REGULATION (EU) No 1027/2012 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL
of 25 October 2012
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,

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) 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 authori-
sation and supervision of medicinal products for
human and veterinary use and establishing a European
Medicines Agency (3), should systematically include
medicinal products that are subject to certain post-auth-
­orisation safety conditions.

(2) In addition, voluntary action by the marketing authori-
­sation 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 European Medicines Agency (3), should systematically include medicinal products that are subject to certain post-authorisation safety conditions.

(3) 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

(4) Regulation (EC) No 726/2004 should therefore be
amended accordingly,

HAVE ADOPTED THIS REGULATION:

Article 1

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

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

‘The marketing authorisation holder shall notify the Agency
if the product ceases to be placed on the market of a
Member State, either temporarily or permanently. Such
notification shall, other 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 Agency of the reasons
for such action in accordance with Article 14b.’;

(2) the following Article is inserted:

‘Article 14b

1. The marketing authorisation holder shall notify the Agency
forthwith of any action the holder takes 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 or
Article 117(1) of Directive 2001/83/EC.

2. The marketing authorisation holder shall also make
the notification pursuant to paragraph 1 of this Article if
the action is taken in a third country and such action is
based on any of the grounds set out in Article 116 or
Article 117(1) of Directive 2001/83/EC.

3. In the cases referred to in paragraphs 1 and 2, the Agency
shall forward the information to the competent
authorities of the Member States without undue delay;

(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.
'8. Where the procedure is initiated as a result of 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 the conditions referred to in point (cb) of Article 9(4), point (a) of the first subparagraph of Article 10a(1) or Article 14(7) or (8);

(d) medicinal products that are authorised pursuant to Directive 2001/83/EC, subject to the conditions referred to in points (b) and (c) of the first paragraph of Article 21a, Article 22, or point (a) of the first subparagraph of Article 22a(1) thereof.

1a. At the request of the Commission, following consultation with the Pharmacovigilance Risk Assessment Committee, medicinal products that are authorised pursuant to this Regulation, subject to the conditions referred to in points (c), (ca) or (cc) of Article 9(4), point (b) of the first subparagraph of Article 10a(1) or Article 21(2), may also be included in the list referred to in paragraph 1 of this Article.

At the request of a national competent authority, following consultation with the Pharmacovigilance Risk Assessment Committee, medicinal products that are authorised pursuant to Directive 2001/83/EC, subject to the conditions referred to in points (a), (d), (e) or (f) of the first paragraph of Article 21a, point (b) of the first subparagraph of Article 22a(1) or Article 104a(2) thereof, may also be included in the list referred to in paragraph 1 of this Article.

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 and in paragraph 1a of this Article, the Agency shall remove a medicinal product from the list once the conditions have been fulfilled.

4. For medicinal products included in the list referred to in paragraph 1, 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 by 2 July 2013, following a recommendation of the Pharmacovigilance Risk Assessment Committee, and shall be followed by an appropriate standardised explanatory sentence.

4a. By 5 June 2018, the Commission shall present to the European Parliament and the Council a report on the use of the list referred to in paragraph 1 based on the experience and data provided by the Member States and the Agency.

The Commission shall, if appropriate, on the basis of that report, and after consultation with the Member States and other appropriate stakeholders, present a proposal in order to adjust the provisions relating to the list referred to in paragraph 1:

(5) Article 57 is amended as follows:

(a) in the second subparagraph of paragraph 1, points (c) and (d) are replaced by the following:

'(c) coordinating the monitoring of medicinal products which have been authorised within the Union and providing advice on the measures necessary to ensure the safe and effective use of those medicinal products, in particular by coordinating the evaluation and implementation of pharmacovigilance obligations and systems and the monitoring of such implementation;

(d) ensuring the collation and dissemination of information on suspected adverse reactions to medicinal products authorised in the Union by means of a database which is permanently accessible to all Member States;'

(b) in the second subparagraph of paragraph 2, point (b) is replaced by the following:

'(b) marketing authorisation holders shall, by 2 July 2012 at the latest, electronically submit to the Agency information on all medicinal products for human use authorised in the Union, using the format referred to in point (a));'

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.
It shall apply from 5 June 2013 with the exception of Article 23(4), points (c) and (d) of the second subparagraph of Article 57(1) and point (b) of the second subparagraph of Article 57(2) of Regulation (EC) No 726/2004, as amended by this Regulation, which shall apply from 4 December 2012.

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

Done at Strasbourg, 25 October 2012.

For the European Parliament
The President
M. SCHULZ

For the Council
The President
A. D. MAVROYIANNIS