EUROPEAN PARLIAMENT 2009 - 2014

Committee on the Internal Market and Consumer Protection

2008/0257(COD)

24.2.2010

OPINION

of the Committee on the Internal Market and Consumer Protection

for the Committee on the Environment, Public Health and Food Safety

on the proposal for a regulation of the European Parliament and of the Council amending, as regards pharmacovigilance of medicinal products for human use, Regulation (EC) No 726/2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency
(COM(2008)0664 – C6-0515/2008 – 2008/0257(COD))

Rapporteur: Claude Turmes

SHORT JUSTIFICATION

Medicinal products contribute considerably to the health of EU citizens. They can however also have adverse effects, leading to about 5% of all hospital admissions according to the European Commission (underreporting does however not allow for accurate estimates). The rofecoxib (Vioxx) case, an anti-inflammatory that was withdrawn of the market in 2004 because of increased cardiovascular risks (more than 30.000 estimated strokes in the US, some of which were fatal) permitted to raise awareness about the need to strengthen pharmacovigilance.

Pharmacovigilance is the process and science of monitoring the safety of medicines, including the collection and management of data on the safety of medicines, the assessment of that data to detect whether there is a safety issue, action to address the possible safety issue including informing on this issue, and the evaluation of the procedure followed and results obtained.

As regards centrally authorised medicines the pharmacovigilance procedure is laid down by Regulation 726/2004. As regards nationally authorised medicinal products the procedure is laid down by Directive 2001/83. This opinion concerns the amendments to Regulation 726/2004.

The Commission wishes to improve the current system of pharmacovigilance by clarifying the roles of the various actors involved, simplifying procedures, enhanced transparency and communication, better data collection and evaluation procedures, more involvement of stakeholders and the establishment of best practices.

Though the rapporteur for opinion welcomes the proposal, he is of the view that there is a room for further improvement, mainly with regard to consumer protection issues, transparency and data protection**.** He therefore proposes amendments along the following lines:

- The processing of personal data of users of medication taking place at several stages of the pharmacovigilance process, should take place in accordance with the data protection principles laid down by Directive 95/46/EC.
- The proposed summary of essential information about the safe and effective use of medicines should be rejected since the concept of 'essential information' is misleading and might be misunderstood.
- Patient reports can bring a new contribution to the understanding of adverse drug reactions (ADR) as it was the case for paroxetine (Deroxat/Seroxat), an antidepressant which was found, thanks to patient reports, to increase the risk of suicides and to cause a deprivation syndrome (“electric head”) if the patients wanted to stop their treatment.
- Consumers should report directly to national authorities. Decentralised reporting systems whereby communication of all adverse drug reactions (reported whether by patients, health professionals and pharmaceutical companies) to the European database is coordinated at a national level, increase the safety for data protection and guarantees the quality of the data which are registered at the European level. Proximity also allows national health authorities to:
  - investigate the reports to add valuable information whereby they apply their particular expertise,

- to have a clear view of the adverse effects occurring on their territory,
- and to make this information accessible to their country's population in its own language (as the UK and the Netherlands already do).

- Consumers and Healthcare professionals should also have full access to the central European Eudravigilance database in order to prevent the repetition of preventable adverse drug reactions by making validated information easily available. It is an effective way to tackle inequalities of information on adverse drug reactions among Member States. This public access to Eudravigilance is needed to restore citizens' trust in health authorities' capacity to protect public health.
- The use of a web format for reporting should be supplemented by other means, such as mail, fax and phone as it is the case in the US and in the UK, in order to not exclude those who do not have access to or cannot use the internet and to improve patient reporting.
- All assessment reports concerning a medication in the framework of the national and European pharmacovigilance systems should be available to the public. When an overriding public interest is at stake, as it is the case concerning pharmacovigilance data, full disclosure has always to be guaranteed.
- The funding of the pharmacovigilance systems should remain public as recognition of the public authorities' responsibility to protect their populations, and in order to guarantee their independency.

AMENDMENTS

The Committee on the Internal Market and Consumer Protection calls on the Committee on the Environment, Public Health and Food Safety, as the committee responsible, to incorporate the following amendments in its report:

Amendment 1

Proposal for a regulation – amending act
Recital 7

Text proposed by the Commission	*Amendment*
(7) In order to ensure the availability of the necessary expertise and resources for pharmacovigilance assessments at Community level, it is appropriate to create a new scientific committee within the Agency, the Pharmacovigilance ***Risk*** Assessment Advisory Committee. That committee should be composed of independent scientific experts with competence in the safety of medicines including the detection, assessment, minimisation and communication of risk, and the design of post-authorisation safety studies and pharmacovigilance audit.	(7) In order to ensure the availability of the necessary expertise and resources for pharmacovigilance assessments at Community level, it is appropriate to create a new scientific committee within the Agency, the Pharmacovigilance ***Risk-Benefit*** Assessment Advisory Committee. That committee should be composed of independent scientific experts with competence in the safety of medicines including the detection, assessment, minimisation and communication of risk, and the design of post-authorisation safety studies and pharmacovigilance audit.

