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Plenary sitting

A7-0290/2010

19.10.2010

***I
REPORT

on the proposal for a directive of the European Parliament and of the Council amending, as regards information to the general public on medicinal products subject to medical prescription, Directive 2001/83/EC on the Community code relating to medicinal products for human use
(COM(2008)0663 – C6-0156/2008 – 2008/0256(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 directive of the European Parliament and of the Council amending, as regards information to the general public on medicinal products subject to medical prescription, Directive 2001/83/EC on the Community code relating to medicinal products for human use
(COM(2008)0663 – C6-0516/2008 – 2008/0256(COD))

(Ordinary legislative procedure: first reading)

The European Parliament,

– having regard to the Commission proposal to the European Parliament and the Council (COM(2008)0663),

– having regard to Article 251(2) and Article 95 of the EC Treaty, pursuant to which the Commission submitted the proposal to Parliament (C6-0516/2008),

– 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 interistitutional 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 10 June 2009 of the European Economic and Social Committee[1] and the opinion of 7 October 2009 of the Committee of the Regions[2],

– 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 (A7-0290/2010),

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.

[1] OJ C 306, 16.12.2009, p. 19.
[2] OJ C

Amendment 1

Proposal for a directive - amending act
Recital 2

Text proposed by the Commission	*Amendment*
(2) In the area of information, Directive 2001/83/EC lays down detailed rules on the documents to be annexed to the marketing authorisation and intended for information purposes: the summary of product characteristics (distributed to health-care professionals) and the package leaflet (inserted in the product's packaging when it is dispensed to the patient). On the other hand, as regards the ***dissemination*** of information from the marketing authorisation holder to the general public, the Directive only provides that certain information activities are not covered by the rules on advertising, without providing for a harmonised framework on the contents and the quality of non promotional information on medicinal products or on the channels through which this information may be ***disseminated***.	(2) In the area of information, Directive 2001/83/EC lays down detailed rules on the documents to be annexed to the marketing authorisation and intended for information purposes: the summary of product characteristics (distributed to health-care professionals) and the package leaflet (inserted in the product's packaging when it is dispensed to the patient). On the other hand, as regards the ***making available*** of information from the marketing authorisation holder to ***patients and*** the general public, the Directive only provides that certain information activities are not covered by the rules on advertising, without providing for a harmonised framework on the contents and the quality of non promotional information on medicinal products or on the channels through which this information may be ***made available***. *(This amendment applies throughout the text. Adopting it will necessitate corresponding changes throughout.)*

Justification

This Directive must be patient-centered. Therefore non-promotional information on medicinal products must be made available to patients and 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 2

Proposal for a directive - amending act
Recital 3

Text proposed by the Commission	*Amendment*
(3) On the basis of Article 88a of Directive 2001/83/EC, on 20 December 2007 the Commission submitted a Communication to the European Parliament and the Council on a "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***.	(3) On the basis of Article 88a of Directive 2001/83/EC, on 20 December 2007 the Commission submitted a Communication to the European Parliament and the Council on a "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 ***in the package leaflet and in the summary of product characteristics***. ***Such unjustifiable inequalities in accessing information that is publicly available in other Member States should be redressed.***

Justification

All information needs to be available regardless of severity of diseases.

Amendment 3

Proposal for a directive - amending act
Recital 4

Text proposed by the Commission	*Amendment*
(4) Experience gained from the application of the current legal framework has also shown that ***certain restrictions on the possibilities of pharmaceutical companies to provide information result from the fact that*** the distinction between the notions of advertising and information is not interpreted consistently across the ***Community***.	(4) Experience gained from the application of the current legal framework has also shown that the distinction between the notions of advertising and information is not interpreted consistently across the ***Union, and that this has given rise to situations where the general public is exposed to disguised advertising***. ***As a result citizens in certain Member States may be denied the right to have access, in their own language, to high-quality, non-***

promotional information on medicines. Each notion should be defined and should be interpreted uniformly across all Member States so to ensure patient safety.

Amendment 4

Proposal for a directive – amending act
Recital 5

Text proposed by the Commission	*Amendment*
(5) Those disparities in the interpretation of the Community rules on ***advertising***, and between national provisions on information have a negative impact on the uniform application of Community rules on ***advertising***, and on the effectiveness of the provisions on product information contained in the summary of products characteristics and the package leaflet. Although those rules are fully harmonised to ensure the same level of protection of public health across the Community, this objective is undermined if widely divergent national rules on the ***dissemination*** of such key information are allowed.	(5) Those disparities in the interpretation of the Community rules on ***providing information to patients and the general public,*** and between national provisions on information have a negative impact on the uniform application of Community rules on ***providing information to patients and the general public,*** and on the effectiveness of the provisions on product information contained in the summary of products characteristics and the package leaflet. Although those rules are fully harmonised to ensure the same level of protection of public health across the Community, this objective is undermined if widely divergent national rules on the ***making available*** of such key information are allowed.

Justification

The focus of the Directive should be not on advertising but on making information available to the public.

Amendment 5

Proposal for a directive – amending act
Recital 7

Text proposed by the Commission	*Amendment*
(7) In the light of the above and taking into account technological progress with regard to modern communication tools and the	(7) In the light of the above and taking into account technological progress with regard to modern communication tools and the

fact that patients throughout the European Union have become increasingly active as regards healthcare, it is necessary to amend the existing legislation in order to reduce differences in access to information and to allow for the availability of good-quality, objective, reliable and non promotional information on medicinal products.	fact that patients throughout the European Union have become increasingly active as regards healthcare, it is necessary to amend the existing legislation in order to reduce differences in access to information and to allow for the availability of good-quality, objective, reliable and non promotional information on medicinal products ***by placing emphasis on the rights and interests of patients***. ***They should have the right to easily access certain information such as a summary of product characteristics and the package leaflet in electronic and printed form***. ***Certified and registered websites for independent, objective and non-promotional information are therefore necessary.***

Justification

The Amending Directive has to focus on the patients and their interests. The new provisions have to emphasise the right of patients for information instead of the right of the pharmaceutical companies to disseminate information.

