



# EUROPEAN UNION

THE EUROPEAN PARLIAMENT

THE COUNCIL

Brussels, 3 October 2012  
(OR. en)

2012/0025 (COD)

PE-CONS 43/1/12  
REV 1

MI 468  
PHARM 59  
SAN 171  
ECO 99  
ENT 166  
CODEC 1830  
OC 374

## LEGISLATIVE ACTS AND OTHER INSTRUMENTS

Subject: DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF  
THE COUNCIL amending Directive 2001/83/EC, as regards  
pharmacovigilance  
**COMMON GUIDELINES**  
**Consultation deadline for Croatia: 3.10.2012**

**DIRECTIVE 2012/.../EU**  
**OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL**

**of ...**

**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,

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

Having regard to the opinion of the European Economic and Social Committee<sup>1</sup>,

After consulting the Committee of the Regions,

Acting in accordance with the ordinary legislative procedure<sup>2</sup>,

---

<sup>1</sup> OJ C 181, 21.6.2012, p. 201.

<sup>2</sup> Position of the European Parliament of 11 September 2012 (not yet published in the Official Journal) and decision of the Council of ....

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<sup>1</sup>, 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.

---

<sup>1</sup> OJ L 311, 28.11.2001, p. 67.

- (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:

## *Article 1*

Directive 2001/83/EC is hereby amended as follows:

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

"If the product ceases to be placed on the market of a Member State, either temporarily or permanently, the marketing authorisation holder shall notify the competent authority of that Member State. 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 marketing authorisation holder shall inform the competent authority of the reasons for such action in accordance with Article 123(2)."

- (2) Article 31 is amended as follows:

- (a) In paragraph 1, the third subparagraph is replaced by the following:

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

(b) Paragraph 2 is replaced by the following:

"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 a 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. Without prejudice to paragraph 1, a Member State may, where urgent action is necessary to protect public health at any stage of the procedure, suspend the marketing authorisation and prohibit the use of the medicinal product concerned on its territory until a definitive decision is adopted. It shall inform the Commission, the Agency and the other Member States no later than the following working day of the reasons for its action.

4. Where the scope of the procedure initiated under this Article, as determined in accordance with paragraph 2, includes medicinal products authorised in accordance with Regulation (EC) No 726/2004, the Commission may, where urgent action is necessary to protect public health at any stage of the procedure, suspend the marketing authorisations and prohibit the use of the medicinal products concerned until a definitive decision is adopted. The Commission shall inform the Agency and the Member States no later than the following working day of the reasons for its action."

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

"Where the scope of the procedure initiated under Article 31 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 or revoke the marketing authorisations or to refuse the renewal of the marketing authorisations concerned."

(4) In Article 37, the words "Articles 35 and 36 shall apply" are replaced by the words "Article 35 shall apply".



(5) Article 63 is amended as follows:

(a) In paragraph 1, the first subparagraph is replaced by the following:

"The particulars for labelling listed in Articles 54, 59 and 62 shall appear in an official language or official languages of the Member State where the medicinal product is placed on the market, as specified, for the purposes of this Directive, by that Member State.";

(b) In paragraph 2, the first subparagraph is replaced by the following:

"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, as specified, for the purposes of this Directive, by that Member State.";

(c) Paragraph 3 is replaced by the following:

"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, as specified, for the purposes of this Directive, by that Member State."

(6) Article 85a is replaced by the following:

*"Article 85a*

In the case of wholesale distribution of medicinal products to third countries, Article 76 and point (c) of Article 80 shall not apply. Moreover, points (b) and (ca) of Article 80 shall not apply where a product is directly received from a third country but not imported.

However, 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. Where wholesale distributors supply medicinal products to persons in third countries, they shall ensure that such supplies are only made to persons who are authorised or entitled to receive medicinal products for wholesale distribution or supply to the public in accordance with the applicable legal and administrative provisions of the third country concerned. The requirements set out in Article 82 shall apply to the supply of medicinal products to persons in third countries authorised or entitled to supply medicinal products to the public."

(7) In Article 107i, paragraph 1 is replaced by the following:

"1. A Member State or the Commission, as appropriate, shall, on the basis of concerns resulting from the evaluation of data from pharmacovigilance activities, initiate the procedure provided for in this section by informing the other Member States, the Agency and the Commission where:

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

- 1a. A Member State or the Commission, as appropriate, shall, on the basis of concerns resulting from the evaluation of data from pharmacovigilance activities, inform the other Member States, the Agency and the Commission where it considers that a new contraindication, a reduction in the recommended dose or a restriction to the indications of a medicinal product is necessary. The information shall outline the action considered and the reasons therefor.

Any Member State or the Commission, as appropriate, shall, when urgent action is considered necessary, initiate the procedure provided for in this section in any of the cases referred to in this paragraph.

Where the procedure provided for in this section is not initiated, for medicinal products authorised in accordance with the procedures laid down in Chapter 4 of Title III, the case shall be brought to the attention of the coordination group.

Article 31 is applicable where the interests of the Union are involved.

- 1b. Where the procedure provided for in this section is initiated, 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."

- (8) In Article 107i(2) the words "paragraph 1 of this Article" are replaced by the words "paragraphs 1 and 1a of this Article".
- (9) In the second subparagraph of Article 107i(3) the words "in accordance with paragraph 1" are replaced by the words "in accordance with paragraphs 1 and 1a".
- (10) In Article 107i(5) the words "in paragraph 1" are replaced by the words "in paragraphs 1 and 1a".
- (11) In Article 107j(1) the words "in Article 107i(1)" are replaced by the words "in paragraphs 1 and 1a of Article 107i".

(12) Article 123 is amended as follows:

(a) paragraph 2 is replaced by the following:

- "2. The marketing authorisation holder shall be obliged to notify the Member States concerned forthwith of any action taken by the holder 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 based on any of the grounds set out in Article 116 and Article 117(1).
- 2a. The marketing authorisation holder shall also make the notification pursuant to paragraph 2 of this Article in cases where the action is taken in a third country and where such action is based on any of the grounds set out in Article 116 and Article 117(1).
- 2b. The marketing authorisation holder shall furthermore notify the Agency where the action referred to in paragraph 2 or 2a of this Article is based on any of the grounds referred to in Article 116 or Article 117(1).
- 2c. The Agency shall forward notifications received in accordance with paragraph 2b to all Member States without undue delay.";

(b) paragraph 4 is replaced by the following:

"4. Each year, the 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."

### *Article 2*

1. Member States shall adopt and publish the laws, regulations and administrative provisions necessary to comply with this Directive by ...\* at the latest. They shall forthwith communicate to the Commission the text of those provisions.

They shall apply those provisions from ...\* .

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.

---

\* OJ: please, insert the date: 12 months after the date of publication of this Directive in the Official Journal.



*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 ...

*For the European Parliament*

*The President*

*For the Council*

*The President*

---