Justification

The name 'Pharmacovigilance Risk Assessment Advisory Committee' is too restrictive and overlooks the need for risk-benefit assessment of medicinal products, instead concentrating on risk analysis alone. After all, the committee's remit includes 'any question relating to (...) pharmacovigilance' (proposal for a regulation, Article 1(12)).

This amendment should be applied throughout the text of the proposal for a regulation.

Amendment 2

Proposal for a regulation – amending act
Article 1 — point 1
Regulation (EC) No 726/2004
Article 5 – paragraph 2

Text proposed by the Commission	*Amendment*
"For the fulfilment of its pharmacovigilance tasks, it shall be assisted by the Pharmacovigilance ***Risk*** Assessment Advisory Committee referred to in Article 56(1)(aa)."	'For the fulfilment of its pharmacovigilance tasks, it shall be assisted by the Pharmacovigilance ***Risk-Benefit*** Assessment Advisory Committee referred to in Article 56(1)(aa).'

Justification

The name 'Pharmacovigilance Risk Assessment Advisory Committee' is too restrictive and overlooks the need for risk-benefit assessment of medicinal products, instead concentrating on risk analysis alone. After all, the committee's remit includes 'any question relating to (...) pharmacovigilance' (proposal for a regulation, Article 1(12)).

This amendment should be applied throughout the text of the proposal for a regulation.

Amendment 3

Proposal for a regulation – amending act
Article 1 – point 11
Regulation (EC) No 726/2004
Article 24 – paragraph 2

Text proposed by the Commission	*Amendment*
2. The Eudravigilance database shall be fully accessible to the competent authorities of the Member States and to the Agency and the Commission. It shall also be accessible to marketing authorisation	2. The Eudravigilance database shall be fully accessible to the competent authorities of the Member States and to the Agency and the Commission. It shall also be accessible to marketing authorisation

holders ***to the extent necessary for them to comply with their pharmacovigilance obligations***.	holders***, healthcare professionals and the public, with personal data protection being guaranteed.***
The Agency shall ensure that health-care professionals and the public have appropriate levels of access to the Eudravigilance database, with personal data protection being guaranteed.	
The data held on the Eudravigilance database shall be made publicly accessible in an aggregated format together with an explanation of how to interpret the data.	The data held on the Eudravigilance database shall be made publicly accessible in an aggregated format together with an explanation of how to interpret the data.

Justification

The Pharmacovigilance system should be entirely transparent in order to guarantee full information of all stakeholders, notably in order to restore patients' and citizens' trust in Health authorities' accountability.

Amendment 4

Proposal for a regulation – amending act
Article 1 – point 11
Regulation (EC) No 726/2004
Article 24 – paragraph 3

Text proposed by the Commission	*Amendment*
3. Individual adverse reaction reports held on the Eudravigilance database may be requested by the public. Those reports shall be provided by the Agency or the national competent authority from which they are requested within 90 days, ***unless disclosure would compromise the anonymity of the subjects of the reports***.	3. Individual adverse reaction reports held on the Eudravigilance database may be requested by the public. Those reports shall be provided by the Agency or the national competent authority from which they are requested within 90 days, ***with personal data protection being guaranteed***.

Justification

The Pharmacovigilance system should be entirely transparent in order to guarantee full information of all stakeholders, notably in order to restore patients' and citizens' trust in Health authorities' accountability. Data protection regulations should be respected.

Amendment 5

Proposal for a regulation – amending act
Article 1 — point 11
Regulation (EC) No 726/2004
Article 25

Text proposed by the Commission	*Amendment*
The Agency, in collaboration with the Member States, shall develop standard web-based structured forms for the reporting of suspected adverse reactions by health-care professionals and patients.	The Agency, in collaboration with the Member States, shall develop standard web-based structured forms for the reporting of suspected adverse reactions by health-care professionals and patients. ***All citizens of the Union shall have the option of submitting online declarations in their mother tongue.*** ***The Agency shall also make available to the public other means for patients to report undesirable effects, such as a dedicated telephone number or special email address.***

Amendment 6

Proposal for a regulation – amending act
Article 1 – point 11
Regulation (EC) No 726/2004
Article 26 – paragraph 1 – point 2

Text proposed by the Commission	*Amendment*
(2) ***a summary*** of each meeting of the committees referred to in points (a) and (aa) of Article 56(1) of this Regulation and the coordination group as regards pharmacovigilance activities;	(2) ***detailed minutes*** of each meeting of the committees referred to in points (a) and (aa) of Article 56(1) of this Regulation and the coordination group as regards pharmacovigilance activities;

Justification

The Pharmacovigilance system should be entirely transparent in order to guarantee full information of all stakeholders, notably in order to restore patients' and citizens' trust in Health authorities' accountability.