Amendment 6

Proposal for a directive - amending act
Recital 8

Text proposed by the Commission	*Amendment*
(8) National competent authorities and health care professionals should remain ***important sources*** of information on medicinal products for the general public. Member States should facilitate the access of citizens to high-quality information through appropriate channels***. Marketing authorisation holders may be a valuable source of non promotional information on their medicinal products. This Directive should therefore establish a legal framework for the dissemination of specific information on medicinal products by marketing authorisation holders to the general public. The ban on advertising to the general public for***	(8) National competent authorities and health care professionals should remain ***the main source*** of information on medicinal products for the general public. ***While there is already a lot of independent information on pharmaceuticals, for example information provided by national authorities or healthcare professionals, the situation differs very much between Member States and among the different products available.*** Member States ***and Commission*** should ***make much greater efforts to*** facilitate the access of citizens to high-quality information through appropriate channels.

prescription-only medicinal products should be maintained.

Amendment 7

Proposal for a directive - amending act
Recital 8 a (new)

Text proposed by the Commission	*Amendment*
	(8a) Without prejudice to the importance of the role played by national competent authorities and healthcare professionals in better informing patients and the general public, marketing authorisation holders may be an additional source of non-promotional information on their medicinal products. This Directive should therefore establish a legal framework for the making available of specific information on medicinal products by marketing authorisation holders to the general public. The ban on advertising to the general public for prescription-only medicinal products should be maintained.

Amendment 8

Proposal for a directive – amending act
Recital 9

Text proposed by the Commission	*Amendment*
(9) In accordance with the principle of proportionality, it is appropriate to limit the scope of this Directive to prescription-only medicinal products, as current Community rules allow the advertising to the general public of medicinal products not subject to prescription, under certain conditions.	(9) In accordance with the principle of proportionality, it is appropriate to limit the scope of this Directive to ***the making available of information on*** prescription-only medicinal products as current Community rules allow the advertising to the general public of medicinal products not subject to prescription, under certain conditions. ***The provisions of this Directive are without prejudice to the right of any other person or organisation,***

in particular the press or patients and patient organisations, to express their views on prescription-only medicinal products, provided that they are acting independently and not directly or indirectly on behalf of, on the instructions of, or in the interest of the marketing authorisation holder. This Directive requires Member States to permit, via certain channels and subject to appropriate monitoring, the provision by a marketing authorisation holder or a third party acting on its behalf of certain information on authorised medicines subject to prescription to the general public. Communications that do not fall within Title VIIIa are permitted, provided that they do not constitute advertising.

Justification

With reference to recent developments in the case law it has to be emphasised that the provisions of this Directive do not affect the right of any other person or organisation, in particular the press or patients' groups to express their views on prescription-only medicines as long as they are acting not in the interest of, or on behalf of the pharmaceutical companies.

Amendment 9

Proposal for a directive - amending act
Recital 10

Text proposed by the Commission	*Amendment*
(10) Provisions should be established to ensure that only high-quality non-promotional information about the benefits and the risks of medicinal products subject to medical prescription ***may be disseminated.*** The information should take into account patients needs and expectations in order to empower patients, allow informed choices and enhance the rational use of medicinal products. Therefore, any information to the general public on prescription-only medicinal products should ***comply with a set of quality criteria***.	(10) Provisions should be established to ensure that only high-quality non-promotional information about the benefits and the risks of ***authorised*** medicinal products subject to medical prescription ***is accessible***. The information should take into account patients needs and expectations in order to empower patients, allow informed choices and enhance the rational use of medicinal products. Therefore, any information to the general public on prescription-only medicinal products should ***be approved in advance by the competent authorities and should***

be supplied only in an approved form.

Amendment 10

Proposal for a directive – amending act
Recital 11

Text proposed by the Commission	*Amendment*
(11) In order to further ensure that marketing authorisation holders ***disseminate*** only high-quality information and to distinguish non-promotional information from advertising, the types of information which ***may be disseminated*** should be defined. It is appropriate to allow marketing authorisation holders to ***disseminate the contents of the approved summaries of product characteristics and package leaflet, information that is compatible with those documents without going beyond their key elements, and*** other well-defined medicinal product-related information.	(11) In order to further ensure that marketing authorisation holders ***make available*** only high-quality information and to distinguish non-promotional information from advertising, the types of information which ***are made available*** should be defined. ***Marketing authorisation holders should make available the approved and most recent contents of summaries of product characteristics, labelling and package leaflet and the publicly accessible version of the assessment report.*** It is appropriate to allow marketing authorisation holders to ***make available*** other well-defined medicinal product-related information.

JustificationCorresponding recital.

Amendment 11

Proposal for a directive – amending act Recital 11 a (new)

Text proposed by the Commission	*Amendment*
	(11a) The summary of product characteristics, labelling and package leaflet, and the publicly accessible version of the assessment report or any updated versions of these documents shall require approval by the competent authorities during the course of marketing authorisation. Therefore this information should not be subject to further approval prior to its being made available pursuant

to this Directive.

Justification

Clarifying recital.

Amendment 12

Proposal for a directive – amending act
Recital 12

Text proposed by the Commission	*Amendment*
(12) Information to the general public on prescription-only medicinal products should only be provided through specific channels of communication, including Internet ***and health-related publications***, to avoid that the effectiveness of the prohibition on advertising is undermined by unsolicited provision of information to the public. Where information is ***disseminated*** via television ***or*** radio, patients are not protected against such unsolicited information and such dissemination should therefore not be allowed.	(12) Information to the general public on prescription-only medicinal products should only be provided through specific channels of communication, including Internet, to avoid that the effectiveness of the prohibition on advertising is undermined by unsolicited provision of information to the public. Where information is ***made available*** via television, radio, ***newspapers, magazines and similar publications***, patients are not protected against such unsolicited information and such dissemination should therefore not be allowed.

Justification

Amendment 13

Proposal for a directive - amending act
Recital 14

Text proposed by the Commission	*Amendment*
(14) Monitoring of information on prescription-only medicinal products should ensure that marketing authorisation holders only ***disseminate*** information which is in compliance with Directive 2001/83/EC. Member States should adopt rules establishing effective monitoring mechanisms and allowing effective enforcement in cases of non-compliance.	(14) Monitoring of information on ***authorised*** prescription-only medicinal products ***under this Directive*** should ensure that marketing authorisation holders only ***make available*** information which is in compliance with Directive 2001/83/EC. Member States should adopt rules establishing effective monitoring mechanisms and allowing effective

Monitoring should be based on the control of information prior to its ***dissemination***, ***unless the substance of the*** information has ***already*** been ***agreed*** by the competent authorities ***or if there is a different mechanism*** in ***place to ensure an equivalent level of adequate and effective monitoring***.	enforcement in cases of non-compliance. ***These rules should be harmonised at Union level so as to ensure consistency. In cases of non-compliance, procedures should be put in place for marketing authorisation holders to be represented and heard in the course of the consideration of their case.*** Monitoring should be based on the control of information prior to ***its being made available***. ***Only*** information ***that*** has been ***approved in advance*** by the competent authorities ***should be provided and it should be provided*** in ***an approved form only***.

