Pharmacovigilance: transparency and efficiency of the system. Regulation

2012/0023(COD) - 11/09/2012 - Text adopted by Parliament, 1st reading/single reading

The European Parliament adopted by 665 votes to 9, with 10 abstentions, a legislative resolution on the proposal for a Regulation of the European Parliament and of the Council amending Regulation No 726 /2004 as regards pharmacovigilance.

Parliament adopted its position on first reading following the ordinary legislative procedure. The agreement was the result of a compromise negotiated between Parliament and Council. The main amendments are as follows:

Information requirements: the marketing authorisation holder **shall notify the Agency forthwith** of any action the holder takes to suspend the marketing of a medicinal product, to withdraw a medicinal product from the market, to request the withdrawal of a marketing authorisation or not to apply for the renewal of a marketing authorisation, together with the reasons for such action. He shall in particular declare if such action is based on any of the grounds set out in Directive 2001/83/EC. He shall also make the notification if the action is taken in a third country.

List of medicinal products: the Agency shall, in collaboration with the Member States, set up, maintain and make public a list of medicinal products that are subject to additional monitoring.

The amended text stipulates that, at the request of the Commission, following consultation with the Pharmacovigilance Risk Assessment Committee, medicinal products that are authorised pursuant to this Regulation and subject to certain conditions may also be included in the list.

Tasks of the Agency: the Agency will assume, among other things, the following tasks:

- coordinating the monitoring of medicinal products which have been authorised within the Union and providing advice on the measures necessary to ensure the safe and effective use of those medicinal products, in particular by coordinating the evaluation and implementation of pharmacovigilance obligations and systems and the monitoring of such implementation;
- ensuring the collation and dissemination of information on suspected adverse reactions to medicinal products authorised in the Union by means of a database which is permanently accessible to all Member States.

Marketing authorisation holders shall, by 2 July 2012 at the latest, electronically submit to the Agency information on all medicinal products for human use authorised in the Union, using the format referred to in the Regulation.