Pharmacovigilance: transparency and efficiency of the system. Directive

2012/0025(COD) - 12/07/2012 - Committee report tabled for plenary, 1st reading/single reading

The Committee on the Environment, Public Health and Food Safety adopted the report by Linda McAVAN (S&D, UK) on the proposal for a directive of the European Parliament and of the Council amending Directive 2001/83/EC as regards pharmacovigilance.

The committee recommends that the European Parliament's position in first reading following the ordinary legislative procedure should amend the Commission proposal as follows:

Obligations regarding information: Members want to reinsert two obligations which make the referral procedure work more smoothly. Accordingly:

- the Member State concerned or the Commission shall clearly identify the question which is referred to the Committee for consideration and shall inform the applicant or marketing authorisation holder accordingly;

- the Member States and the applicant or marketing authorisation holder shall supply the Committee with all available information relating to the matter in question.

Drug-Fact-Box: the notice must include a Drug-Fact-Box - a brief description of essential/necessary facts and details of the medicinal product, which are required by the patient to understand the usefulness as well as possible risks of the medicinal product and to use it in a safe and proper way. The information contained in the Drug-Fact-Box shall be presented in a clear and legible way, and shall be distinguishable from the rest of the text form.

Third countries: the marketing authorisation holder shall also make the notification to Member States and the Agency of action to suspend the marketing of a medicinal product, or the non-renewal of a marketing authorization if the action is taken in a third country.

Notification to the Agency: the marketing authorisation holder shall be obliged to notify the Agency as well as Member States forthwith of any action taken by him 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.

Transparency: the Agency shall not only make public annually a list of the medicinal products for which marketing authorisations have been refused, revoked or suspended, whose supply has been prohibited or which have been withdrawn from the market, but also the reasons for such action.