Directive 2012/26/EU of the European Parliament and of the Council of 25 October 2012 amending Directive 2001/83/EC as regards pharmacovigilance (Text with EEA relevance)

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THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 114 and Article 168(4)(c) thereof,

Having regard to the proposal from the European Commission,

After transmission of the draft legislative act to the national parliaments,

Having regard to the opinion of the European Economic and Social Committee[(1)],

After consulting the Committee of the Regions,

Acting in accordance with the ordinary legislative procedure[(2)],

Whereas:

(1) 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 scope of different Union procedures concerning products authorised at national level, as laid down in Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use[(3)], should be clarified.

(2) In addition, 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 marketing authorisation holder should 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.

(3) It is appropriate to further clarify and strengthen 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. It is appropriate that the coordination group and the Committee for Medicinal Products for Human Use rely on that recommendation when carrying out the assessment of the issue.

(4) It is appropriate that Member States 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.

(5) Since the objective of this Directive, namely to harmonise the rules on pharmacovigilance across the Union, cannot be sufficiently achieved by the Member States and can therefore be better achieved at Union level, the Union may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty on European Union. In accordance with the principle of proportionality, as set out in that Article, this Directive does not go beyond what is necessary in order to achieve that objective.

(6) Directive 2001/83/EC should therefore be amended accordingly,

HAVE ADOPTED THIS DIRECTIVE:

(**1**) OJ C 181, 21.6.2012, p. 201.

(**2**) Position of the European Parliament of 11 September 2012 (not yet published in the Official Journal) and decision of the Council of 4 October 2012.

(**3**) OJ L 311, 28.11.2001, p. 67.