EUROPEAN PARLIAMENT 2009 - 2014

Plenary sitting

A7-0289/2010

19.10.2010

***I
REPORT

on the proposal for a regulation of the European Parliament and of the Council on amending, as regards information to the general public on medicinal products for human use subject to medical prescription, 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)0662 – C6-0517/2008 – 2008/0255(COD))

Committee on the Environment, Public Health and Food Safety

Rapporteur: Christofer Fjellner

PR_COD_1am

Symbols for procedures

*	Consultation procedure
***	Consent procedure
***I	Ordinary legislative procedure (first reading)
***II	Ordinary legislative procedure (second reading)
***III	Ordinary legislative procedure (third reading)

(The type of procedure depends on the legal basis proposed by the draft act.)

Amendments to a draft act

In amendments by Parliament, amendments to draft acts are highlighted in ***bold italics***. Highlighting in *normal italics* alerts the relevant departments to parts of the draft act which may require correction when the final text is prepared – for instance, obvious errors or omissions in a language version. Suggested corrections of this kind are subject to the agreement of the departments concerned.

The heading for any amendment to an existing act which the draft act seeks to amend includes a third and fourth line identifying respectively the existing act and the provision in that act affected by the amendment. Passages in a provision of an existing act that Parliament wishes to amend, but the draft act has left unchanged, are highlighted in **bold**. Any deletions that Parliament wishes to make in passages of this kind are indicated thus: [...].

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DRAFT EUROPEAN PARLIAMENT LEGISLATIVE RESOLUTION

on the proposal for a regulation of the European Parliament and of the Council on amending, as regards information to the general public on medicinal products for human use subject to medical prescription, 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)0662 – C6-0517/2008 – 2008/0255(COD))

(Ordinary legislative procedure: first reading)

The European Parliament,

– having regard to the Commission proposal to the European Parliament and the Council (COM(2008)0662),

– having regard to Article 251(2) and Article 95 of the EC Treaty, pursuant to which the Commission submitted the proposal to Parliament (C6-517/2008),

– having regard to the communication from the Commission to the European Parliament and the Council entitled: 'Consequences of the entry into force of the Treaty of Lisbon for ongoing interinstitutional decision-making procedures' (COM (2009)0665),

– having regard to Article 294(3), Article 114 and Article 168(4)(c) of the Treaty on the Functioning of the EU,

– having regard to the opinion of the European Economic and Social Committee,

– having regard to the opinion of the Committee of the Regions,

– having regard to Rule 55 of its Rules of Procedure,

– having regard to the report of the Committee on the Environment, Public Health and Food Safety and the opinions of the Committee on Industry, Research and Energy and the Committee on the Internal Market and Consumer Protection (A7-0289/2010),

1. Adopts the position at first reading hereinafter set out;

2. Calls on the Commission to refer the matter to Parliament again if it intends to amend the proposal substantially or replace it with another text;

3. Instructs its President to forward its position to the Council, to the Commission and to the national parliaments.

Amendment 1

Proposal for a regulation – amending act
Recital 1

Text proposed by the Commission	*Amendment*
(1) On 20 December 2007, the Commission submitted a Communication to the European Parliament and the Council concerning the "Report on current practices with regard to the provision of information to patients on medicinal products". The report concludes that Member States have adopted divergent rules and practices with regard to the provision of information, resulting in a situation where patients and the public at large have unequal access to information on medicinal products. Experience gained from the application of the current legal framework has also shown disparities in the interpretation of the *Community* rules on advertising, and between national provisions on information.	(1) On 20 December 2007, the Commission submitted a Communication to the European Parliament and the Council concerning the "Report on current practices with regard to the provision of information to patients on medicinal products". The report concludes that Member States have adopted divergent rules and practices with regard to the provision of information, resulting in a situation where patients and the public at large have unequal access to information on medicinal products. Experience gained from the application of the current legal framework has also shown disparities in the interpretation of the *Union* rules on advertising, and between national provisions on information***, highlighting the urgent need for a more precise distinction between advertising and information***.

Justification

The lack of a clear distinction between information and advertising creates distortions in access to information within the EU, and the public is subject to differing, more or less restrictive interpretations by the Member States as regards the definition of what may or may not be considered advertising.

Amendment 2

Proposal for a regulation – amending act
Recital 2

Text proposed by the Commission	*Amendment*
(2) The introduction of a new Title VIII a in Directive 2001/83/EC of the European Parliament and of the Council of 6	(2) The introduction of a new Title VIII a in Directive 2001/83/EC of the European Parliament and of the Council of 6

November 2001 on a Community code relating to medicinal products for human use addresses those concerns through various provisions intended to ensure the availability of good-quality, objective, reliable and non promotional information on medicinal products for human use subject to prescription.	November 2001 on a Community code relating to medicinal products for human use addresses those concerns through various provisions intended to ensure the availability of good-quality, objective, reliable and non promotional information on medicinal products for human use subject to prescription ***and to place emphasis on the rights and interests of patients***.

Justification

The Amending Directive has to focus on the patients and their interests and it has to be reflected in the Amending Regulation as well. The new provisions of the Amending Directive have to emphasise the right of patients for information instead of the right of the pharmaceutical companies to disseminate information.