Amendment 14

Proposal for a directive – amending act
Recital 15

Text proposed by the Commission	*Amendment*
(15) As this Directive introduces for the first time harmonised rules on the provision of information on medicinal products subject to medical prescription to the general public, the Commission should assess its operation and the necessity for a review five years after its entry into force. Provision should also be made for the drawing up of guidelines by the Commission based on Member States' experience in the monitoring of information.	(15) As this Directive introduces for the first time harmonised rules on the provision of information on medicinal products subject to medical prescription to the general public, the Commission should assess its operation and the necessity for a review five years after its entry into force. Provision should also be made for the drawing up of guidelines by the Commission based on Member States' experience***, in cooperation with patient organisations and healthcare professionals,*** in the monitoring of information

Justification

As the information is targeted at patients, patients' organizations have to be involved into the process of establishing the guidelines. The perspective of health professionals is also crucial as they are, and they should remain the main source of information to patients on prescribed medicines.

Amendment 15

Proposal for a directive – amending act
Recital 15 a (new)

Text proposed by the Commission	*Amendment*
	(15a) The Commission should be empowered to adopt delegated acts in accordance with Article 290 of the Treaty on the Functioning of the European Union in respect of the quality criteria of information provided to the general public, and web accessibility guidelines.

Justification

The comitology regime has to be aligned to the system of delegated acts introduced by Article 290 of the Treaty on the Functioning of the European Union (i.e. the Lisbon Treaty).

Amendment 16

Proposal for a directive - amending act
Recital 15 a (new)

Text proposed by the Commission	*Amendment*
	(15a) The Commission should consult independent patient, health and consumer organisations and healthcare professionals on issues relating to the implementation of this Directive and its application by the Member States.

Justification

Healthcare professionals` views related to the implementation and application of this Directive should also be taken into account.

Amendment 17

Proposal for a directive – amending act
Article 1 – point – 1 a (new)
Directive 2001/83/EC
Article 1 – point 26

Text proposed by the Commission	*Amendment*
	(-1a) Article 1, point 26 shall be replaced by the following:
	"*26. *Patient* leaflet: A leaflet containing information for the *patient* which accompanies the medicinal product *and which corresponds to patients' real needs.

Justification

See amendment to Recital 2.

Amendment 18

Proposal for a directive – amending act
Article 1 – point -1 (new)
Directive 2001/83/EC
Article 59 – paragraph 3 a (new)

Text proposed by the Commission	*Amendment*
	(-1) In Article 59 the following paragraph shall be added:
	"3a. The package leaflet shall correspond to patients' real needs. To this end, patient organisations should be involved in developing and reviewing the information on medicinal products by national regulatory authorities and the European Medicines Agency. The package leaflet shall include a short paragraph which sets out the benefit and potential harm of a medicinal product as well as a short description of further information aiming at safe and effective use of a medicinal product."

Justification

Studies involving patients show that often the package leaflets are not read by most people (e.g. information in the wrong order, most important information does not stand out). Thus, patient leaflets should be developed in cooperation with patients' representatives, as proposed e.g. by the EMA Patient and Consumer Working Group in 2005. The EMA's work to

improve the readability and patient-friendliness of the leaflet should be continued and should be followed as a model of good practice for national regulatory authorities.

Amendment 19

Proposal for a directive – amending act
Article 1 – point 1
Directive 2001/83/EC
Article 86 – paragraph 2 – indent 1

Text proposed by the Commission	*Amendment*
- the labelling and the accompanying package leaflets, which are subject to the provisions of Title V;	- the labelling***, which shall always at least specify the International Non-proprietary Name,*** and the accompanying package leaflets, which are subject to the provisions of Title V;

Justification

The International Non-proprietary Name (INN) (the name of the active substance which common stem identifies the therapeutic class the substance belongs to) should be systematically used to empower patients (it helps to raise awareness among patients of what active substance they are taking used).

Amendment 20

Proposal for a directive - amending act
Article 1 – point 1
Directive 2001/83/EC
Article 86 – paragraph 2 – indent 1 a (new)

Text proposed by the Commission	*Amendment*
	– correspondence, possibly accompanied by material of a non-promotional nature, needed to answer a specific question about a particular medicinal product;

Amendment 21

Proposal for a directive – amending act
Article 1 – point 1
Directive 2001/83/EC
Article 86 – paragraph 2 – indent 2

Text proposed by the Commission	*Amendment*
- factual, informative announcements and reference material relating, for example, to pack changes, adverse-reaction warnings as part of general drug precautions, trade catalogues and price lists, provided ***they*** include no product claims;	- factual, informative announcements ***(including announcements or statements such as those made to media organisations either in response to a direct enquiry or by dissemination of such information via conferences or written releases*** and ***announcements or reports to shareholders and/or regulators)*** and reference material relating ***to a medicinal product***, for example, to ***availability,*** pack changes, adverse-reaction warnings as part of general drug precautions, trade catalogues, price lists, ***reimbursement and information on the environmental risk of the medicinal product and information relating to the disposal of unused medicinal product or waste derived from medicinal products as well as reference to any collection system in place,*** provided ***that such announcements and reference material*** include no product ***promotional*** claims ***and that they do not encourageor promote the consumption of the medicinal product***;

Amendment 22

Proposal for a directive - amending act
Article 1 – point 1
Directive 2001/83/EC
Article 86 **–** paragraph 2 – indent 3

Text proposed by the Commission	*Amendment*
- information relating to human health or diseases, provided that there is no reference, even indirect, to medicinal	- information relating to human health or diseases, provided that there is no reference, even indirect, to ***individual***

products;	medicinal products;

Justification

Clarification of scope of the Directive. Companies should be allowed to continue to provide certain information. For instance, stock market rules require that companies keep investors fully informed of significant developments and employees must be kept informed of business developments. "Product claim" could be taken to mean any statement about the properties of a product, positive and negative, and might inadvertently prohibit statements about adverse reactions and warnings.

