AMENDMENTS 001-007
by the Committee on the Environment, Public Health and Food Safety

Report
Linda McAvan **A7-0164/2012**
Pharmacovigilance (amendment of Regulation (EC) No 726/2004)

Proposal for a regulation (COM(2012)0051 – C7-0034/2012 – 2012/0023(COD))

Amendment 1

Proposal for a regulation
Recital 1

Text proposed by the Commission	*Amendment*
(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, as amended by Regulation (EU) No 1235/2010, should systematically include medicinal products that are subject to post-authorisation safety conditions.	(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, as amended by Regulation (EU) No 1235/2010, should systematically include medicinal products that are subject to ***certain*** post-authorisation safety conditions.

Amendment 2

Proposal for a regulation
Article 1 – point 4
Regulation (EC) No 726/2004
Article 23 – paragraph 1 – points c and d

Text proposed by the Commission	*Amendment*
(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)***;	(c) medicinal products that are authorised pursuant to this Regulation subject to conditions referred to in points (cb) and (cc) of Article 9(4), or in Article 10a ***and*** Article 14(7) and (8);
(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;	(d) medicinal products that are authorised pursuant to Directive 2001/83/EC, subject to the conditions referred to in ***points (b), (c) and (f) of Article*** 21a, ***or in Articles*** 22, ***and*** 22a of that Directive;

Justification

The list of products subject to additional monitoring should only include products subject to the most serious conditions and safety concerns, as otherwise the list becomes too long and loses meaning.

It should automatically include all new products containing new active substances, as well as all new biosimilars, for the first five years. It should also automatically include any products subject to:

– *a PASS (as was the case for Mediator)*[1]*;*

– *a PAES* [2]*;*

– *stricter-than-normal rules on ADR reporting*[3]*;*

– *a "conditional market authorisation" (i.e. for unmet medical need)* [4]

– *an "exceptional market authorisation" (i.e. for orphan diseases)*[5]

Products subject to any other conditions should only be included at the discretion of Member States and the Commission, after consultation of the PRAC.

[1] Regulation articles 9(4)cb and 10a, and Directive articles 21a(b) and 22a.
[2] Regulation articles 9(4)cc and 10a, and Directive articles 21a(f) and 22a.
[3] Regulation article 9(4)cb and Directive article 21a(c).
[4] Regulation article 14(7).
[5] Regulation article 14(8) and Directive article 22.

Amendment 3

Proposal for a regulation
Article 1 – point 4
Regulation (EC) No 726/2004
Article 23 – paragraph 1 a (new)

Text proposed by the Commission	*Amendment*
	1a. At the request of the Commission, following consultation with the Pharmacovigilance Risk Assessment Committee, medicinal products that are authorised pursuant to this Regulation may, subject to conditions referred to in points (c) and (ca) of Article 9(4) and in Article 21(2), also be included in the list.
	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 may, subject to the conditions referred to in points (d) and (e) of Article 21a, and Article 104a of that Directive, also be included in the list.

Justification

The list of products subject to additional monitoring should only include products subject to the most serious conditions and safety concerns, as otherwise the list becomes too long and loses meaning.

It should automatically include all new products containing new active substances, as well as all new biosimilars, for the first five years. It should also automatically include any products subject to:

– *a PASS (as was the case for Mediator)*[1]*;*

– *a PAES* [2]*;*

– *stricter-than-normal rules on ADR reporting*3*;*

– *a "conditional market authorisation" (i.e. for unmet medical need)* 4

– *an "exceptional market authorisation" (i.e. for orphan diseases)*[5]

Products subject to any other conditions should only be included at the discretion of Member

1 Regulation articles 9(4)cb and 10a, and Directive articles 21a(b) and 22a.
2 Regulation articles 9(4)cc and 10a, and Directive articles 21a(f) and 22a.
3 Regulation article 9(4)cb and Directive article 21a(c).
4 Regulation article 14(7).
5 Regulation article 14(8) and Directive article 22.

States and the Commission, after consultation of the PRAC.

Amendment 4

Proposal for a regulation
Article 1 – point 4
Regulation (EC) No 726/2004
Article 23 – paragraph 4

Text proposed by the Commission	*Amendment*
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.	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 July 2013***, and shall be followed by an appropriate standardised explanatory sentence.

Justification

This amendment corrects a drafting mistake in the current legislation. The PRAC is not constituted until July 2012, and so the 12 month deadline should start from then.

Amendment 5

Proposal for a regulation
Article 1 – point 4 a (new)
Regulation (EC) No 726/2004
Article 67 – paragraph 3 – subparagraph 2 a (new)

Text proposed by the Commission	*Amendment*
	(4a) In Article 67(3) the following subparagraphs are added:
	"By way of derogation from Article 70(1), fees that are required for services provided by the Agency as regards activities relating to pharmacovigilance and by the coordination group as regards the fulfilment of its tasks referred to in the first subparagraph shall be specified by the Commission.
	For this purpose the Commission shall,

	after consultation with the Agency, adopt by means of delegated acts, in accordance with Article 87ba, and subject to the conditions of Articles 87c and 87d, measures supplementing the third subparagraph as regards the structure and the level of those fees.".

Justification

In order to ensure full implementation of the new provisions related to pharmacovigilance, it is urgent to empower the European Medicines Agency to charge fees to marketing authorisation holders for the fulfilment of the pharmacovigilance tasks.

Consequently, the Commission should be empowered to adopt a delegated act in accordance with Article 290 TFEU in order to supplement the provisions in Article 67(3) as regards services provided by the Agency or the coordination group with respect to pharmacovigilance.

Amendment 6

Proposal for a regulation
Article 1 – point 4 b (new)
Regulation (EC) No 726/2004
Article 87b – paragraph 1 a (new)

Text proposed by the Commission	*Amendment*
	(4b) In Article 87b, the following paragraph is inserted:
	"1a. The power to adopt the delegated acts referred to in Article 67(3) shall be conferred on the Commission for a period of 5 years from 1 July 2012. The Commission shall draw up a report in respect of the delegated powers not later than 6 months before the end of the 5 year period. The delegation of powers shall be automatically extended for periods of an identical duration, unless the European Parliament or the Council revokes it in accordance with Article 87c.".

Amendment 7

Proposal for a regulation
Article 1 – point 4 c (new)
Regulation (EC) No 726/2004
Article 87c – paragraph 1

Text proposed by the Commission	*Amendment*
	(4c) Article 87c(1) is replaced by the following:
	"1. The delegation of powers referred to in Article 10b *and Article 67(3)* may be revoked at any time by the European Parliament or by the Council.".