Amendment 3

Proposal for a regulation – amending act
Recital 4

Text proposed by the Commission	*Amendment*
(4) Directive 2001/83/EC provides that certain types of information are subject to control by the Member States' national competent authorities prior to ***their dissemination. This concerns information about non-interventional scientific studies, or accompanying measures to prevention and medical treatment, or information which presents the medicinal product in the context of the condition to be prevented or treated.*** In the case of medicinal products for human use authorised pursuant to Title II of Regulation (EC) No 726/2004, provision should also be made for certain types of information to be subject to prior vetting by the European Medicines Agency (hereinafter referred to as the 'Agency').	(4) Directive 2001/83/EC provides that certain types of information are subject to control by the Member States' national competent authorities prior to ***being made available.*** In the case of medicinal products for human use authorised pursuant to Title II of Regulation (EC) No 726/2004, provision should also be made for certain types of information to be subject to prior vetting by the European Medicines Agency (hereinafter referred to as the 'Agency')***, and for the Agency to monitor the measures to be taken by the manufacturer following a report of adverse reactions, and the consequent updating of the literature***.

Justification

The proposed amendment relates to information not approved by competent authorities during the registration of medicinal products and is in fact hidden "push" information. Any relevant information relating to studies is included in the patient leaflet and the Summary of Product Characteristics (SmPC), which is part of the registration file for approval.

Amendment 4

Proposal for a regulation – amending act
Recital 5 a (new)

Text proposed by the Commission	*Amendment*
	(5a) In the event that the additional costs incurred by the Agency as a result of its preliminary checking of certain types of information pursuant to this Regulation are not covered by the fees payable by the marketing authorisation holders for this purpose, the amount of the European Union's contribution to the Agency's budget should be reviewed. Accordingly, efforts should be initiated at Member State level with a view to the possible amendment of the European Union's contribution to the Agency.

Amendment 5

Proposal for a regulation – amending act
Article 1 – point -1 (new) Regulation (EC) No 726/2004
Article 9 – paragraph 4 – point e a (new)

Text proposed by the Commission	*Amendment*
	(-1) In Article 9(4), the following point is added:
	"(ea) the public summary of the assessment report referred to in Article 13(3)".

Amendment 6

Proposal for a regulation – amending act
Article 1 – point 1
Regulation (EC) No 726/2004
Article 20b – paragraph 1

Text proposed by the Commission	*Amendment*
1. By way of derogation from Article 100g(1) of Directive 2001/83/EC, medicinal product-related information referred to in Article 100b(d) of that Directive shall be subject to vetting by the Agency prior to its ***dissemination.***	1. By way of derogation from Article 100g(1) of Directive 2001/83/EC, medicinal product-related information referred to in Article 100b(d) of that Directive shall be subject to vetting by the Agency prior to its ***being made available, unless this information appears on a website, the responsibility for monitoring the content of which rests with a Member State in accordance with Article 100h of Directive 2001/83/EC***.

Justification

Consistency with the provisions of Article 100h of Directive 2001/83/EC.

Amendment 7

Proposal for a regulation – amending act
Article 1 – point 1
Regulation (EC) No 726/2004
Article 20b – paragraph 2

Text proposed by the Commission	*Amendment*
2. For the purposes of paragraph 1, the marketing authorisation holder shall submit to the Agency a mock-up of the information to be ***disseminated***.	2. For the purposes of paragraph 1, the marketing authorisation holder shall submit to the Agency a mock-up of the information to be ***made available***.

Justification

This Directive must be patient-centered. Therefore non-promotional information on medicinal products must be made available to patients and to the general public by marketing authorisation holders according to the "pull principle" whereby patients/the public have access to information if they need it (contrary to the "push principle" whereby the marketing authorisation holders disseminate information among the patients and the general public).

Amendment 8

Proposal for a regulation – amending act
Article 1 – point 1
Regulation (EC) No 726/2004
Article 20b – paragraph 3

Text proposed by the Commission	*Amendment*
3. The Agency may object to the information submitted or parts thereof on grounds related to non-compliance with the provisions of Title VIIIa of Directive 2001/83/EC within ***60 days*** after receipt of the notification. If the Agency does not object within ***60 days***, the information shall be deemed accepted and may be published.	3. The Agency may object to the information submitted or parts thereof on grounds related to non-compliance with the provisions of Title VIIIa of Directive 2001/83/EC within ***120 days*** after receipt of the notification. If the Agency does not object within ***120 days***, the information shall be deemed accepted and may be published. ***The marketing authorisation holder shall remain fully liable and responsible for the information provided in all cases.***

Justification

It is essential to extend the timeline for the evaluation of the information in order to meet the organisational needs of the Agency and to ensure that the companies remain fully liable for the information they provide to the general public.

Amendment 9

Proposal for a regulation
Article 1 – point 1
Regulation (EC) No 726/2004
Article 20b – paragraph 3 a (new)

Text proposed by the Commission	*Amendment*
	3a. If the Agency asks for changes to a document submitted by the marketing authorisation holder, and if the latter resubmits an improved proposal within 30 working days, the Agency shall communicate its response to the new proposal within 60 working days.

The Agency shall charge the marketing authorisation holder a new fee for this assessment.

Justification

This amendment aims to ensure greater efficiency in the process with a reduction of the assessment time to 60 days instead of 120 days if the marketing authorisation holder corrects a document previously submitted within 30 days.

Amendment 10

Proposal for a regulation – amending act
Article 1 – point 1 a (new)
Regulation (EC) No 726/2004
Article 57 – paragraph 1 – point l

Text proposed by the Commission	*Amendment*
	(1a) In Article 57(1), point (l) is replaced by the following:
	"*(l) creating a database on medicinal products, to be accessible to the general public*, in all official languages of the EU,* and ensuring that it is updated, and managed independently of *the commercial interests of* pharmaceutical companies; the database shall facilitate the search for information already authorised for package leaflets; it shall include a section on medicinal products authorised for the treatment of children; the information provided to the public shall be worded in an appropriate and comprehensible manner *designed for non-experts*;*"

Justification

Strengthening the EMEA's role with regard to information for the public on medicinal products for which a medical prescription is required is crucial in order to ensure that all citizens have equal access to high-quality information. The management of the database of information for the public should comply with exemption criteria for that information.

