 1 February 2005, the SVMMD has been reorganised under the name of the Technical Office for Medical Devices (TOMD), which in its turn merged with the National Medicines Agency (NMA) in 2010. NAMMD organisation and operation have been approved by Government Decision No. 734 of 21 July 2010.

The NAMMD is the Romanian competent authority in the field of medicinal products for human use, as regards marketing authorisation, surveillance of the safety of medicinal products in therapeutic use, authorisation of clinical trials and issuance of regulations in the medicinal product field, as approved by the Ministry of Health.

Strategy and Objectives of NAMMD: Phramacovigilance Activity

This organisational strategy is issued and updated in the context of the legal framework establishing the relation between the NAMMD and the Ministry of Health, as well as between the NAMMD and its stakeholders. It covers a 5-year period 2011-2015 and is updated every year.

Protection and promotion of public health is the NAMMD general objective, as well as the core of its activity throughout the entire process related to surveillance of the development and use of medicinal products for human use and control of the use of medical devices.

The NAMMD carries out inspections of all aspects concerning medicinal product development and manufacturing process, taking measures against the companies or persons who fail to comply with their obligations.

The NAMMD authorises performance of clinical trials with medicinal products in various stages of development and is responsible for deciding whether they are granted marketing authorisations.

The NAMMD monitors safe use of medicinal products for human use throughout their entire lifecycle, by means of an advanced adverse reaction reporting system, so as to ensure maintenance of an acceptable risk/benefit balance for the respective products, as well as careful information in that respect of relevant interested parties, patients and healthcare professionals.

Significant improvement of the NAMMD safety monitoring systems and their legislation underlying this activity as well as increased NAMMD efforts for better patient and public understanding of the benefits and risks associated with medicinal product use which have been apparent in late years.

For the years to come, the NAMMD plans to further develop the adverse reactions/events reporting system, in order to ensure solid proof for its regulatory decisions.

The NAMMD pursues further emphasis of the value of reports received by providing quick feedback to reporters and continued development of public and patient level of understanding of decisions concerning the risk/benefit balance of medicinal products for human use available on the Romanian pharmaceutical market. Moreover, the NAMMD pursues to carry on its efforts directed towards the education and encouragement of healthcare professionals in view of adverse reaction reporting.

At the same time, the NAMMD plans on being actively involved in expected talks concerning future development of a European community system for monitoring medicinal product safety, which, through combined information from the 27 Member States, will further reinforce the elements underlying decision-making in safety matters.

For the following 5 years, the NAMMD envisages the following:

Insurance of authorised medicinal products compliance with the adequate quality, safety, efficacy standards and authorisation in the shortest time possible.

Authorising modifications/variations to marketing authorisation of medicinal products for human use (for new strengths or pharmaceutical forms etc.) in the shortest time possible, while safeguarding public health;

Further authorisation of those clinical trials and investigations only that give appropriate warranty to patients, in line with harmonised community regulations.

Further development of the National Pharmacovigilance Centre

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operating within the NAMMD and improvement of the adverse reactions/events reporting system, so that gathering of information is allowed from the most comprehensive sources, reporting is undertaken in the simplest manner and feedback is quickly delivered to encourage participation.

The performance of actions for ensuring firm and efficient surveillance of medicinal products for human use throughout Romania; Insurance of full NAMMD undertaking of its role in enforcing EU legislation on increasing the number of authorised medicinal products, particularly for the treatment of children;

Provision of certain adequate information/instructions to the public on the safe use of medicinal products, as well as warnings concerning their safe use, when needed, for both on-prescription and over-the-counter (OTC) medicinal products.

Communication, Information and Cooperation

Address healthcare professionals with targeted information, for improved adverse reactions/events reporting and promotion of safe use of human medicinal products (e.g. by adequate description, search and request of adequate information from the NAMMD);

Make targeted information available to the public, in view of better adverse reaction reporting by the patient, promotion of better informed patient decision concerning the use of medicinal products for human use;

Contribute to better understanding by the public and/or healthcare professionals of the benefit/risk balance of medicinal products for human use;

Cooperate with professional bodies, academic staff and others, in order to ensure an adequate content of training programmes for healthcare professionals, in such issues as safety and risk in prescription and use of medicinal products for human use;

Particularly following accession, within the European pharmaceutical regulatory system, the NAMMD cooperates with all national competent authorities in the European Union (EU) and in the European Economic Area (EEA), as well as with the European Medicines Agency (EMA).

Via the EMA, the NAMMD hopes to be able to also further develop international connections with the US Food and Drug Administration (FDA), within the cooperation framework established between the EMA/EU and the FDA/USA.