Amendment 23

Proposal for a directive – amending act
Article 1 - point 1
Directive 2001/83/EC2
Article 86 - paragraph 2 - indent 4

Text proposed by the Commission	*Amendment*
- information ***by the marketing authorisation holder to the general public on medicinal products*** subject to medical prescription, which is subject to the provisions of Title VIII a."	- information ***on medicinal products that meets the quality criteria, that has been approved*** by the ***competent authorities in*** the ***Member States and that has been made available to the*** general public ***in approved form by the marketing authorisation holder and that is*** subject to medical prescription, which is subject to the provisions of Title VIII a."

Justification

The information provided to patients and the general public needs to meet the core quality criteria in order to ensure patient safety and safeguard public health.

Amendment 24

Proposal for a directive – amending act
Article 1 – point 1
Directive 2001/83/EC
Article 86 – paragraph 2 – indent 4 a (new)

Text proposed by the Commission	*Amendment*
	- factual, informative announcements for investors and employees on significant business developments, provided they are not used to promote the product to the general public;

Justification

Article 86(2) of the existing Directive 2001/83/EC lists specific sources that are excluded from the definition of "advertising". The current wording raises the problem of the definition of advertising and "information" disseminated by the MAH. The numerous exceptions proposed by the Commission highly endanger the objectiveness of "information": advertisings could de facto be covered by a too broad definition of "information". It is therefore preferable to refer to specific "documents" produced by the MAH as listed in Title VIII a.

Amendment 25

Proposal for a directive – amending act
Article 1 – point 1 a (new)
Directive 2001/83/EC
Article 86 – paragraph 2 a (new)

Text proposed by the Commission	*Amendment*
	(1a) In Article 86, the following paragraph shall be added:
	"(2a) When exemptions to advertising referred to in paragraph 2 are made available, the marketing authorisation holder and any third party shall be identified, and any third party acting on behalf of the marketing authorisation holder shall be identified as such."

Justification

It has to be clear for the public that information is made available by the pharmaceutical company: in case information is made available by a third party, it also has to be clear that the third party is acting on behalf of the pharmaceutical company.

Amendment 26

Proposal for a directive – amending act
Article 1 - point 2
Directive 2001/83/EC
Article 88 – paragraph 4

Text proposed by the Commission	*Amendment*
4. The prohibition set out in paragraph 1 shall not apply to vaccination campaigns ***and other campaigns in the interest of public health*** carried out by the industry and approved by the competent authorities of the Member States.	4. The prohibition set out in paragraph 1 shall not apply to vaccination campaigns carried out by the industry and approved by the competent authorities of the Member States. ***Such campaigns shall be approved by the competent authorities of the Member States only if it is ensured that objective, non-biased information is provided in the frame of the campaign by the industry on the causes of the disease, the efficacy of the vaccine, the suspected adverse reactions and contra-indications of the vaccination.***

Justification

Amendment 27

Proposal for a directive – amending act
Article 1 – point – 4 a (new)
Directive 2001/83/EC
Article 94 – paragraph 1

Text proposed by the Commission	*Amendment*
	(4a) Article 94(1) shall be replaced by the following: ***"*****1. Where medicinal products are being promoted** ***directly or indirectly by a marketing authorisation holder or a third party acting on its behalf or following its instructions*** **to persons qualified to prescribe or supply them, no gifts, pecuniary advantages or benefits in kind may be supplied, offered or promised to such persons.*****"**

Justification

There should be no gifts or other advantages whatsoever, as research evidence indicates that the instinct to reciprocate is a powerful influence on the behaviour even when small gifts are concerned.

Amendment 28

Proposal for a directive – amending act
Article 1 - point 5
Directive 2001/83/EC
Article 100 a - paragraph 1

Text proposed by the Commission	*Amendment*
1. Member States shall ***allow*** the marketing authorisation holder to ***disseminate***, either directly or indirectly through a third party, information to the general public or members thereof on authorised medicinal products subject to medical prescription provided that ***it*** is in accordance with the provisions of this Title. Such information shall not be considered advertising for the purposes of the application of Title VIII.	1. ***Without prejudice to the importance of the role that national competent authorities and healthcare professionals play in better informing patients and the general public on authorised medicinal products subject to medical prescription,*** Member States shall ***require*** the marketing authorisation holder to ***make available***, either directly or indirectly through a third party ***acting on behalf of the marketing authorisation holder,*** information ***that has been officially approved by national or European competent authorities*** to the general public or members thereof on authorised medicinal products subject to medical prescription provided that ***such information and the manner in which it is made available*** is in accordance with the provisions of this Title. Such information shall not be considered advertising for the purposes of the application of Title VIII. ***When such information is made available, the marketing authorisation holder and any third party shall be identified, and any third party acting on behalf of the marketing authorisation holder shall be clearly indentified as such.***

Justification

(i)The Directive should be made patient-centred and therefore its focus has to be shifted: emphasis should be put on the right of patients to access information and not on the opportunity for pharmaceutical companies to disseminate information. (ii) It has to be clear for the public that information is made available by the pharmaceutical company: in case information is made available by a third party, it also has to be clear that the third party is acting on behalf of the pharmaceutical company.

Amendment 29

Proposal for a directive – amending act
Article 1 – point 5
Directive 2001/83/EC
Article 100 a – paragraph 1 a (new)

Text proposed by the Commission	*Amendment*
	1a. Health professionals who deliver information on medicinal products or medical devices during a public event, in print or broadcast media shall declare publicly their interests, for example any financial ties with marketing authorisation holders or with third parties working on their behalf. This also includes the provision of consulting services and technical advice about the product(s) in question.

Amendment 30

Proposal for a directive – amending act
Article 1 – point 5
Directive 2001/83/EC
Article 100 a – paragraph 1 b (new)

Text proposed by the Commission	*Amendment*
	1b. Information campaigns aimed at raising awareness among the general public and members thereof about the risks of falsified medicinal products should be organised. Such information campaigns may be conducted by national

	competent authorities in collaboration with industry, healthcare professionals and patient organisations.

Justification

In order to better protect human health, information campaigns about the risks of falsified medicines, initiated by national authorities, could be very useful and beneficial to patients. In order to increase the quality of these information campaigns and to ensure that they reach patients in an effective way, national authorities should take into consideration the expertise on the matter coming from the industry, health care professionals and patient organisations.