Amendment 11

Proposal for a regulation – amending act
Article 1 – point 2 a (new)
Regulation (EC) No 726/2004
Article 57 – paragraph 1 – point ua (new)

Text proposed by the Commission	*Amendment*
	(2a) In Article 57(1), the following point is added:
	"(ua) promoting existing sources of independent reliable health information."

Justification

There are many sources of independent and evidence-based information on treatment choices available within the European Union. These resources take into account cultural specificities and contexts for the population, including health determinants. They are developed by health authorities, medical products agencies, healthcare assessment bodies, healthcare providers, healthcare professionals, consumer organisations, and independent patients' organisations. These information sources should be actively promoted to the general public.

Amendment 12

Proposal for a regulation – amending act
Article 1 – point 2 b (new)
Regulation (EC) No 726/2004
Article 57 – paragraph 2

Text proposed by the Commission	*Amendment*
	(2b) In Article 57, paragraph 2 shall be replaced by the following:
	2. The database provided for in paragraph 1(l) shall include the summaries of product characteristics, the patient or user package leaflet and the information shown on the labelling. The database shall be developed in stages, priority being given to medicinal products authorised under this Regulation and those authorised under Chapter 4 of Title III of Directive 2001/83/EC and of Directive 2001/82/EC

respectively. The database shall subsequently be extended to include any medicinal product placed on the market within the Community. ***This database shall be actively promoted to European citizens.***

Where appropriate, the database shall also include references to data on clinical trials currently being carried out or already completed, contained in the clinical trials database provided for in Article 11 of Directive 2001/20/EC. The Commission shall, in consultation with the Member States, issue guidelines on data fields which could be included and which may be accessible to the public.

The information submitted by marketing authorisation holders and approved by the national authorities shall be sent to the Agency by those authorities and included in its database available to the public.

Justification

The database should be publicly accessible as a prime source of objective information. With this aim in mind, the Member States, the Commission and the Agency itself should make every effort to ensure that proper use is made of this database.

EXPLANATORY STATEMENT

The Rapporteur welcomes the proposal by the Commission on information to patients on prescription-only medicines (COM(2008)0662-0663). The Parliament and patient organizations have been asking for such a proposal for a long time, in order to enable patients to better informed on the medicines they are prescribed and taking.

Increased access to quality information will contribute to achieving better health outcome for patients as better informed patients are more likely to continue necessary treatments and better understand decisions related to their treatment; so the proposal, if properly phrased and implemented, will bring an added value.

Therefore the objective of the proposal can not only be harmonisation of European legislation but also to improve health through improved health literacy. The pharmaceutical industry has an important role to play in promoting health literacy and good health, but their role must be clearly defined and their involvement strictly regulated, in order to avoid commercially driven overconsumption of pharmaceuticals.

There are many problems with the current legal framework and the situation within Europe when it comes to patients' access to information on prescription-only medicine. The differences in interpretations of the Directive by the Member States give patients in different parts of Europe different access to high quality information on pharmaceuticals. In some Member States patients lack easy access to even the most basic information about the pharmaceuticals they are prescribed. This is unacceptable and creates health inequalities within the Union.

Today's regulation is not adjusted to technical development and the possibilities and challenges created by Internet. Patients in Europe already have infinite access to uncontrolled and often incorrect information about prescribed-only pharmaceuticals in a few seconds. The access to controlled and safe information about pharmaceuticals on internet though is very limited for most patients. This is especially a problem for those who need information in their mother tongue.

The current and different interpretation of the Directive by courts throughout Europe shows that there is a certain legal unclarity that creates uncertainty about how the Directive should be implemented and to whom it is applicable. This is also shown through the differences in the way different Member States have implemented the Directive. Therefore it is essential to create a increased clarity in the provisions.

Altogether it is therefore necessary to update the provisions regarding information about prescribed pharmaceuticals, and that new rules come into place soon.

The Rapporteur, however, raises several concerns about the Commission's proposal. This explanatory statement highlights the most important changes put forward in the draft reports.

- The Commission's proposal focuses on the pharmaceutical companies' right to disseminate information rather then the patients' right to access quality information. The Rapporteur therefore proposes to shift the focus of the proposal and to mandate pharmaceutical companies to provide certain information to the patients and thus, to put the "patients' right to know" into the centre of the legislation. The possibility to make information available to patients may not be used as an advertisement opportunity for the pharmaceutical companies; information should really serve patients' interests. The Rapporteur wishes to oblige pharmaceutical industry to make certain fundamental information on prescription-only pharmaceuticals available and easy accessible to European patients, e.g. summary of product specifications and package leaflets.

- The making available of information should be based on the "pull principle", i.e. information should be made available to those patients who are searching for information themselves. Thus the channels through which information is made available should be more carefully selected. While the role of internet is increasing, internet penetration and access varies considerably from one Member State to the other, not to mention the differences in internet literacy. For that reason information should be made available through more "traditional" channels as well e.g. correspondence.

- Concerning, though, the use of printed media as information channel the Rapporteur has reservations. Information in newspapers or magazines is available to everyone not only to those who are seeking for information themselves, i.e. patients are not protected from unsolicited information. The Rapporteur therefore proposes to delete the possibility to make information available by the pharmaceutical companies in newspapers, magazines and similar publications.

- The Rapporteur also wishes to make a clearer distinction between advertisement and information. Though Article 86 of the Directive sets the definition of advertising, and Article 88 (1) prohibits the advertisement of prescription-only medicines, for the sake of clarity it should underlined that no promotional material on prescription-only medicines could be made available.

