Pharmacovigilance: transparency and efficiency of the system. Regulation

2012/0023(COD) - 25/10/2012 - Final act

PURPOSE: determination of precise rules on pharmacovigilance and the improvement of medicines for human use in accordance with Regulation (EC) No 726/2004.
LEGISLATIVE ACT: Regulation (EC) No 1027/2012of the European Parliament and of the Council amending Regulation (EC) No 726/2004 relating to pharmacovigilance.

CONTENT: following a first reading agreement with the European Parliament, the Council adopted this Regulation as well as a Directive **to improve medicines for human use (pharmacovigilance)** so as to further improve general patient safety.

The main changes introduced to the legislation in force are as follows:

Information requirements:

- if the product **ceases to be placed on the market of a Member State, either temporarily or permanently**. Such notification shall, other than in exceptional circumstances, be made no less than two months before the interruption in the placing on the market of the product;

- 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. The marketing authorisation holder shall in particular declare if such action is based on any of the grounds set out in Article 116 or Article 117(1) of Directive 2001/83/EC. They 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 list referred to shall include an electronic link to the product information and to the summary of the risk management plan.

At the request of the Commission, medicinal products that are authorised pursuant to this Regulation, subject to certain conditions may also be included in the list.

By 5 June 2018, the Commission shall present to the European Parliament and the Council a report on the use of the list, based on the experience and data provided by the Member States and the Agency.

Missions of the Agency: the Agency will ensure, inter alia, the following functions:

- 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.

ENTRY INTO FORCE: 04/12/2012.

APPLICATION: from 05/06/2013, with the exception of some sections which shall apply from 04/12 /2012.