COUNCIL OF THE EUROPEAN UNION

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PROPOSAL

from:	European Commission
dated:	13 February 2012
No Cion doc.:	COM(2012) 52 final
Subject:	Proposal for a Directive of the European Parliament and of the Council amending Directive 2001/83/EC as regards pharmacovigilance

Delegations will find attached a proposal from the Commission, submitted under a covering letter from Mr Jordi AYET PUIGARNAU, Director, to Mr Uwe CORSEPIUS, Secretary-General of the Council of the European Union.

Encl.: COM(2012) 52 final

EUROPEAN COMMISSION

Brussels, 10.2.2012
COM(2012) 52 final

2012/0025 (COD)

Proposal for a

DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

amending Directive 2001/83/EC as regards pharmacovigilance

(Text with EEA relevance)

EXPLANATORY MEMORANDUM

The Commission presents a proposal for a Directive of the European Parliament and of the Council amending, as regards pharmamacovigilance, Directive 2001/83/EC. It is complemented by parallel changes to Regulation (EC) No 726/2004.

1. CONTEXT OF THE PROPOSAL

On 15 December 2010, the European Parliament and the Council adopted Directive 2010/84/EU and Regulation (EU) No 1235/2010 ("2010 pharmacovigilance legislation") amending respectively, as regards pharmacovigilance, Directive 2001/83/EC and Regulation (EC) No 726/2004. The new legislation shall apply in July 2012.

The adopted measures have substantially strengthened the legal framework for the surveillance of medicinal products, with provisions that reinforce the coordinating role of the European Medicines Agency, the possibilities for signal detection, and the operation of coordinated procedures at European level to respond to safety concerns.

However, recent pharmacovigilance events in the European Union, in particular the so-called “Mediator case”, have shown the need for a further improvement of the pharmacovigilance system.

Following an analysis of the Mediator case in the light of the 2010 pharmacovigilance legislation ("Stress test"), the Commission has detected certain weaknesses in the pharmacovigilance system which should be addressed.

In particular, Directive 2001/83/EC provides for an automatic assessment at Union level when specific serious safety issues have been identified with regard to nationally authorised products. In the 2010 pharmacovigilance legislation, changes to the Commission's proposal during co-decision have led to the automatism being lost, as the initiation of the procedure is linked to an appreciation by the Member State or the Commission as to whether an urgent action is considered necessary. Thus, when a Member State considers suspending, revoking or refusing renewal of a marketing authorisation, but does not consider that urgent action is needed, no evaluation of the safety concern will be conducted at Union level.

Moreover, marketing authorisation holders are not required to declare the reasons for the withdrawal of a marketing authorisation or product. Therefore, it cannot be ruled out that voluntary withdrawal of a marketing authorisation or product by the marketing authorisation holder could lead to safety issues being missed, in particular if the company is not transparent about possible safety concerns.

Finally, the public list of medicinal product subject to additional monitoring provided for in Article 23 of Regulation (EC) No 726/2004 will include certain medicinal products subject to post-authorisation safety conditions. Those products will be included in the list, following consultation with the Pharmacovigilance Risk Assessment Committee, only if the Commission or a Member States' competent authorities make a request. Therefore, competent authorities will have to decide on a

case-by-case basis whether to make public the fact that products are subject to strengthened surveillance.

2. OBJECTIVE OF THE COMMISSION'S PROPOSALS

The general policy objectives of the proposals to amend Directive 2001/83/EC and Regulation (EC) No 726/2004 are in line with the overall objectives of the EU pharmaceutical legislation. These are intended to ensure the proper functioning of the internal market for medicinal products for human use and to better protect health of EU citizens. Following this line, the proposals aim specifically to address weaknesses identified in the EU pharmacovigilance system and provide for more transparency and efficiency of the system in cases where safety concerns are identified.

3. EXPLANATORY DOCUMENTS ACCOMPANYING THE NOTIFICATION OF TRANSPOSITION MEASURES AND BUDGETARY IMPLICATION

As the proposed Directive aims to amend only a very limited number of legal obligations of Directive 2001/83/EC, correlation tables or other explanatory documents are not required to accompany the notification of transposition measures by the Member States.

The proposals have no implication for the budget of the Union.

The proposals only make minor adjustments to the system set forth by the 2010 pharmacovigilance legislation. They do not require additional human or administrative resources for the functioning of the pharmacovigilance system.

2012/0025 (COD)

Proposal for a

DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

amending Directive 2001/83/EC as regards pharmacovigilance

(Text with EEA relevance)

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[1],

Having regard to the opinion of the European Economic and Social Committee[2],

Having regard to the opinion of the Committee of the Regions[3],

Acting in accordance with the ordinary legislative procedure,

Whereas:

(1) Recent pharmacovigilance events in the Union have shown the need for an automatic procedure at Union level in the 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 nationally authorised products should be clarified.