- In order to avoid confusion, it has to be emphasised that the provisions of the Directive would apply to the pharmaceutical companies only and would not affect, under any circumstances, the right of either the press or patients and their organisations to express their views on certain medicines and treatment, as long as they are acting independently and not on behalf of, in the interest of, or upon instructions by the pharmaceutical companies. This is a regulation on the industry, and not a broader regulation that affects freedom of speech or the freedom of the press etc.

- In order to make patients' voice heard, patients' organisation should be actively involved into the implementation of the Directive and the Regulation. The Rapporteur welcomes the idea to have guidelines and a code of conduct drafted concerning the information which is made available to the patients, and wants the Commission to cooperate with patients' organisations when drafting those guidelines and code of conduct.

- There is a need to emphasise the important relationship between doctor and patient. The most important source of information about prescription-only medicines is, and should remain, the prescribing doctor. This relationship has a fundamental value and can only be supplemented by other channels of information.

- With regard to the scope of information the Rapporteur welcomes that the publicly accessible version of the assessment report is made public. He is, however, of the opinion that the pharmaceutical and pre-clinical tests and the clinical trials of the given medicines *could* also be made available. Given the commercial sensitivity of such information, pharmaceutical companies could not be mandated to publish this information, but as this information can be of value to patients and their organisation making available of the information should not be prohibited.

Putting the proposals into context, the Rapporteur underlines that information to patients on prescription-only medicines should be part of a wider "information to patients strategy" and a broader strategy of health literacy. Patients and everyone interested should be able to find accurate and unbiased information on healthy lifestyle, the prevention of illness and specific diseases, and various treatment options. This, however, goes beyond the scope of the current proposal and report. The Rapporteur though expects the Commission to present a new proposal in a near future as a part of such wider "information to patients strategy" and to complement this one.

24.3.2010

OPINION OF THE COMMITTEE ON INDUSTRY, RESEARCH AND ENERGY

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 information to the general public on medicinal products for human use subject to medical prescription, 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)0662 – C6-0517/2008 – 2008/0255(COD))

Rapporteur: Jorgo Chatzimarkakis

SHORT JUSTIFICATION

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 to ensure the proper functioning of the internal market for medicinal products for human use and to better protect the health of EU citizens. Following this line, the proposals aim specifically to provide for a clear framework for provision of information about prescription-only medicines to the general public with a view to enhancing the rational use of these medicines. The proposals ensure that the prohibition of direct-to-consumer advertising of prescription-only medicines continues to apply.

These aims are to be achieved by:

- Ensuring the high quality of information provided by coherent application of clearly defined standards across the Community;

- Allowing information to be provided through channels addressing needs and capabilities of different types of patients;

- Allowing marketing authorisation holders to provide in an understandable way objective and non-promotional information about the benefits and the risks of their medicines;

- Ensuring that monitoring and enforcement measures are in place to ensure that information providers comply with the quality criteria, while avoiding unnecessary

bureaucracy.

As to the individual aims:

The Commission has recognised that patients are increasingly interested in their health and wish to be involved more actively in health-related processes. Optimum treatment is therefore only possible if patients have access to information about the medicinal products that they are taking so that informed choices can be made and the rational use of these medicines is enhanced. The author of the report agrees with the Commission that Community action on patient information can have a positive impact in terms of promoting public health. He also wishes to stress that information about prescription-only medicines that takes account of patients' needs and expectations can promote the prevention aspect.

Nonetheless, it is a fact that the information currently available in the EU about prescription-only medicines is neither adequate nor timely. Access to information depends on how proficiently the citizen can use the Internet and which language he or she speaks.

Furthermore, due to the lack of harmonised conditions on the content of information, the provision of this information is subject to a wide variety of rules and approaches in the individual Member States, resulting in inequality of access to information about medicinal products.

Action in this area is particularly important at the present time as technological advances make it possible for citizens to obtain information via the Internet, but also expose them subconsciously to advertising from all over the world, and hence to misleading and flawed information. For that reason, the author sees an urgent need to rectify this situation so as to provide citizens with objective and non-promotional information that complies with EU rules. Through the provision of certified information, the EU must take action to provide an informative counterweight to the misleading advertising in circulation in the Internet.

Attention must focus primarily on the package leaflet. The information contained in the package leaflet must be redesigned so that it can be understood by every citizen. This is especially important because the package leaflet is inadequate in its current form, in that it can awaken patients' fears and cause them to discontinue treatment. The Commission proposal is therefore directed primarily at the redesigning of the package leaflet.

The author of the report wishes to emphasise, once again, that the ban on direct-to-consumer advertising of prescription-only medicine in the EU should be maintained. He also points out that the national competent authorities and health professionals are still important sources of information on medicinal products for the general public, but he recognises that marketing authorisation holders also constitute a valuable source of non-promotional information about medicinal products.

The author is aware that monitoring systems are required to safeguard compliance with harmonised quality standards and hence the provision of high-quality non-promotional information.

He therefore welcomes the Commission's proposal that Member States should be free to choose the most appropriate monitoring mechanisms, the general rule being that monitoring should take place after the distribution of information since this is the most effective and least bureaucratic approach.

In particular, the author of the opinion identifies a need for improvement in relation to the funding of the European Medicines Agency (EMEA). This issue is addressed in the amendments.