Amendment 31

Proposal for a directive - amending act
Article 1 – point 5
Directive 2001/83/EC
Article 100 a – paragraph 2

Text proposed by the Commission	*Amendment*
2. This Title shall not cover the following:	2. This Title shall not cover the following:
(a) ***information relating to human health or diseases, provided that there is no reference, even indirect, to medicinal products;***	(a) ***factual, informative announcements (including announcements or statements made to media organisations either in response to a direct enquiry or by dissemination of such information via conferences or written releases and announcements or reports to shareholders and/or regulators) and reference material on a medicinal product relating, for example, to pack changes, adverse-reaction warnings as part of general drug precautions, trade catalogues, price lists and reimbursement, provided that they do not intend to promote an individual medicinal product;***
(b) ***material provided by the marketing authorisation holder to healthcare professionals for distribution to patients.***	(b) ***material provided to healthcare professionals for their own use.***

Justification

For consistency and coherency with the stated aims of the proposal and to better ensure that

information provided is not of promotional nature, of the directive points the provisions set our in point a) and b) should fall under the scope of Title VIII.

This amendment is coherent with the amendment on article 86(2) and aims at clarifying the scope of the directive. Market authorization holders should be allowed to provide certain information. Stock market rules require that companies keep investors fully informed of significant developments and employees must be kept informed of business developments. It is necessary to specify this to allow appropriate provision of such information.

It should be ensured that information provided to healthcare professionals for their own use is not covered by the Directive.

Amendment 32

Proposal for a directive – amending act
Article 1 - point 5
Directive 2001/83/EC
Article 100 a - paragraph 2 a (new)

Text proposed by the Commission	*Amendment*
	2a. The provisions of this Directive shall be without prejudice to the right of any other person or organisation, in particular the press or patients and patient organisations, to express their views on prescription-only medicinal products, provided that they are acting independently and not directly or indirectly on behalf of, on the instructions of, or in the interest of the marketing authorisation holder.

Justification

With reference to recent developments in the case law it has to be emphasised that the provisions of this Directive do not affect the right of any other person or organisation, in particular the press or patients' groups to express their views on prescription-only medicines as long as they are acting not in the interest of, or on behalf of the pharmaceutical companies.

Amendment 33

Proposal for a directive – amending act
Article 1 - point 5
Directive 2001/83/EC
Article 100b

Text proposed by the Commission	*Amendment*
The following types of information on authorised medicinal products subject to medical prescription ***may be disseminated by the marketing authorisation holder*** to the general public or members thereof:	***1. The marketing authorisation holder shall, in respect of*** authorised medicinal products subject to medical prescription***,*** ***make available*** to the general public or members thereof the ***following information:***
	(a) ***the most recent*** summary of product characteristics ***as approved by the competent authorities during the course of marketing authorisation and authorisation renewal;***
	(b) the most recent labelling and package leaflet as approved by the competent authorities ***during the course of marketing authorisation or authorisation variation;*** and
	(c) the ***most recent,*** publicly accessible version of the assessment report ***as*** drawn up by the competent authorities ***during the course of marketing authorisation and authorisation updates***.
(a) the summary of product characteristics***,*** labelling and package leaflet ***of the medicinal product***, as approved by the competent authorities***,*** and the publicly accessible version of the assessment report drawn up by the competent authorities.	
	That information shall be presented in a format that faithfully represents the officially approved information drawn up by the competent authorities. The information shall be made available both in electronic and printed form, and in formats appropriate for the blind and partially-sighted.
(b) information which does not go beyond the elements of the summary of product characteristics, labelling and the package leaflet of the medicinal product, and the publicly accessible version of the assessment report drawn up by the competent authorities, but presents them	

in a different way;

2. The marketing authorisation holder may, in respect of authorised medicinal products subject to medical prescription, make available to the general public or members thereof the following information:

(c) information on the environmental impact of the medicinal product, prices and ***factual, informative announcements and reference material relating, for example, to*** pack changes ***or*** adverse-reaction warnings;

(a) information on the environmental impact of the medicinal product ***further to the information provided on the disposal and collection system pursuant to Article 54 (j) and made available pursuant to paragraph 1 of this Article;***

(b) information on prices***;***

(c) information on pack changes***;***

(d) adverse-reaction warnings ***further to the information provided pursuant to Article 59 (1) (e) and made available pursuant to paragraph 1 of this Article***;

(e) instructions for use of the medicinal product, further to the information provided pursuant to Article 59 (1) (d) and made available pursuant to paragraph 1 of this Article. This information may be completed, where necessary, with still or moving images of a technical nature demonstrating the proper way of using the product;

(f) the pharmaceutical and pre-clinical tests and the clinical trials of the medicinal product concerned that are contained in the publicly accessible version of the assessment report referred to in paragraph 1;

(g) a summary of the frequently submitted requests for information pursuant to Article 100c (c), and the subsequent answers.

(d) medicinal product-related 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.

Information pursuant to points (a) to (g) shall be made available both in electronic and printed form, and in formats appropriate for the blind and partially-sighted.

Information pursuant to points (a) to (g) shall be approved by the competent authorities, or in case of Community marketing authorisation, by the Agency, prior to its being made available for the purpose of this Article.

Justification

Amendment 34

Proposal for a directive – amending act
Article 1 - point 5
Directive 2001/83/EC
Article 100c

Text proposed by the Commission	*Amendment*
Information on authorised medicinal products subject to medical prescription ***disseminated*** by the marketing authorisation holder to the general public or members thereof shall not be made available on television or radio. It shall only be made available through the following channels:	Information on authorised medicinal products subject to medical prescription ***made available*** by the marketing authorisation holder to the general public or members thereof shall not be made available on television, radio ***or newspapers, magazines and similar publications***. It shall only be made available through the following channels:
(a) health-related publications as defined by the Member State of publication, to the exclusion of unsolicited material actively distributed to the general public or members thereof;	
(b) internet websites on medicinal products, to the exclusion of unsolicited material actively distributed to the general public or members thereof;	(b) internet websites on medicinal products ***registered and managed in accordance with Article 100h***, to the exclusion of unsolicited material actively distributed to the general public or members thereof;
(c) ***written*** answers to requests for information of a member of the general	(c) answers to ***specific*** requests for information ***about a medicinal product*** of

public**.**	a member of the general public***;***
	(ca) printed materials about a medicinal product prepared by the marketing authorisation holder pursuant to Article 100b upon specific request by a member of the general public.