(2) In addition, voluntary action by the marketing authorisation holder should not lead to a situation where concerns related to the risks or benefits of a medicinal product authorised in the Union are not properly addressed in all Member States. Therefore, provisions should be made for the marketing authorisation holder to inform competent authorities of the reasons for the withdrawal of a medicinal product, for interrupting the placing on the market of a medicinal product, for requests for revoking a marketing authorisation, or for not renewing a marketing authorisation.

(3) Directive 2001/83/EC should therefore be amended accordingly.

(4) Since the objective of this Directive to harmonise the rules on pharmacovigilance across the Union cannot be sufficiently achieved by the Member States and can

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1 OJ C , , p. .
2 OJ C , , p. .
3 OJ C , , p. .

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. 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 this objective,

HAVE ADOPTED THIS DIRECTIVE:

Article 1

Directive 2001/83/EC is amended as follows:

(1) In Article 23a, the second subparagraph is replaced by the following:

"The holder shall also notify the competent authority if the product ceases to be placed on the market of the Member State, either temporarily or permanently. Such notification shall, otherwise than in exceptional circumstances, be made no less than two months before the interruption in the placing on the market of the product. The holder shall inform the competent authorities of the reasons for such action in accordance with Article 123."

(2) Article 31 is replaced by the following:

"Article 31

1. The Member States, the Commission, the applicant or the marketing authorisation holder shall, in specific cases where the interests of the Union are involved, refer the matter to the Committee for application of the procedure laid down in Articles 32, 33 and 34 before any decision is reached on an application for a marketing authorisation or on the suspension or revocation of a marketing authorisation, or on any other variation of the marketing authorisation which appears necessary.

Where the referral results from the evaluation of data relating to pharmacovigilance of an authorised medicinal product, the matter shall be referred to the Pharmacovigilance Risk Assessment Committee and Article 107j(2) may be applied. The Pharmacovigilance Risk Assessment Committee shall issue a recommendation according to the procedure laid down in Article 32. The final recommendation shall be forwarded to the Committee for Medicinal Products for Human Use or to the coordination group, as appropriate, and the procedure laid down in Article 107k shall apply.

However, where one of the criteria listed in Article 107i(1) is met, the procedure laid down in Articles 107i to 107k shall apply.

2. Where the referral to the Committee concerns a range of medicinal products or a therapeutic class, the Agency may limit the procedure to certain specific parts of the authorisation.

In that event, Article 35 shall apply to those medicinal products only if they were covered by the authorisation procedures referred to in this Chapter.

Where the scope of the procedure initiated under this Article concerns a range of medicinal products or therapeutic class, medicinal products authorised in accordance with Regulation (EC) No 726/2004 which belong to that range or class shall also be included in the procedure."

(3) In Article 34(3), the following subparagraph is added:

"Where the scope of the procedure includes medicinal products authorised in accordance with Regulation (EC) No 726/2004 pursuant to the third subparagraph of Article 31(2) of this Directive, the Commission shall where necessary adopt decisions to vary, suspend, revoke or refuse renewal of the marketing authorisations concerned."

(4) Article 107i(1) is replaced by the following:

"1. A Member State or the Commission, as appropriate, shall initiate the procedure provided for in this section, by informing the other Member States, the Agency and the Commission, in any of the following cases:

(a) it considers suspending or revoking a marketing authorisation;

(b) it considers prohibiting the supply of a medicinal product;

(c) it considers refusing the renewal of a marketing authorisation;

(d) it is informed by the marketing authorisation holder that, on the basis of safety concerns, he has interrupted the placing on the market of a medicinal product or has taken action to have a marketing authorisation withdrawn, or that he intends to do so or has not applied for the renewal of a marketing authorisation;

(e) it considers that a new contraindication, a reduction in the recommended dose, or a restriction to the indications is necessary.

The Agency shall verify whether the safety concern relates to medicinal products other than the one covered by the information, or whether it is common to all products belonging to the same range or therapeutic class.

Where the medicinal product involved is authorised in more than one Member State, the Agency shall without undue delay inform the initiator of the procedure of the outcome of this verification, and the procedures laid down in Articles 107j and 107k shall apply. Otherwise, the safety concern shall be addressed by the Member State concerned. The Agency or the Member State, as applicable, shall make information that the procedure has been initiated available to marketing authorisation holders."

(5) Article 123(2) is replaced by the following:

"2. The marketing authorization holder shall be obliged to notify 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. The marketing authorisation holder shall in particular declare if such action is linked to any of the grounds set out

in Articles 116 and 117. In such case, Member States shall ensure that this information is brought to the attention of the Agency."

Article 2

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by [*12 months after publication in the Official Journal; exact date inserted at time of publication*] at the latest. They shall forthwith communicate to the Commission the text of those provisions.

   When Member States adopt those provisions, they shall contain a reference to this Directive or be accompanied by such a reference on the occasion of their official publication. Member States shall determine how such reference is to be made.

2. Member States shall communicate to the Commission the text of the main provisions of national law which they adopt in the field covered by this Directive.

Article 3

This Directive shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

Article 4

This Directive is addressed to the Member States.

Done at Brussels, 10.2.2012

For the European Parliament	*For the Council*
The President	*The President*