AMENDMENTS

The Committee on Industry, Research and Energy 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 1

Text proposed by the Commission	*Amendment*
(1) On 20 December 2007, the Commission submitted a Communication to the European Parliament and the Council concerning the "Report on current practices with regard to the provision of information to patients on medicinal products". The report concludes that Member States have adopted divergent rules and practices with regard to the provision of information, resulting in a situation where patients and the public at large have unequal access to information on medicinal products. Experience gained from the application of the current legal framework has also shown disparities in the interpretation of the Community rules on advertising, and between national provisions on information.	(1) On 20 December 2007, the Commission submitted a Communication to the European Parliament and the Council concerning the "Report on current practices with regard to the provision of information to patients on medicinal products". The report concludes that Member States have adopted divergent rules and practices with regard to the provision of information, resulting in a situation where patients and the public at large have unequal access to information on medicinal products. Experience gained from the application of the current legal framework has also shown disparities in the interpretation of the Community rules on advertising, and between national provisions on information***, highlighting the urgent need for a more precise distinction between advertising and information***.

Justification

The lack of a clear distinction between information and advertising creates distortions in access to information within the EU, and the public is subject to differing, more or less restrictive interpretations by the Member States as regards the definition of what may or may not be considered advertising.

Amendment 2

Proposal for a regulation – amending act
Recital 4

Text proposed by the Commission	*Amendment*
(4) Directive 2001/83/EC provides that certain types of information are subject to control by the Member States' national competent authorities prior to their dissemination. This concerns information about non-interventional scientific studies, or accompanying measures to prevention and medical treatment, or information which presents the medicinal product in the context of the condition to be prevented or treated. In the case of medicinal products for human use authorised pursuant to Title II of Regulation (EC) No 726/2004, provision should also be made for certain types of information to be subject to prior vetting by the European Medicines Agency (hereinafter referred to as the 'Agency').	(4) Directive 2001/83/EC provides that certain types of information are subject to control by the Member States' national competent authorities prior to their dissemination. This concerns information about non-interventional scientific studies ***based on experimental observation***, or accompanying measures to prevention and medical treatment, or information which presents the medicinal product in the context of the condition to be prevented or treated. In the case of medicinal products for human use authorised pursuant to Title II of Regulation (EC) No 726/2004, provision should also be made for certain types of information to be subject to prior vetting by the European Medicines Agency (hereinafter referred to as the 'Agency')***, and for the Agency to monitor the measures to be taken by the manufacturer following a report of adverse reactions, and the consequent immediate updating of the literature***.

Justification

It should be taken into account that, after the risk reports provided for in Articles 24 to 26 of the Regulation have been drawn up, further developments in the process need to be closely monitored, in particular by incorporating the result of the scientific appraisal of experience observed in the use of the medicinal products.

Amendment 3

Proposal for a regulation – amending act
Recital 5 a (new)

Text proposed by the Commission	*Amendment*
	(5a) In the event that the additional costs incurred by the Agency as a result of its preliminary checking of certain types of information pursuant to this Regulation are not covered by the fees payable by the marketing authorisation holders for this purpose, the amount of the European Union's contribution to the Agency's budget should be reviewed. Accordingly, efforts should be initiated at Member State level with a view to the possible amendment of the European Union's contribution to the Agency.

Amendment 4

Proposal for a regulation – amending act
Article 1 – point 1
Regulation (EC) No 726/2004
Article 20b – paragraph 1

Text proposed by the Commission	*Amendment*
1. By way of derogation from Article 100g(1) of Directive 2001/83/EC, medicinal product-related information referred to in Article 100b(d) of that Directive shall be subject to vetting by the Agency prior to its dissemination.	1. By way of derogation from Article 100g(1) of Directive 2001/83/EC, medicinal product-related information referred to in Article 100b(d) of that Directive shall be subject to vetting by the Agency prior to its dissemination***, unless this information is given on an internet website where responsibility for monitoring the content disseminated rests with a Member State in accordance with Article 100h of Directive 2001/83/EC***.

Justification

Consistency with the provisions of Article 100h of Directive 2001/83EC.

Amendment 5

Proposal for a regulation – amending act
Article 1 – point 1
Regulation (EC) No 726/2004
Article 20b – paragraph 3

Text proposed by the Commission	*Amendment*
3. The Agency may object to the information submitted or parts thereof on grounds related to non-compliance with the provisions of Title VIIIa of Directive 2001/83/EC within ***60 days*** after receipt of the notification. If the Agency does not object within ***60 days***, the information shall be deemed accepted and may be published.	3. The Agency may object to the information submitted or parts thereof on grounds related to non-compliance with the provisions of Title VIIIa of Directive 2001/83/EC***, stating the grounds for its decision,*** within ***120 days*** after receipt of the notification. If the Agency does not object within ***120 days***, the information shall be deemed accepted and may be published.

Justification

Requiring the European Medicines Agency to state the grounds for its decision will make the process of drawing up information more transparent and efficient. Extending the time-limit for the tacit acceptance of the information from 60 to 120 days will better enable the Agency to give clear reasons for its decisions.

Amendment 6

Proposal for a regulation – amending act
Article 1 – point 1
Regulation EC No 726/2004
Article 20b – paragraph 3 a (new)

Text proposed by the Commission	*Amendment*
	3a. If the Agency objects to the submitted information and the marketing authorisation holder believes that the objections are not justified, the Agency shall allow the marketing authorisation holder, upon request, to make further representations, in writing and/or by way of an oral hearing to be held within 30 working days of receipt by the Agency of

	such a request. The Agency shall communicate its response to the marketing authorisation holder within 30 working days.

Justification

This amendment aims to ensure greater efficiency and transparency in the process.