Justification

Amendment 35

Proposal for a directive – amending act
Article 1 – point 5
Directive 2001/83/EC
Article 100d **–** paragraph 1 **–** introductory part

Text proposed by the Commission	*Amendment*
1. The content and presentation of information on authorised medicinal products subject to medical prescription ***disseminated*** by the marketing authorisation holder to the general public or members thereof shall fulfil the following conditions:	1. The content and presentation of information on authorised medicinal products subject to medical prescription ***made available*** by the marketing authorisation holder to the general public or members thereof shall fulfil the following conditions:

Justification

Information should not be disseminated by the marketing authorization holder as it may imply an active role (push) in passing information to the public. Information may, however, be made available to the public by the marketing authorization holder: the public must have a proactive role in seeking such information (pull).

Amendment 36

Proposal for a directive - amending act
Article 1 – point 5
Directive 2001/83/EC
Article 100d – paragraph 1 – point b

Text proposed by the Commission	*Amendment*
b) it must ***take into account the general*** needs ***and expectations of patients***;	b) it must ***be patient oriented to better meet patients'*** needs;

Justification

Re-wording to better reflect one of the main objectives of the proposal, namely to provide information that patients want and that better meets their individual needs.

Amendment 37

Proposal for a directive – amending act
Article 1 – point 5
Directive 2001/83/EC
Article 100d – paragraph 1 – point f

Text proposed by the Commission	*Amendment*
(f) it must be understandable for the general public ***or*** members thereof;	(f) it must be understandable ***and perfectly legible*** for the general public ***and*** members thereof***, paying particular attention to elderly people***;

Amendment 38

Proposal for a directive – amending act
Article 1 - point 5
Directive 2001/83/EC
Article 100 d - paragraph 1 a (new)

Text proposed by the Commission	*Amendment*
	1a. By ...*, the Commission shall present to the European Parliament and the Council an assessment report on current shortcomings in the summary of product characteristics and the package leaflet and how they could be improved in order to better meet the needs of patients and healthcare professionals. The Commission shall, if appropriate, and on the basis of the report, and after consultation with appropriate stakeholders, present proposals in order to improve the readability, layout and content of these documents. **** OJ: Insert date 24 months after the entry into force of this Directive***

JustificationAlignment to Directive on Pharmacovigilance.

Amendment 39

Proposal for a directive – amending act
Article 1 – point 5
Directive 2001/83/EC
Article 100d – paragraph 2 – point b

Text proposed by the Commission	*Amendment*
(b) a statement indicating that the information is intended to support, not to replace, the relationship between patient and health professionals and that a health professional should be contacted if the patient requires clarification on the information provided;	(b) a statement indicating that the information is intended to support, not to replace, the relationship between patient and health professionals and that a health professional should be contacted if the patient requires clarification ***or further information*** on the information provided;

Justification

To clarify in the statement that a health professional should be contacted if a patient requires further information. The health professional may however not be in a position to answer specific questions relating to the information provided by the manufacturer.

Amendment 40

Proposal for a directive - amending act
Article 1 – point 5
Directive 2001/83/EC
Article 100 d – paragraph 2 – point c

Text proposed by the Commission	*Amendment*
(c) a statement indicating that the information is ***disseminated*** by a marketing authorisation holder;	(c) a statement indicating that the information is ***made available*** by***, or on behalf of,*** a ***named*** marketing authorisation holder;

Justification

A third party may undertake dissemination on behalf of the Marketing Authorisation Holder. Readers of the statement may not be familiar with the term "marketing authorisation holder". A statement bearing the name of the marketing authorisation holder is more meaningful and understandable.

Amendment 41

Proposal for a directive - amending act
Article 1 – point 5
Directive 2001/83/EC
Article 100 d – paragraph 2 – point d

Text proposed by the Commission	*Amendment*
(d) a ***mail*** address or e-mail address allowing members of the general public to send comments to the marketing authorisation holder.	(d) a ***postal*** address or e-mail address allowing members of the general public to send comments to***, or requests for further information from,*** the marketing authorisation holder***. Comments sent by private individuals and the replies from marketing authorisation holders shall be duly recorded and monitored***.

Justification

The word 'postal' is better than ´mailing`.

Amendment 42

Proposal for a directive – amending act
Article 1 – point 5
Directive 2001/83/EC
Article 100 d – paragraph 2 – point d a (new)

Text proposed by the Commission	*Amendment*
	(da) a postal address or e-mail address allowing members of the general public to send comments to the national competent authorities;

Justification

The general public should know who to contact of the authorities if the information is misleading or inappropriate.

Amendment 43

Proposal for a directive – amending act
Article 1 – point 5
Directive 2001/83/EC
Article 100d – paragraph 2 – point d b (new)

Text proposed by the Commission	*Amendment*
	(db) the text of the current package leaflet or an indication as to where that text may be found. In the case of Internet sites under the control of marketing authorisation holders that are directed specifically at citizens of one or more Member States, they shall contain the summary of product characteristics and the package leaflet of the medicinal products concerned in the official languages of the Member States where they are authorised if the information on medicinal products is presented in those languages.

Justification

It is important that the reader is able to access the current package leaflet text. The requirement for Internet websites is better dealt with under this paragraph than as a monitoring requirement for Member States.

Amendment 44

Proposal for a directive - amending act
Article 1 – point 5
Directive 2001/83/EC
Article 100 d – paragraph 2 – point d c (new)

Text proposed by the Commission	*Amendment*
	dc) a statement indicating that members of the general public are encouraged to report all suspected adverse reactions of medicinal products to their doctor, pharmacist, healthcare professional, or to the national competent authority, and indicating the name and web-address, postal address and /or telephone number

of that national competent authority.

