Medicinal products for human use: pharmacovigilance of products

2008/0257(COD) - 10/12/2008 - Legislative proposal

PURPOSE: to improve the functioning of Community rules on the pharmacovigilance of medicinal products for human use, with the overall objectives of better protecting public health, ensuring proper functioning of the internal market and simplifying the current rules and procedures.

PROPOSED ACT: Directive of the European Parliament and of the Council.

CONTENT: it is estimated that 5% of all hospital admissions are due to an adverse drug reaction, that 5% of all hospital patients suffer an adverse drug reaction and adverse drug reactions are the fifth most common cause of hospital death. Some adverse reactions will only be detected after a medicine has been authorised and the full safety profile of medicinal products can only be known once they have entered the market.

Community rules so far adopted have made a major contribution to the achievement of the objective that medicinal products authorised to be placed on the Community market are continuously monitored as regards their safety. However, in the light of the experience acquired and following an assessment by the Commission of the Community system of pharmacovigilance, it has become clear that new measures are necessary to improve the operation of the Community rules on the pharmacovigilance of medicinal products for human use.

Therefore, the proposals aim at the strengthening and rationalizing the Community pharmacovigilance system of medicinal products for human use through the amendment of the two legal acts governing this field, i.e. Directive 2001/83/EC (see COD/2008/0260) and Regulation (EC) No 726/2004. The specific objectives are:

- providing for clear roles and responsibilities for the key responsible parties and clear obligations against which they perform their roles;
- rationalising EU decision-making on drug safety issues;
- strengthening medicines safety transparency and communication;
- strengthening companies' pharmacovigilance systems;
- ensuring the proactive and proportionate collection of high quality data relevant to the safety of medicines through risk management and structured data collection;
- involving stakeholders in pharmacovigilance;
- simplification of the current Community pharmacovigilance procedures.

The key elements of the proposals can be summarised as follows:

Clear roles and responsibilities:

- the key tasks of the Agency in the area of pharmacovigilance are overall maintained, but the Agency's coordinating role at the centre of the Community pharmacovigilance system is reinforced;
- the Member States should remain core to the operation of pharmacovigilance in the Community, with increased cooperation and work-sharing mechanisms;

- the pharmacovigilance responsibilities of marketing authorisation holders are also clarified, in particular as regards the scope of the obligation of marketing authorisation holders to continuously monitor the safety of products to ensure that all information available is brought to the attention of the authorities;
- a new scientific committee responsible for pharmacovigilance is created within the Agency: the Pharmacovigilance Risk Assessment Advisory Committee. This Committee is intended to play a key role in the pharmacovigilance assessments in the Community;
- the mandate of the coordination group composed of Member States representatives is enhanced;
- the Community procedure for the assessment of serious safety issues for nationally authorised products is stream-lined through clear and binding initiation criteria for the Member States.

Transparency and communication in terms of drug safety issues:

- strengthening of the Eudravigilance database, which should become the single point of receipt of pharmacovigilance information for medicinal products for human use authorised in the Community;
- Community coordination of communication about safety issues and establishment of a European medicines safety web-portal;
- introduction of a new 'key information' section in the summary of the product characteristics and the package leaflet which accompany every medicinal product placed on the Community market.

Pharmacovigilance obligations of the marketing authorisation holder: the proposals simplify the requirement that a 'detailed description of the pharmacovigilance system' be submitted in marketing authorisation applications. In the marketing authorisation application, only key elements of the pharmacovigilance system should be submitted, but this is balanced with a requirement for companies to maintain a detailed pharmacovigilance system master file on site.

Risk management planning and non-interventional safety studies:

- the establishment of a risk management system for each medicinal product to be newly authorised in the Community (or for existing products on the basis of safety concerns), which should be proportionate to the identified risks, potential risks, and the need for additional information on the medicinal product;
- the establishment of harmonised guiding principles and a procedure for the supervision of non-interventional post-authorisation safety studies (i.e. safety studies of authorised products that are not clinical trials), in particular to ensure that they are non promotional, and the follow-up of any safety data generated in such studies.

Adverse drug reaction case reports: the proposals are intended to make reporting proportionate to risks, to empower patients to report their side effects, and to ensure that overdoses and medication errors are reported. The following has therefore been proposed:

- simplification of adverse reaction reporting by providing that all adverse reaction data are reported directly to the Eudravigilance database;
- requiring the Agency to assume the role of monitoring scientific literature by the Agency and to enter case reports of adverse effects into the Eudravigilance database;
- clarification of the definition of adverse drug reaction to make clear that companies report medication errors that result in an adverse reaction to the competent authorities for medicines and ensure that all the relevant Member State authorities share data;
- clarification of the legal basis for patients to report suspected adverse drug reactions.

Periodic safety update reports and other safety related assessments: the proposals simplify periodic safety update report submission by industry and make it proportional to the knowledge about the safety /risk of the product. They introduce work-sharing mechanisms for the assessments, with a prominent role

in all cases by the Pharmacovigilance Risk Assessment Advisory Committee, and faster updating of product information through the establishment of clear procedures.