Amendment 7

Proposal for a regulation – amending act
Article 1 – point 1 a (new)
Regulation (EC) No 726/2004
Article 57 – paragraph 1 – point l

Text proposed by the Commission	*Amendment*
	(1a) In Article 57(1), second subparagraph, point (l) shall be replaced by the following:
	(l) creating a database on medicinal products, to be accessible to the general public*, in all the official languages of the EU,* **and ensuring that it is updated, and managed independently of *the commercial interests of*** **pharmaceutical companies*;*** **the database shall facilitate the search for information already authorised for package leaflets; it shall include a section on medicinal products authorised for the treatment of children; the information provided to the public shall be worded in an appropriate and comprehensible manner, *designed for the non-expert public*;**

Justification

Strengthening the agency's role with regard to information for the public on medicinal products for which a medical prescription is required is crucial in order to ensure that all citizens have equal access to high-quality information. The management of the database of information for the public should comply with exemption criteria for that information.

Amendment 8

Proposal for a regulation – amending act
Article 1 – point 2 a (new)
Regulation (EC) No 726/2004
Article 57 – paragraph 2

Text proposed by the Commission	*Amendment*
	(2a) In Article 57, paragraph 2 shall be replaced by the following:
	2. The database provided for in paragraph 1(l) shall include the summaries of product characteristics, the patient or user package leaflet and the information shown on the labelling. The database shall be developed in stages, priority being given to medicinal products authorised under this Regulation and those authorised under Chapter 4 of Title III of Directive 2001/83/EC and of Directive 2001/82/EC respectively. The database shall subsequently be extended to include any medicinal product placed on the market within the Community. *This database shall be actively promoted to European citizens.*
	Where appropriate, the database shall also include references to data on clinical trials currently being carried out or already completed, contained in the clinical trials database provided for in Article 11 of Directive 2001/20/EC. The Commission shall, in consultation with the Member States, issue guidelines on data fields which could be included and which may be accessible to the public.
	The information submitted by holders of marketing authorisation and approved by the national authorities shall be sent to the Agency by those authorities and included in its database available to the public.

Justification

The database should be publicly accessible as a prime source of objective information. With

this aim in mind, the Member States, the Commission and the Agency itself should make every effort to ensure that proper use is made of this database.

PROCEDURE

Title	Information on medicinal products subject to medical prescription (amendment of Regulation (EC) No 726/2004)
References	COM(2008)0662 – C6-0517/2008 – 2008/0255(COD)
Committee responsible	ENVI
Opinion by Date announced in plenary	ITRE 19.10.2009
Rapporteur Date appointed	Jorgo Chatzimarkakis 16.9.2009
Discussed in committee	15.10.2009 27.1.2010
Date adopted	18.3.2010
Result of final vote	+: 42 –: 5 0: 0
Members present for the final vote	Jean-Pierre Audy, Zigmantas Balčytis, Zoltán Balczó, Bendt Bendtsen, Jan Březina, Reinhard Bütikofer, Maria Da Graça Carvalho, Giles Chichester, Pilar del Castillo Vera, Ioan Enciu, Adam Gierek, Norbert Glante, Fiona Hall, Jacky Hénin, Romana Jordan Cizelj, Sajjad Karim, Arturs Krišjānis Kariņš, Judith A. Merkies, Angelika Niebler, Jaroslav Paška, Herbert Reul, Teresa Riera Madurell, Michèle Rivasi, Paul Rübig, Francisco Sosa Wagner, Britta Thomsen, Patrizia Toia, Evžen Tošenovský, Ioannis A. Tsoukalas, Marita Ulvskog, Vladimir Urutchev, Adina-Ioana Vălean, Kathleen Van Brempt, Alejo Vidal-Quadras, Henri Weber
Substitute(s) present for the final vote	António Fernando Correia De Campos, Rachida Dati, Ilda Figueiredo, Andrzej Grzyb, Jolanta Emilia Hibner, Oriol Junqueras Vies, Ivailo Kalfin, Marian-Jean Marinescu, Vladko Todorov Panayotov, Silvia-Adriana Ţicău, Hermann Winkler
Substitute(s) under Rule 187(2) present for the final vote	Britta Reimers

30.4.2010

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 information to the general public on medicinal products for human use subject to medical prescription, 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)0662 – C6-0517/2008 – 2008/0255(COD))

Rapporteur: António Correia de Campos

SHORT JUSTIFICATION

The proposal for a regulation amending, as regards information to the general public on medicinal products for human use subject to medical prescription, 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 aims to provide a clear framework for information on prescription-only medicines to consumers with a view to promoting more informed consumer choices.

Information for patients must comply with three key criteria:

1. It must be reliable: information for patients must be based on the most recent scientific knowledge, with a clear reference to its source;

2. It must be independent: it must be made clear who supplies and who finances the information so that consumers can identify potential conflicts of interest;

3. It must be designed for the non-expert public: it must be easy to understand and assess the information, bearing in mind the particular needs of consumers (age, cultural differences and the need to make information available in all EU languages).

- The proposed regulation introduces a legal structure allowing the pharmaceutical industry to make information available to consumers. The question that arises is to ascertain what role the pharmaceutical industry should play in providing information on prescription-only medicinal products direct to patients. Pharmaceutical companies have extremely valuable information resulting from their scientific research. This may represent an important source of information for consumers. However, pharmaceutical companies cannot be seen as independent providers of information on medicinal products, given the inherent conflict of interest;

- The distinction between information and advertising is not clear. Consumers require comprehensible, high-quality sources of information in the field of health (particularly on the Internet) so that they can assess their options and take an informed decision;

- The regulatory agency must be given sufficient time to check the quality and independence of the information to be provided by pharmaceutical companies;

- The EudraPharm database may provide a useful tool for providing information to consumers. More use should be made of the EMEA's resources.

