Pharmacovigilance: transparency and efficiency of the system. Directive

2012/0025(COD) - 11/09/2012 - Text adopted by Parliament, 1st reading/single reading

The European Parliament adopted by 659 votes to 9, with 9 abstentions, a legislative resolution on the proposal for a directive of the European Parliament and of the Council amending Directive 2001/83/EC 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:

Obligations regarding information: the marketing authorisation holder shall be obliged to inform the relevant competent authorities and the European Medicines Agency of the reasons for withdrawing or interrupting the placing on the market of a medicinal product, for requesting that a marketing authorisation be revoked, or for not renewing a marketing authorisation.

Normal Procedure and Urgent Union Procedure: the amended text clarifies and further strengthens the normal procedure and the urgent Union procedure in order to ensure coordination, swift assessment in case of urgency and the possibility to take immediate action, where necessary to protect public health, before a decision is taken at Union level.

- The Normal Procedure should be initiated for matters concerning quality, safety or efficacy of medicinal products where the interests of the Union are involved.
- The Urgent Union Procedure should be initiated when there is a need to swiftly assess concerns resulting from the evaluation of data from pharmacovigilance activities.

Regardless of whether the Urgent Union Procedure or the Normal Procedure is applied, and regardless of the procedure by means of which the medicinal product was authorised, be it centralised or otherwise, the **Pharmacovigilance Risk Assessment Committee** should always give its recommendation when the reason for taking action is based on pharmacovigilance data. The coordination group and the Committee for Medicinal Products for Human Use shall rely on that recommendation when carrying out the assessment of the issue.

Drug-Fact-Box: the package leaflet must be written and designed in such a way as to be **clear and understandable**, enabling users to act appropriately, when necessary with the help of health professionals. The package leaflet must be clearly legible in an official language or official languages of the Member State where the medicinal product is placed on the market

Where the medicinal product is not intended to be delivered directly to the patient, or where there are severe problems in respect of the availability of the medicinal product, the competent authorities may, subject to measures they consider necessary to safeguard human health, **grant an exemption to the obligation** that certain particulars should appear on the labelling and in the package leaflet. They may also grant a full or partial exemption to the obligation that the labelling and the package leaflet must be in an official language or official languages of the Member State where the medicinal product is placed on the market.

Wholesale distribution of medicinal products to third countries: in this case, wholesale distributors shall ensure that the medicinal products are obtained only from persons who are authorised or entitled to

supply medicinal products in accordance with the applicable legal and administrative provisions of the third country concerned.