Medicinal products for human use: pharmacovigilance of products

2008/0257(COD) - 22/09/2010 - Text adopted by Parliament, 1st reading/single reading

The European Parliament adopted by 559 votes to 7, with 12 abstentions, a legislative resolution 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.

The Parliament adopted its position at first reading under the ordinary legislative procedure (formerly known as the codecision procedure). The amendments adopted in plenary are the result of a compromise reached between the European Parliament and the Council. They amend the Commission's position as follows:

Strengthened Risk Assessment Committee: in order to ensure harmonised responses across the Union 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.

It is appropriate that the Pharmacovigilance Risk Assessment Committee should give a recommendation as part of any Union-wide post-authorisation assessment based on pharmacovigilance data relating to medicinal products as well as on the agreement and monitoring of the risk management systems. Such Union-wide assessments should follow the procedures laid down in Directive 2001/83/EC also for medicinal products that were authorised through the centralised procedure.

Market authorisation: **post authorisation efficacy and safety studies**: the amended text stipulates that it is necessary from a public health perspective to complement the data available at the time of authorisation with additional data about the safety and, in certain cases, also about the efficacy of medicinal products authorised. The Commission should therefore be empowered to require the marketing authorisation holder to conduct post-authorisation studies on safety and on efficacy. It should be possible to impose this requirement at the time of granting the marketing authorisation or later, and it should be part of the marketing authorisation. These additional studies may be aimed at collecting data to enable the assessment of safety or efficacy of medicinal products in everyday medical practice. The supervisory authorities for pharmacovigilance may, as considered necessary, conduct pre-authorisation pharmacovigilance inspections to verify the accuracy and successful implementation of the pharmacovigilance system as described by the applicant in support of the application.

Products authorised subject to additional monitoring: some medicinal products are authorised subject to additional monitoring. This includes all medicinal products with a new active substance and biological medicinal products including biosimilars for which pharmacovigilance activities are prioritised. This may also apply, at the request of the competent authorities, to specific products, subject to the requirement to conduct a post-authorisation safety study or subject to conditions or restrictions with regard to the safe and effective use of the medicinal product that will be specified in the risk management plan.

Risk management plans are normally required for new active substances, biosimilars, medicinal products for paediatric use and for products involving a significant change in the marketing authorisation, including

a new manufacturing process of a biotechnologically-derived product. Products subject to additional monitoring should be identified as such by a **black symbol**, which will be selected by the Commission on a recommendation by the Pharmacovigilance Risk assessment Committee, and a **relevant standard explanatory sentence** on the summary of product characteristics and on the patient information leaflet, and a publicly available list of such medicinal products should be kept up to date by the Agency.

Data protection: this Regulation shall apply without prejudice to Directive 95/46/EC on the protection of individuals with regard to the processing of personal data and on the free movement of such data and Regulation (EC) No 45/2001 on the protection of individuals with regard to the processing of personal data by the Union institutions and bodies and on the free movement of such data.

In order to detect, assess, understand and prevent adverse reactions, identify and take actions to reduce risks and increase benefits from medicinal products for the purpose of safeguarding public health, it should be possible to process personal data within the Eudravigilance system while respecting EU data protection legislation.

Tasks of the Agency: the amended text specifies that the Regulation and Directive amending Directive 2001/83/EC on the Community Code relating to medicinal products for human use widen the task of the Agency with regard to pharmacovigilance, including literature monitoring, improved information technology tools and provision of more information to the general public. The Agency should be enabled to fund these activities from fees paid by marketing authorisation holders. These fees should not cover tasks carried out by national competent authorities for which such authorities charge fees in accordance with the provisions of Directive 2001/83/EC.

Uniform conditions: a recital states that uniform conditions be established as concerns the contents and maintenance of the pharmacovigilance system master file, as well the minimum requirements of the quality system for the performance of pharmacovigilance activities by the national competent authorities and marketing authorisation holders, the use of internationally agreed terminology, formats and standards for the conduct of pharmacovigilance, and the minimum requirements for the monitoring of data in the Eudravigilance database to determine whether there are new or changed risks.

The format and content of electronic transmission of suspected adverse reactions by Member States and marketing authorisation holders, the format and content of electronic periodic safety update reports and risk management plans and the format of protocols, abstracts and final study reports for the post-authorisation safety studies should also be established. In this respect, pending the adoption of a new Regulation based on Article 291 of the TFEU, Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission continues to apply, with the exception of the regulatory procedure with scrutiny, which is not applicable.

Executive Director of the Agency: the Executive Director of the Agency shall ensure appropriate coordination between the Committee for Advanced Therapies and the other Committees of the Agency, in particular the Committee for Medicinal Products for Human Use, the Pharmacovigilance Risk Assessment Committee and the Committee for Orphan Medicinal Products, their working parties and any other scientific advisory groups.