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 1

Text proposed by the Commission	*Amendment*
(1) On 20 December 2007, the Commission submitted a Communication to the European Parliament and the Council concerning the "Report on current practices with regard to the provision of information to patients on medicinal products" . The report concludes that Member States have adopted divergent rules and practices with regard to the provision of information, resulting in a situation where patients and the public at large have unequal access to information on medicinal products. Experience gained from the application of the current legal	(1) On 20 December 2007, the Commission submitted a Communication to the European Parliament and the Council concerning the "Report on current practices with regard to the provision of information to patients on medicinal products" . The report concludes that Member States have adopted divergent rules and practices with regard to the provision of information, resulting in a situation where patients and the public at large have unequal access to information on medicinal products. Experience gained

framework has also shown disparities in the interpretation of the Community rules on advertising, and between national provisions on information.	from the application of the current legal framework has also shown disparities in the interpretation of the Community rules on advertising, and between national provisions on information***, highlighting the urgent need for a more precise distinction between advertising and information***.

Justification

The lack of a clear distinction between information and advertising creates distortions in access to information within the EU, and the public is subject to differing, more or less restrictive interpretations by the Member States as regards the definition of what may or may not be considered advertising.

Amendment 2

Proposal for a regulation – amending act
Recital 4

Text proposed by the Commission	*Amendment*
(4) Directive 2001/83/EC provides that certain types of information are subject to control by the Member States' national competent authorities prior to ***their dissemination. This concerns information about non-interventional scientific studies, or accompanying measures to prevention and medical treatment, or information which presents the medicinal product in the context of the condition to be prevented or treated.*** In the case of medicinal products for human use authorised pursuant to Title II of Regulation (EC) No 726/2004, provision should also be made for certain types of information to be subject to prior vetting by the European Medicines Agency (hereinafter referred to as the 'Agency').	(4) Directive 2001/83/EC provides that certain types of information are subject to control by the Member States' national competent authorities prior to ***being made available.*** In the case of medicinal products for human use authorised pursuant to Title II of Regulation (EC) No 726/2004, provision should also be made for certain types of information to be subject to prior vetting by the European Medicines Agency (hereinafter referred to as the 'Agency')***, and for the Agency to monitor the measures to be taken by the manufacturer following a report of adverse reactions, and the consequent updating of the literature***.

Justification

The proposed amendment relates to information not approved by competent authorities during the registration of medicinal products and is in fact hidden "push" information. Any

relevant information relating to studies is included in the patient leaflet and the Summary of Product Characteristics (SmPC), which is part of the registration file for approval.

Amendment 3

Proposal for a regulation – amending act
Article 1 – point 1
Regulation (EC) No 726/2004
Article 20b – paragraph 1

Text proposed by the Commission	*Amendment*
1. By way of derogation from Article 100g(1) of Directive 2001/83/EC, medicinal product-related information referred to in Article 100b(d) of that Directive shall be subject to vetting by the Agency prior to its ***dissemination.***	1. By way of derogation from Article 100g(1) of Directive 2001/83/EC, medicinal product-related information referred to in Article 100b(d) of that Directive shall be subject to vetting by the Agency prior to its ***being made available, unless this information appears on a website, the responsibility for monitoring the content of which rests with a Member State in accordance with Article 100h of Directive 2001/83/EC***.

Justification

Consistency with the provisions of Article 100h of Directive 2001/83/EC.

Amendment 4

Proposal for a regulation – amending act
Article 1 – point 1
Regulation (EC) No 726/2004
Article 20b – paragraph 2

Text proposed by the Commission	*Amendment*
2. For the purposes of paragraph 1, the marketing authorisation holder shall submit to the Agency a mock-up of the information to be ***disseminated***.	2. For the purposes of paragraph 1, the marketing authorisation holder shall submit to the Agency a mock-up of the information to be ***made available***.

Justification

This Directive must be patient-centered. Therefore non-promotional information on medicinal

products must be made available to patients and to the general public by marketing authorisation holders according to the "pull principle" whereby patients/the public have access to information if they need it (contrary to the "push principle" whereby the marketing authorisation holders disseminate information among the patients and the general public).

Amendment 5

Proposal for a regulation – amending act
Article 1 – point 1
Regulation (EC) No 726/2004
Article 20b – paragraph 3

Text proposed by the Commission	*Amendment*
3. The Agency may object to the information submitted or parts thereof on grounds related to non-compliance with the provisions of Title VIIIa of Directive 2001/83/EC within ***60 days*** after receipt of the notification. If the Agency does not object within ***60 days***, the information shall be deemed accepted and may be published.	3. The Agency may object to the information submitted or parts thereof on grounds related to non-compliance with the provisions of Title VIIIa of Directive 2001/83/EC***, stating the grounds for its decision,*** within ***120 days*** after receipt of the notification. If the Agency does not object within ***120 days***, the information shall be deemed accepted and may be published.

Justification

Requiring the European Medicines Agency to state the grounds for its decision will make the process of drawing up information more transparent and efficient. Extending the time-limit for the tacit acceptance of the information from 60 to 120 days will better enable the Agency to give clear reasons for its decisions.

Amendment 6

Proposal for a regulation – amending act
Article 1 – point 1
Regulation (EC) No 726/2004
Article 20b – paragraph 3a (new)

Text proposed by the Commission	*Amendment*
	3a. If the Agency raises objections to the information submitted and the applicant takes the view that those objections are not justified, the Agency shall give the applicant, on his or her request, an

	opportunity to support his or her arguments in writing or at an oral hearing within 30 working days of the Agency's receipt of the request. The Agency shall justify its reply within 30 working days of receipt of the applicant's reasoned statement.

Justification

To make the process more transparent by giving both sides the opportunity to put their case.