Amendment 45

Proposal for a directive - amending act
Article 1 – point 5
Directive 2001/83/EC
Article 100 d – paragraph 3 – point a

Text proposed by the Commission	*Amendment*
a) comparisons between medicinal products;	a) comparisons between medicinal products ***regarding their quality, safety and efficiency, if disseminated by marketing authorisation holders except where those comparisons are:*** ***- included in officially approved documents, such as the Summary of Product Characteristics***; ***- based on comparative scientific studies published by the relevant national authorities or the European Medicines Agency;*** ***- contained in the summary of the European Public Assessment Reports referred to in Article 13 of Regulation (EC) No 726/2004, which shall list the other available therapeutic options and whether the new medicinal product brings about a therapeutic value.***

Justification

Comparisons exist in the Summary of Product Characteristics (SmPC) and package leaflets of some medicines. To exclude those existing comparisons would in effect require that information provided by marketing authorisation holders is incomplete. This could also prejudice the approval process. Comparative scientific studies on the quality, safety and efficiency of different medicinal products by independent National Authorities and the EMEA should not be discouraged as they can provide a valuable source for consumer information.

Amendment 46

Proposal for a directive – amending act
Article 1 - point 5
Directive 2001/83/EC
Article 100 d - paragraph 3 - point a a (new)

Text proposed by the Commission	*Amendment*
	(aa) any inducement to, or promotion of, the consumption of the medicinal product;

Justification

The distinction between information and advertisement should be further emphasised. 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.

Amendment 47

Proposal for a directive - amending act
Article 1 – point 5
Directive 2001/83/EC
Article 100 d – paragraph 3 – point b a (new)

Text proposed by the Commission	*Amendment*
	(ba) information on other medicinal products for which the pharmaceutical company is not the marketing authorisation holder.

Justification

Misinformation campaigns by third party companies on medicinal products which have obtained a marketing authorisation from competent authorities must be prohibited by any means. The prohibition should be extended to advertising and information to healthcare professionals. Misinformation campaigns from originator companies on generic medicines, for instance, towards the general public has been identified as one of the delaying strategies in the Preliminary Report of the Pharmaceutical Sector Inquiry.

Amendment 48

Proposal for a directive – amending act
Article 1 - point 5
Directive 2001/83/EC
Article 100 d - paragraph 4

Text proposed by the Commission	*Amendment*
4. The Commission shall adopt the measures necessary for the ***implementation*** of paragraphs 1, 2 and 3.	4. ***In order to ensure the quality of information made available to the general public and members thereof,*** the Commission shall adopt, ***by means of delegated acts in accordance with Article 100 kb and subject to the conditions of Articles 100 kc and 100 kd,*** the measures necessary for the ***application*** of paragraphs 1, 2 and 3.
Those measures, designed to amend non-essential elements of this Directive by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 121(2a).	

Justification

The comitology regime has to be aligned to the system of delegated acts introduced by Article 290 of the Treaty on the Functioning of the European Union (i.e. the Lisbon Treaty).

Amendment 49

Proposal for a directive – amending act
Article 1 – point 5
Directive 2001/83/EC
Article 100 e – paragraph 1

Text proposed by the Commission	*Amendment*
1. Member States shall ensure that marketing authorisation holders' Internet websites ***for*** the ***dissemination*** of ***information on medicinal products subject to medical prescription reproduce*** the summary of product characteristics and the package leaflet of the medicinal products ***concerned*** in the official	1. Member States shall ensure that marketing authorisation holders' Internet websites ***reproduce*** the ***last updated version as approved by the competent authorities*** of the summary of product characteristics and ***of*** the package leaflet of the medicinal products ***subject to medical prescription that they commercialise*** in the

languages of the Member States where they are authorised.	official languages of the Member States where they are authorised.

Justification

The documents on prescription-only medicinal products provided by marketing authorisation holders via their Internet websites should be up-to-date.

Amendment 50

Proposal for a directive - amending act
Article 1 – point 5
Directive 2001/83/EC
Article 100 e – paragraph 1 a (new)

Text proposed by the Commission	*Amendment*
	1a. Member States shall ensure that each webpage from a marketing authorisation holders' website referring to a medicinal product subject to medical prescription includes a link to the corresponding webpage of the Community database referred to in Articles 57(1)(l) and 57(2) of Regulation EC 726/2004, and the national or Community safety web portal referred to in Article 106 of Directive 2001/83/EC, and Article 26 of Regulation (EC) No 726/2004.

Justification

A link to the Eudrapharm database would raise awareness of this useful source of information to patients, which offers a wide range of functionalities and search facilities. A link to the national and Community safety web portals would allow patients to access additional information about the safety of a medicinal product.

Amendment 51

Proposal for a directive - amending act
Article 1 – point 5
Directive 2001/83/EC
Article 100 e – paragraph 1 b (new)

Text proposed by the Commission	*Amendment*
	1b. The summary of the European Public Assessment Reports referred to in Article 13 of Regulation (EC) No 726/2004 shall be hyperlinked with the corresponding studies in the clinical trials database provided for in Article 11 of Directive 2001/20/EC (hereinafter 'the EudraCT database').

Justification

Such a link to the EudraCT database would facilitate access to the scientific results of studies. The scientific results of studies are essential to the development and to the understanding of reliable information.

Amendment 52

Proposal for a directive – amending act
Article 1 – point 5
Directive 2001/83/EC
Article 100 e – paragraph 2

Text proposed by the Commission	*Amendment*
2. Member States shall ensure that requests for information to a marketing authorisation holder on a medicinal product subject to medical prescription by a member of the general public may be drafted in any of the official languages of the Community which are official languages in the Member States where the medicinal product is authorised. The reply shall be drafted in the language of the request.	2. Member States shall ensure that requests for information to a marketing authorisation holder on a medicinal product subject to medical prescription by a member of the general public may be drafted in any of the official languages of the Community which are official languages in the Member States where the medicinal product is authorised. The reply shall be drafted in the language of the request. ***The replies shall be kept available for inspections by national competent authorities.***

Justification

Marketing authorisation holder need to keep available the replies to allow easy control by the National Competent Authorities.

Amendment 53

Proposal for a directive – amending act
Article 1 - point 5
Directive 2001/83/EC
Article 100 f - paragraph 2 - subparagraph 2

Text proposed by the Commission	*Amendment*
The Commission may ***amend this paragraph to take account of technical progress. This measure, designed to amend non-essential elements of this Directive, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 121(2a)***.	***In order to take account of technical progress,*** the Commission may ***adopt, by means of delegated acts in accordance with Article 100 kb and subject to the conditions of Articles 100 kc and 100 kd, measures necessary for the application of this paragraph***.

Justification

The comitology regime has to be aligned to the system of delegated acts introduced by Article 290 of the Treaty on the Functioning of the European Union (i.e. the Lisbon Treaty).

