Pharmacovigilance: transparency and efficiency of the system. Directive

2012/0025(COD) - 10/02/2012 - Legislative proposal

PURPOSE: to amend Directive 2001/83/EC as regards pharmacovigilance in order to address weaknesses identified in the EU pharmacovigilance system.

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

BACKGROUND: in December 2010, the European Parliament and the Council adopted Directive 2010/84/EU and Regulation (EU) No 1235/2010 ("2010 pharmacovigilance legislation") amending respectively, as regards pharmacovigilance, Directive 2001/83/EC and Regulation (EC) No 726/2004. The new legislation will apply from July 2012.

These measures have substantially strengthened the legal framework for the surveillance of medicinal products, with provisions to reinforce the coordinating role of the Agency, the possibilities for signal detection, and the operation of coordinated procedures at European level to respond to safety concerns.

However, recent pharmacovigilance events in the European Union, in particular the “Mediator case”, have shown the **need for a further improvement of the pharmacovigilance system**. Following an analysis of the Mediator case in the light of the 2010 pharmacovigilance legislation ("Stress test"), the Commission has detected certain weaknesses in the pharmacovigilance system that need to be addressed.

It should be noted that this proposal is closely linked to the proposal to amend Regulation (EC) No 726/2004.

IMPACT ASSESSMENT: no impact assessment has been undertaken.

LEGAL BASIS: Article 114 and Article 168(4)(c) of the Treaty on the Functioning of the EU.

CONTENT: the general policy objectives of the proposals to amend Directive 2001/83/EC and Regulation (EC) No 726/2004 are to ensure the proper functioning of the internal market for medicinal products for human use and to protect better the health of EU citizens. Following this line, the proposals aim specifically to address weaknesses identified in the EU pharmacovigilance system and provide for more transparency and efficiency of the system in cases where safety concerns are identified.

The main amendments to the Regulation are as follows:

Automatic assessment at EU level: Directive 2001/83/EC provides for an automatic assessment at Union level when specific serious safety issues have been identified with regard to nationally authorised products. In the 2010 pharmacovigilance legislation, changes to the Commission's proposal during co-decision have led to the automatic assessment being lost, as the initiation of the procedure is linked to an appreciation by the Member State or the Commission as to whether an urgent action is considered necessary. Thus, when a Member State considers suspending, revoking or refusing renewal of a marketing authorisation, but does not consider that urgent action is needed, no evaluation of the safety concern will be conducted at Union level.

Recent pharmacovigilance events in the Union have shown the need for an automatic procedure at Union level in the cases of specific safety issues to ensure that a matter is assessed and addressed in all Member

States where the medicinal product is authorised. The scope of different Union procedures concerning nationally authorised products is clarified in the text.

Transparency: marketing authorisation holders are not required to declare the reasons for the withdrawal of a marketing authorisation or product. Therefore, it cannot be ruled out that voluntary withdrawal of a marketing authorisation or product by the marketing authorisation holder could lead to safety issues being missed, in particular if the company is not transparent about possible safety concerns.

Voluntary action by the marketing authorisation holder should not lead to a situation where concerns related to the risks or benefits of a medicinal product authorised in the Union are not properly addressed in all Member States. Therefore, provision is made for the marketing authorisation holder to **inform competent authorities of the reasons for the withdrawal of a medicinal product**, for interrupting the placing on the market of a medicinal product, for requests for revoking a marketing authorisation, or for not renewing a marketing authorisation.

BUDGETARY IMPLICATIONS: the proposal has no implication for the budget of the Union. It makes minor changes to the system set forth by the 2010 pharmacovigilance legislation, and does not require additional human or administrative resources.