Amendment 7

Proposal for a regulation – amending act
Article 1 — point 11
Regulation (EC) No 726/2004
Article 26 — point 3

Text proposed by the Commission	*Amendment*
(3) risk management systems for medicinal products authorised in accordance with this Regulation;	(3) ***a summary of*** risk management systems for medicinal products authorised in accordance with this Regulation;

Justification

Information on national safety web portals should be presented in an easy and understandable way. Technical documents should be presented in a summary format and in lay version. The Package Leaflet (PL) and the Summary of Product Characteristics Additional should also be published in national safety web-portals as they contain basic information on the use of medicines which is key for their safe use.

Amendment 8

Proposal for a regulation – amending act
Article 1 — point 11
Regulation (EC) No 726/2004
Article 26 – point 4 a (new)

Text proposed by the Commission	*Amendment*
	(4a) the most up-to-date electronic version of the package leaflet and summary of product characteristics for all existing and new medicinal products;

Justification

Information on national safety web portals should be presented in an easy and understandable way. Technical documents should be presented in a summary format and in lay version. The Package Leaflet (PL) and the Summary of Product Characteristics Additional should also be published in national safety web-portals as they contain basic information on the use of medicines which is key for their safe use.

Amendment 9

Proposal for a regulation – amending act
Article 1 — point 11
Regulation (EC) No 726/2004
Article 26 – point 4 b (new)

Text proposed by the Commission	*Amendment*
	(4b) a brief document history of changes made to the product information.
	All information on medicines safety web-portals, including all information set out in points 1 to 4b of this Article, shall be presented in a manner that is comprehensible to the general public.

Justification

Information on the EU safety web portal should be presented in an easy and understandable way. While this legislation provides for very detailed information to be published on the European web-portal, it does not include reference to key information to ensure safe use of medicines : This is why the package leaflet, the Summary of Product Characteristics or the European Public Assessment Reports should be made easily accessible to the public. Additionally, a brief document history of changes would allow patients and healthcare professionals to see updates made to product information over time.

Amendment 10

Proposal for a regulation – amending act
Article 1 – point 11
Regulation (EC) No 726/2004
Article 26 – paragraph 1 a (new)

Text proposed by the Commission	*Amendment*
	Before the design and launch of this portal, the Agency consults relevant stakeholders (including patient groups, healthcare professionals and industry representatives) to get their opinion.

Justification

Before the launch of this website, it seems important to consult stakeholders who are involved in the information provided on the portal of the Agency.

Amendment 11

Proposal for a regulation – amending act
Article 1 – point 11
Regulation (EC) No 726/2004
Article 28 – paragraph 4 – subparagraph 1

Text proposed by the Commission	*Amendment*
4. Within 30 days of receipt of the report by the Pharmacovigilance Risk Assessment Advisory Committee, the Committee for Medicinal Products for Human Use shall ***consider the report and*** adopt an opinion on the maintenance, variation, suspension or revocation of the marketing authorisation concerned.	4. Within 30 days of receipt ofthe ***recommendation*** , by the Pharmacovigilance Risk Assessment Advisory Committee, the Committee for Medicinal Products for Human Use *(CHMP)* shall adopt an opinion on the maintenance, variation, suspension or revocation of the marketing authorisation concerned. ***The CHMP shall adopt an opinion that differs from the recommendation of the Pharmacovigilance Risk Assessment Committee, only where there exist strong scientific and public health grounds to do so. The CHMP shall explain such grounds in a justification to be annexed to its opinion. That annex shall also be made available to the public.***

Justification

Bringing it into line with the Agency's new structure, which strictly separates pharmacovigilance from marketing authorisations.

Amendment 12

Proposal for a regulation – amending act
Article 1 – point 11
Regulation (EC) No 726/2004
Article 28 – paragraph 6

Text proposed by the Commission	*Amendment*
6. The opinions and decisions referred to in paragraphs 3 to 5 of this Article shall be made public by means of the European medicines safety web-portal referred to in Article 26.	6. The ***assessment reports,*** opinions and decisions referred to in paragraphs 3 to 5 of this Article shall be made public by means of the European medicines safety web-portal referred to in Article 26.

