Pharmacovigilance: transparency and efficiency of the system. Regulation

2012/0023(COD) - 10/02/2012 - Legislative proposal

PURPOSE: to amend Regulation (EC) No 726/2004 as regards pharmacovigilance in order to address weaknesses identified in the EU pharmacovigilance system.

PROPOSED ACT: Regulation 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 “Mediatorcase”, 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 Directive 2001/83/EC.

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:

Reasons for withdrawal: 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.

Accordingly, provision is made for the marketing authorisation holder to inform the Agency 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.

Transparency: the public list of medicinal product subject to additional monitoring provided for in Article 23 of Regulation (EC) No 726/2004 will include certain medicinal products subject to post-authorisation safety conditions. Those products will be included in the list, following consultation with

the Pharmacovigilance Risk Assessment Committee, only if the Commission or a Member States' competent authorities make a request. Therefore, competent authorities will have to decide on a case-by-case basis whether to make public the fact that products are subject to strengthened surveillance.

The proposal provides that, in order to ensure transparency on the surveillance of authorised medicinal products, the list of medicinal products subject to additional monitoring established by Regulation (EC) No 726/2004 should **systematically include medicinal products that are subject to post-authorisation safety conditions**.

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.