Pharmacovigilance: transparency and efficiency of the system. Directive

2012/0025(COD) - 25/10/2012 - Final act

PURPOSE: to strengthen the rules on pharmacovigilance in order to address weaknesses identified in the EU pharmacovigilance system, and amending Directive 2001/83/EC.

LEGISLATIVE ACT: Directive 2012/26/EU of the European Parliament and of the Council amending Directive 2001/83/EC as regards pharmacovigilance.

CONTENT: following agreement at first reading, the European Parliament and the Council adopted this Directive aimed at strengthening the post-authorisation monitoring of medicines for human use ("pharmacovigilance"), thereby further improving patient safety.

The new legislation focuses in particular on obligations on marketing authorisation holders in relation to adverse reactions to medicinal products and clarifies the procedures when competent authorities follow up such reporting.

The main points of the Directive are as follows:

Automatic assessment at EU level: recent pharmacovigilance incidents in the Union have shown the need for an automatic procedure at Union level in cases of specific safety issues to ensure that a matter is assessed and addressed in all Member States where the medicinal product is authorised. The Directive clarifies the scope of different Union procedures concerning products authorised at national level, as laid down in Directive 2001/83/EC on the Community code relating to medicinal products for human use.

Clarification of Normal Procedure and Urgent Procedure: these procedures are strengthened in order to ensure coordination, swift assessment in case of urgency and the possibility of taking 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 must always give its recommendation when the reason for taking action is based on pharmacovigilance data.

Member States must bring cases concerning new contraindications, reductions in the recommended dose or restrictions to the indication for medicinal products authorised in accordance with the decentralised procedure and the mutual recognition procedure to the attention of the coordination group when the Urgent Union Procedure is not initiated. In order to ensure harmonisation for those products, the coordination group may discuss whether any action is necessary in the event that no Member State has triggered the Normal Procedure.

Notification to competent authorities where product is withdrawn: voluntary action by the marketing authorisation holder should not lead to a situation where concerns relating to the risks or benefits of a medicinal product authorised in the Union are not properly addressed in all Member States. Therefore, the **Directive requires marketing authorisation holder to inform the relevant competent authorities and the European Medicines Agency** of the reasons for with-drawing or interrupting the placing on the market of a medicinal product, for requesting that a marketing auth-orisation be revoked, or for not renewing a marketing authorisation. This also applies if the marketing authorisation holder withdraws a medicine from a third country market.

Transparency: each year, the European Medicines Agency shall make public a list of the medicinal products for which marketing authorisations have been refused, revoked or suspended in the Union, whose supply has been prohibited or which have been withdrawn from the market, including the reasons for such action.

Wholesale distribution of medicinal products: the Directive further strengthens the rules concerning wholesale distribution of medicinal products to third countries.

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APPLICATION: from 28 October 2013.