Justification

Bringing it into line with the Agency's new structure, which strictly separates pharmacovigilance from marketing authorisations.

Amendment 13

Proposal for a regulation – amending act
Article 1 – point 18 - point a
Regulation (EC) No 726/2004
Article 67 – paragraph 3

Text proposed by the Commission	*Amendment*
"The Agency's revenue shall consist of a contribution from the Community and fees paid by undertakings for obtaining and maintaining Community marketing authorisations and for other services provided by the Agency or the coordination group as regards the fulfilment of its tasks in accordance with in accordance with Articles 107c, 107e, 107g, 107l and 107r of Directive 2001/83/EC."	"The Agency's revenue shall consist of a contribution from the Community and fees paid by undertakings for obtaining and maintaining Community marketing authorisations and for other services provided by the Agency or the coordination group as regards the fulfilment of its tasks in accordance with in accordance with Articles 107c, 107e, 107g, 107l and 107r of Directive 2001/83/EC ***and 28b of this Regulation. The budgetary authority, composed of the European Parliament and the Council, shall re-examine, as necessary, the level of the Community contribution on the basis of an evaluation of needs and taking account of the level of fees****."*

Justification

The agency has to have enough financial contributions in order to be able to fulfil its important tasks.

Amendment 14

Proposal for a regulation – amending act
Article 1 – point 18 - point b
Regulation (EC) No 726/2004
Article 67 – paragraph 4

Text proposed by the Commission	*Amendment*
"4. Activities relating to	"4. Activities relating to

pharmacovigilance, to the operation of communications networks and to market surveillance shall be under the permanent control of the Management Board in order to guarantee the independence of the Agency. This shall not preclude the collection of fees to be paid by marketing authorisation holders for the carrying out of these activities by the Agency."	pharmacovigilance, to the operation of communications networks and to market surveillance shall be under the permanent control of the Management Board ***and shall receive public funding,*** in order to guarantee the independence of the Agency. This shall not preclude the collection of fees to be paid by marketing authorisation holders for the carrying out of these activities by the Agency."

Justification

Public authorities are responsible for funding pharmacovigilance, because they are accountable to protect public health and because they have assumed responsibility for granting authorization.

Amendment 15

Proposal for a regulation – amending act
Article 2 – paragraph 1

Text proposed by the Commission	*Amendment*
1. The requirement for the inclusion of a summary of the essential information necessary to use the medicine safely and effectively in the summary of the product characteristics and the package leaflet provided for in point 3a of Article 11 and in point (aa) of Article 59(1) of Directive 2001/83/EC as amended by Directive …/…/EC, which applies to medicinal products authorised pursuant to Regulation (EC) No 726/2004 by virtue of its Article 9(4)(a) and (d), shall apply to a marketing authorisation granted before the date set out in the second paragraph of Article 3 of this Regulation from renewal of that authorisation or from the expiry of a period of three years starting from that date, whichever is the earliest.	***deleted***

Justification

This amendment is consistent with the rapporteur's amendment to the point 3a of Article 11 and to the point (aa) of Article 59(1) of Directive 2001/83/EC.

PROCEDURE

Title	Pharmacovigilance of medicinal products (amendment of Regulation (EC) No 726/2004)
References	COM(2008)0664 – C6-0515/2008 – 2008/0257(COD)
Committee responsible	ENVI
Opinion by Date announced in plenary	IMCO 19.10.2009
Rapporteur Date appointed	Claude Turmes 28.9.2009
Discussed in committee	2.12.2009 27.1.2010
Date adopted	23.2.2010
Result of final vote	+: 37 –: 0 0: 1
Members present for the final vote	Pablo Arias Echeverría, Adam Bielan, Cristian Silviu Buşoi, Lara Comi, Anna Maria Corazza Bildt, António Fernando Correia De Campos, Jürgen Creutzmann, Christian Engström, Evelyne Gebhardt, Louis Grech, Iliana Ivanova, Philippe Juvin, Sandra Kalniete, Alan Kelly, Eija-Riitta Korhola, Edvard Kožušník, Toine Manders, Tiziano Motti, Zuzana Roithová, Heide Rühle, Matteo Salvini, Christel Schaldemose, Andreas Schwab, Laurence J.A.J. Stassen, Catherine Stihler, Róża, Gräfin von Thun Und Hohenstein, Kyriacos Triantaphyllides, Emilie Turunen, Bernadette Vergnaud, Barbara Weiler
Substitute(s) present for the final vote	Cornelis de Jong, Frank Engel, Ashley Fox, Anna Hedh, Othmar Karas, Morten Løkkegaard, Konstantinos Poupakis, Oreste Rossi, Kerstin Westphal