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PROPOSAL

from:	European Commission
dated:	13 February 2012
No Cion doc.:	COM(2012) 51 final
Subject:	Proposal for a Regulation of the European Parliament and of the Council amending Regulation (EC) No 726/2004 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) 51 final

EUROPEAN COMMISSION

Brussels, 10.2.2012
COM(2012) 51 final

2012/0023 (COD)

Proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

amending Regulation (EC) No 726/2004 as regards pharmacovigilance

(Text with EEA relevance)

EXPLANATORY MEMORANDUM

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

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 to reinforce the coordinating role of the 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. BUDGETARY IMPLICATION

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

The proposals only make minor changes 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.

2012/0023 (COD)

Proposal for a

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amending Regulation (EC) No 726/2004 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) In order to ensure transparency on the surveillance of authorised medicinal products, the list of medicinal products subject to additional monitoring established by Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency[4], as amended by Regulation (EU) No 1235/2010[5], should systematically include medicinal products that are subject to post-authorisation safety conditions.

(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 the Agency 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.

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1 OJ C , , p. .
2 OJ C , , p. .
3 OJ C , , p. .
4 OJ L 136, 30.4.2004, p. 1.
5 OJ L 348, 31.12.2010, p. 1.

(3) Regulation (EC) No 726/2004 should therefore be amended accordingly.

(4) Since the objective of this Regulation, namely to provide for specific rules on pharmacovigilance and improve the safety of medicinal products for human use authorised pursuant to Regulation (EC) No 726/2004 cannot be sufficiently achieved by Member States and can 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 Regulation does not go beyond what is necessary in order to achieve this objective,

HAVE ADOPTED THIS REGULATION:

Article 1

Regulation (EC) No 726/2004 is amended as follows:

(1) In Article 13(4), the second subparagraph is replaced by the following:

"The holder shall also notify the Agency 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 Agency of the reasons for such action in accordance with Article 14b."

(2) The following Article 14b is inserted:

"Article 14b

The marketing authorization holder shall notify the Agency 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 of Directive 2001/83/EC.

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

(3) Article 20(8) is replaced by the following:

"8. Where the procedure results from the evaluation of data relating to pharmacovigilance, the opinion of the Agency in accordance with paragraph 2 of this Article shall be adopted by the Committee for Medicinal Products for Human Use on the basis of a recommendation from the Pharmacovigilance Risk Assessment Committee and Article 107j(2) of Directive 2001/83/EC shall apply."

(4) Article 23 is replaced by the following:

"Article 23

1. The Agency shall, in collaboration with the Member States, set up, maintain and make public a list of medicinal products that are subject to additional monitoring.

That list shall include the names and active substances of:

(a) medicinal products authorised in the Union that contain a new active substance which, on 1 January 2011, was not contained in any medicinal product authorised in the Union;

(b) any biological medicinal product not covered by point (a) that was authorised after 1 January 2011;

(c) medicinal products that are authorised pursuant to this Regulation subject to conditions referred to in points (c), (ca), (cb) and (cc) of Article 9(4), or in Article 10a, Article 14(7) and (8) and in Article 21(2);

(d) medicinal products that are authorised pursuant to Directive 2001/83/EC, subject to the conditions referred to in Articles 21a, 22, 22a and 104a of that Directive.

2. The list referred to in paragraph 1 shall include an electronic link to the product information and to the summary of the risk management plan.

3. In the cases referred to in points (a) and (b) of paragraph 1 of this Article, the Agency shall remove a medicinal product from the list five years after the Union reference date referred to in Article 107c(5) of Directive 2001/83/EC.

In the cases referred to in points (c) and (d) of paragraph 1, the Agency shall remove a medicinal product from the list once the conditions have been fulfilled.

4. For medicinal products included in that list, the summary of product characteristics and the package leaflet shall include the statement “This medicinal product is subject to additional monitoring”. That statement shall be preceded by a black symbol which shall be selected by the Commission following a recommendation of the Pharmacovigilance Risk Assessment Committee by 2 January 2012, and shall be followed by an appropriate standardised explanatory sentence."

Article 2

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

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 10.2.2012

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