Amendment 7

Proposal for a regulation – amending act
Article 1 – point 1 a (new)
Regulation (EC) No 726/2004
Article 57 – paragraph 1 – point l

Text proposed by the Commission	*Amendment*
	(1a) In Article 57(1), point (l) is replaced by the following:
	"*(l) creating a database on medicinal products, to be accessible to the general public, *in all official languages of the EU,* and ensuring that it is updated, and managed independently of *the commercial interests of* pharmaceutical companies; the database shall facilitate the search for information already authorised for package leaflets; it shall include a section on medicinal products authorised for the treatment of children; the information provided to the public shall be worded in an appropriate and comprehensible manner *designed for the non-expert public*;*"

Justification

Strengthening the EMEA's role with regard to information for the public on medicinal products for which a medical prescription is required is crucial in order to ensure that all citizens have equal access to high-quality information. The management of the database of information for the public should comply with exemption criteria for that information.

Amendment 8

Proposal for a regulation – amending act
Article 1 – point 2 a (new)
Regulation (EC) No 726/2004
Article 57 – paragraph 2

Text proposed by the Commission	*Amendment*
	(2a) Article 57(2) is replaced by the following:
	***"*2. The database provided for in paragraph 1(l) shall include the summaries of product characteristics, the patient or user package leaflet and the information shown on the labelling. The database shall be developed in stages, priority being given to medicinal products authorised under this Regulation and those authorised under Chapter 4 of Title III of Directive 2001/83/EC and of Directive 2001/82/EC respectively. The database shall [...] be extended to include any medicinal product placed on the market within the Community.**
	Where appropriate, the database shall also include references to data on clinical trials currently being carried out or already completed, contained in the clinical trials database provided for in Article 11 of Directive 2001/20/EC. The Commission shall, in consultation with the Member States, issue guidelines on data fields which could be included and which may be accessible to the public. ***The database shall be actively publicised to European citizens. The information submitted by holders of marketing authorisations and approved by the national authorities shall be sent to the Agency and included in its database available to the public."***

Justification

The database should be publicly accessible as a prime source of objective information. To this end, the Member States, the Commission and the EMEA itself should be proactive in order to ensure that it is used effectively.

PROCEDURE

Title	Information on medicinal products subject to medical prescription (amendment of Regulation (EC) No 726/2004)
References	COM(2008)0662 – C6-0517/2008 – 2008/0255(COD)
Committee responsible	ENVI
Opinion by Date announced in plenary	IMCO 19.10.2009
Rapporteur Date appointed	António Fernando Correia De Campos 14.9.2009
Discussed in committee	1.9.2009 29.9.2009 6.10.2009 17.3.2010
Date adopted	28.4.2010
Result of final vote	+: 34 –: 2 0: 0
Members present for the final vote	Cristian Silviu Buşoi, Lara Comi, Anna Maria Corazza Bildt, António Fernando Correia De Campos, Jürgen Creutzmann, Christian Engström, Evelyne Gebhardt, Louis Grech, Małgorzata Handzlik, Malcolm Harbour, Philippe Juvin, Sandra Kalniete, Alan Kelly, Eija-Riitta Korhola, Edvard Kožušník, Kurt Lechner, Toine Manders, Mitro Repo, Robert Rochefort, Zuzana Roithová, Heide Rühle, Andreas Schwab, Róża Gräfin Von Thun Und Hohenstein, Kyriacos Triantaphyllides, Bernadette Vergnaud, Barbara Weiler
Substitute(s) present for the final vote	Pascal Canfin, Cornelis de Jong, Frank Engel, Anna Hedh, Othmar Karas, Emma McClarkin, Catherine Soullie, Marc Tarabella, Anja Weisgerber, Kerstin Westphal

PROCEDURE

Title	Information on medicinal products subject to medical prescription (amendment of Regulation (EC) No 726/2004)
References	COM(2008)0662 – C6-0517/2008 – 2008/0255(COD)
Date submitted to Parliament	10.12.2008
Committee responsible Date announced in plenary	ENVI 19.10.2009
Committee(s) asked for opinion(s) Date announced in plenary	ITRE IMCO 19.10.2009 19.10.2009
Rapporteur(s) Date appointed	Christofer Fjellner 21.7.2009
Discussed in committee	16.3.2010 3.6.2010
Date adopted	28.9.2010
Result of final vote	+: 51 –: 2 0: 3
Members present for the final vote	János Áder, Kriton Arsenis, Pilar Ayuso, Paolo Bartolozzi, Sergio Berlato, Milan Cabrnoch, Martin Callanan, Nessa Childers, Chris Davies, Bairbre de Brún, Anne Delvaux, Bas Eickhout, Edite Estrela, Elisabetta Gardini, Julie Girling, Nick Griffin, Françoise Grossetête, Satu Hassi, Jolanta Emilia Hibner, Dan Jørgensen, Karin Kadenbach, Christa Klaß, Holger Krahmer, Jo Leinen, Corinne Lepage, Peter Liese, Radvilė Morkūnaitė-Mikulėnienė, Gilles Pargneaux, Antonyia Parvanova, Andres Perello Rodriguez, Sirpa Pietikäinen, Mario Pirillo, Pavel Poc, Frédérique Ries, Oreste Rossi, Dagmar Roth-Behrendt, Daciana Octavia Sârbu, Carl Schlyter, Horst Schnellhardt, Richard Seeber, Bogusław Sonik, Catherine Soullie, Salvatore Tatarella, Anja Weisgerber, Sabine Wils, Marina Yannakoudakis
Substitute(s) present for the final vote	Christofer Fjellner, Matthias Groote, Philippe Juvin, Marisa Matias, Judith A. Merkies, Bill Newton Dunn, Michèle Rivasi, Thomas Ulmer, Marita Ulvskog, Kathleen Van Brempt