

Medicinal products for human use: pharmacovigilance of products

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The Committee on the Environment, Public Health and Food Safety adopted the report by Linda MACAVAN (S&D, UK) on the proposal for a regulation of the European Parliament and of the Council amending, as regards pharmacovigilance of medicinal products for human use, Regulation (EC) No 726/2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency. It recommended that the European Parliament's position at first reading under the ordinary legislative procedure (formerly known as the codecision procedure) should be to amend the Commission proposal as follows:

A Pharmacological Risk Assessment Committee (PRAC) with greater powers: in order to ensure harmonised responses across the Community to safety concerns regarding medicinal products for human use, the Committee for Medicinal Products for Human Use and the coordination group established by Directive 2001/83/EC on the Community code relating to medicinal products for human use should rely on the recommendation of the Pharmacovigilance Risk Assessment Committee on any question relating to the pharmacovigilance of medicinal products for human use.

The CHMP shall adopt an opinion which differs from the recommendation of the Pharmacovigilance Risk Assessment Committee, only where there exist strong scientific and public health grounds for doing so. The CHMP shall explain such grounds in a justification to be annexed to its opinion.

Post-authorisation safety and efficacy studies: after the granting of a marketing authorisation, the Agency may require a marketing authorisation holder to conduct a post-authorisation safety study, or post-authorisation safety and efficacy studies where important questions relating to the efficacy of a product remain; or when scientific advances in the understanding of the disease or in the clinical methodology would significantly change previous efficacy evaluations. For this purpose the Commission shall provide guidelines. The Commission shall also, based on data received from the Agency and Member States, produce a report focusing on the concept of Clinical Effectiveness, studies and data required and methodologies for assessing it.

Renewal of marketing authorisation: the committee deleted the words « insufficient exposure to the product » as a criterion for restricting renewal to a five-year period. The benefits of a harmonised and simplified approach pursued in the current proposal should be preserved. The new proposal should not regress on improvements introduced by the previous revision of the medicines legislation which aimed at reducing the number of renewal procedures.

Pharmacovigilance: the report adds that Member States shall support the development of the expertise of national and regional pharmacovigilance centres. National competent authorities should collect the reports from those centres and should then transfer data to the Eudravigilance database.

The Agency shall work together with all stakeholders, including research institutions, healthcare professionals, and patient and consumer organisations, in order to define the "appropriate level of access" to the Eudravigilance database.

The Agency, in collaboration with the Member States and all relevant stakeholders, shall develop standard structured forms and procedures, including web-based forms, for the reporting of suspected adverse reactions by health-care professionals and patients. To ensure the identification of biological medicinal

products prescribed, dispensed or sold in the territory of the Union, the standard forms and procedures shall include the name of the MAH (marketing authorisation holder), the INN (international non-proprietary name), the name of the medicinal product and the batch number. The Agency shall also make available to the public other means for patients to report undesirable effects, such as a dedicated telephone number or special email address. All citizens of the Union shall have the option of submitting online declarations in their mother tongue.

The Agency must make public the declaration of committee members' interests and agendas for, and records of, each meeting, accompanied by decisions taken. It must also make public the link to the Agency's EudraPharm database which must include the most up-to-date electronic version of the package leaflet and summary of product characteristics for all existing and new medicinal products authorised in accordance with the Regulation and with Directive 2001/83/EC, as well as a link to the Agency's European Public Assessment Report summary database which publishes information sheets on centrally authorised products. These two resources shall be publicised to the general public by the Agency or the competent authorities.

The Agency shall monitor all medical literature for reports of suspected adverse reactions to medicinal products for human use containing well established active substances.

Assessment report following periodic safety update reports: PRAAC shall formulate a recommendation for the Committee for Medicinal Products for Human Use on the basis of the assessment report. The CHMP shall adopt an opinion which differs from the recommendation of the Pharmacovigilance Risk Assessment Committee, only where there exist strong scientific and public health grounds for doing so. The CHMP shall explain such grounds in a justification to be annexed to its opinion.

Public hearings: in assessing updates to the risk management systems, the Pharmacovigilance Risk Assessment Committee may hold a public hearing. Public hearings shall be announced by means of the European medicines safety web-portal. The announcement shall include information on how marketing authorisation holders and the public can participate. The Agency shall provide the opportunity, to all those who request it, to participate in the hearing either in person or through the use of web-based technology. Where a marketing authorisation holder or another person intending to submit information has commercially confidential data relevant to the issue of the procedure, he may request that he be allowed to present those data to the Pharmacovigilance Risk Assessment Committee in a non-public hearing.

Lastly, the committee amended provisions relating to the composition of the Pharmacovigilance Risk Assessment Advisory Committee and stressed that its **independence must be guaranteed**.