Medicinal products for human use: pharmacovigilance of products

2008/0260(COD) - 15/12/2010 - Final act

PURPOSE: to strengthen the Community pharmacovigilance system of medicinal products for human use.

LEGISLATIVE ACT: Directive 2010/84/EU of the European Parliament and of the Council amending, as regards pharmacovigilance, Directive 2001/83/EC on the Community code relating to medicinal products for human use.

CONTENT: following first reading agreement with the European Parliament, the Council adopted a Regulation on pharmacovigilance (COD/2008/0257) and this Directive aimed at strengthening the EU system for the safety monitoring of medicinal products for human use ("pharmacovigilance"), and thereby better protecting public health. The EU pharmacovigilance system seeks to prevent, detect and assess adverse reactions to medicinal products placed on the Union market. It also ensures that any product which presents an unacceptable level of risk can be withdrawn rapidly from the market.

Roles and responsibilities: Member States will remain central for the operation of a pharmacovigilance system, but their responsibilities are clarified. Under the new rules they will collect information on suspected adverse drug reactions not only if the product was used within the terms of the marketing authorisation, but also in case of overdose, misuse, abuse and medication errors.

A new scientific committee, the Pharmacovigilance Risk Assessment Committee, is created within the European Medicines Agency (EMEA), and will advise the EMEA's Committee for medicinal products for human use, which remains responsible for issuing an opinion, on the risk-benefit assessment of centrally-authorised medicinal products for human use.

The mandate of the EMEA's coordination group, responsible for agreeing and monitoring risk management systems, is enlarged. In the future, based on the advice from the Pharmacovigilance Risk Assessment Committee, this group will also examine questions related to the pharmacovigilance of all medicinal products authorised by Member States and to variations to the terms of marketing authorisations granted by Member States. Under the current rules, the coordination group's mandate is limited to the examination of questions relating to a marketing authorisation of a medicinal product in two or more Member States.

Provision is made to allow adequate funding for pharmacovigilance activities through the collection of fees charged to marketing authorisation holders for obtaining and maintaining EU marketing authorisations and for other services provided by EMEA and national competent authorities. However, the management of those collected funds will be under the permanent control of the national competent authorities in order to guarantee their independence in the performance of those pharmacovigilance activities.

Transparency and communication: the existing EU pharmacovigilance database, the "Eudravigilance database", is strengthened and becomes the single point of receipt of pharmacovigilance information for medicinal products for human use authorised in the EU, thus facilitating early discovery of adverse reactions. This reporting system will be gradually introduced, following development of the necessary capacity of the data base.

In order to ensure transparency in pharmacovigilance issues the EMEA will create and maintain a European medicines webportal.

Concerning the readability of the summaries of product characteristics and the packaging leaflets, the Commission is invited to present an assessment report and, if appropriate, table proposals to improve the layout and the content of the summaries of product characteristics and of the packaging leaflet.

Pharmacovigilance obligations by industry. As under the current rules, the marketing authorisation holder must establish a pharmacovigilance system to ensure the monitoring and supervision of its authorised medicinal products. The requirements for applications are, however, simplified. Marketing authorisation holder will have to submit only key elements of their pharmacovigilance system, rather than a detailed description of the system. On the other hand, they will have to maintain a detailed file on site for possible inspections by the competent authorities. The marketing authorisation holders will have continuously to monitor the safety of their products, inform the authorities of any changes that might have an impact on the marketing authorisation, and for ensuring that the product information is kept up to date. In addition, the Commission is empowered to require marketing authorisation holders to conduct post authorisation studies on safety and on efficacy, as part of the marketing authorisation.

Risk management planning and non-interventional safety studies: EMEA may require a marketing authorisation holder to operate a risk management system if there are concerns about the risks affecting the risk-benefit balance of an authorised medicinal product. In order to ensure that non-interventional post-authorisation safety studies (i.e. safety studies of authorised products that are not clinical trials) requested by competent authorities are non promotional, harmonised guiding principles and regulatory supervision are strengthened.

Adverse drug reaction case reports: Member States will have to take appropriate measures to enable patients, besides of doctors, pharmacists and other health-care professionals to report suspected adverse reactions to the national competent authority. Member States will have to report all suspected adverse reactions that occur in their territory to the Eudravigilance database.

Marketing authorisation will be required to submit electronically information on all suspected adverse reactions that occur in the EU and in third countries to the Eudravigilance database.

Periodic safety update reports and other safety related assessments: as under the current rules, marketing authorisation holders will have to submit to EMEA periodic safety update reports. In the future, these periodic safety update reports will, however, constitute a scientific evaluation of the risk-benefit balance of the medicinal product, rather than a detailed presentation of individual case reports, since that information will already have been reported to the Eudravigilance data base. In addition, there may be a single periodic safety update report for products that contain the same active substance or combination thereof but are subject to different marketing authorisations. For medicinal products with a new active substance and biological medicinal products, the pharmacovigilance will be strengthened by making the

authorisation subject to additional monitoring activities and a requirement that they should be identified by a black symbol and an explanatory sentence that encourages reporting of adverse reactions on the summary of product characteristics and on the patient information leaflet. This requirement may also apply, at the request of the competent authorities, to other products.

Member States are invited to consider measures to monitor and evaluate the risk of environmental effects of medicinal products. The Commission is called upon to produce a report on the scale of the problem and assess if the EU legislation in this field should be amended.

This Directive and the Regulation on pharmacovigilance (COD/2008/0257) form part of the pharmaceutical package which also includes a draft directive on falsified pharmaceutical products, as well as a draft directive and a draft regulation concerning information on prescription drugs.

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