Amendment 54

Proposal for a directive – amending act
Article 1 – point 5
Directive 2001/83/EC
Article 100f – paragraph 2 a (new)

Text proposed by the Commission	*Amendment*
	2a. A harmonised procedure shall be established to determine the bases on which information provided on Internet websites and information points is regulated, in such a way as to guarantee the reliability of the data presented and its compliance with the authorisation and registration of the medicinal product, providing a guarantee for consumers that the site or information concerned is accurate and based on facts. A certification or qualification system shall be applied with respect to authorised sites. A list shall also be kept of Internet web

	pages and information points authorised to provide the information referred to in this Directive. That list shall be kept up to date and shall be accessible to consumers.

Amendment 55

Proposal for a directive - amending act
Article 1 – point 5
Directive 2001/83/EC
Article 100 g – paragraph 1 – subparagraph 1

Text proposed by the Commission	*Amendment*
1. Member States shall ensure that ***there are adequate and effective methods of monitoring to avoid*** misuse ***when information on authorised medicinal products subject to medical prescription*** is ***disseminated by*** the marketing authorisation holder to the general public or members thereof.	1. Member States shall ensure that misuse is ***avoided*** by ***ensuring that only*** the marketing authorisation holder ***supplies information, and only such information which has been approved by the competent authorities about approved medicines subject*** to ***medical prescription, and in the form which has been approved for*** the ***making available*** to the general public or members thereof. ***By way of derogation Member States may continue those types of control mechanism which they have been implemented before 31 December 2008. The Commission shall verify and approve these systems.***

Amendment 56

Proposal for a directive – amending act
Article 1 – point 5
Directive 2001/83/EC
Article 100 g – paragraph 1 – subparagraph 3

Text proposed by the Commission	*Amendment*
The methods may include the voluntary control of information on medicinal products by self-regulatory or co-regulatory bodies and recourse to such bodies, if proceedings before such bodies are possible in addition to the judicial or	***deleted***

administrative proceedings available in the Member States.

Justification

From many Member States' points of view a voluntary system of control of information by self-regulatory or co-regulatory bodies is too weak. Nevertheless, a few Member States practice self-regulatory systems. The effectiveness and the assertiveness of self-regulatory systems strongly depend on the cultural and judicial conception of a society and therefore should not be regulated for all Member States.

Amendment 57

Proposal for a directive – amending act
Article 1 - point 5
Directive 2001/83/EC
Article 100 g - paragraph 2

Text proposed by the Commission	*Amendment*
2. After consulting the Member States, the Commission shall draw up guidelines concerning information allowed under this Title and containing a code of conduct for marketing authorisation holders providing information to the general public or members thereof on authorised medicinal products subject to medical prescription. The Commission shall draw up these guidelines on the entry into force of this directive and update them regularly on the basis of the experience gained.	2. After consulting the Member States, ***patient organisations and healthcare professionals,*** the Commission shall draw up guidelines concerning information allowed under this Title and containing a code of conduct for marketing authorisation holders providing information to the general public or members thereof on authorised medicinal products subject to medical prescription. ***The guidelines shall contain provisions to ensure that members of the public may lodge complaints with competent authorities regarding misleading practices in the making available of information.*** The Commission shall draw up these guidelines on the entry into force of this directive and update them regularly on the basis of the experience gained.

Justification

As the information is targeted at patients, patients' organizations have to be involved into the process of establishing the guidelines. The perspective of health professionals is also crucial as they are and should remain the main source of information to patients on prescribed pharmaceuticals.

Amendment 58

Proposal for a directive - amending act
Article 1 – point 5
Directive 2001/83/EC
Article 100 h – paragraph 1 – subparagraph 1

Text proposed by the Commission	*Amendment*
1. Member States shall ensure that marketing authorisation holders register Internet websites ***containing*** information on ***medicinal products with the national competent authorities of the Member State of the country code Top Level Domain used*** by ***the website concerned***, prior to making it available to the general public. Where the website does not use a country code Top Level Domain, the marketing authorisation holder shall select the Member State of registration.	1. Member States shall ensure that marketing authorisation holders register Internet websites ***under their control that are directed specifically at citizens of one or more Member States and that contain authority-approved*** information on ***prescription-only medicines covered*** by ***this Title***, prior to making it available to the general public. Where the website does not use a country code Top Level Domain, the marketing authorisation holder shall select the Member State of registration. ***This information shall comply with the requirements laid down in this Directive and shall be in accordance with the registration dossier for the medicinal product.***

Justification

Necessary clarification as this Directive only covers websites that are under the control of the Marketing Authorisation Holder and aimed at EU citizens. It does not cover websites that are aimed outside the EU nor those aimed at a global audience, irrespective of whether the information was generated or the server was based in the EU. Also it does not cover business sites that contain corporate information including product sales figures and other product related business information.

Amendment 59

Proposal for a directive – amending act
Article 1 - point 5
Directive 2001/83/EC
Article 100h - paragraph 1 - subparagraph 2

Text proposed by the Commission	*Amendment*
After registration of the Internet website, the information on a medicinal product contained therein may be provided by the marketing authorisation holder on other Internet websites throughout the Community if the contents are identical.	After registration of the Internet website, the information on a medicinal product contained therein may be provided by the marketing authorisation holder on other Internet websites ***registered by the marketing authorisation holder in accordance with the provisions of the first subparagraph*** throughout the Community if the contents are identical. ***Such websites shall clearly identify the marketing authorisation holder.***

Justification

Amendment 60

Proposal for a directive - amending act
Article 1 – point 5
Directive 2001/83/EC
Article 100h – paragraph 1 – subparagraph 2 a (new)

Text proposed by the Commission	*Amendment*
	After registration of the Internet website, any amendments to the content relating to medicinal products subject to medical prescription shall be subject to monitoring in accordance with paragraph 3. Such changes shall not require re-registration of the website.

Justification

If changes to the content of a website are made, these should be monitored by the Member State where the Internet website has been registered. A re-registration should not be required to avoid unnecessary bureaucracy.

Amendment 61

Proposal for a directive – amending act
Article 1 - point 5
Directive 2001/83/EC
Article 100 h - paragraph 2 - subparagraph 2

Text proposed by the Commission	*Amendment*
Internet websites registered in accordance with paragraph 1 shall not allow the identification of members of the general public which have access to those websites or the appearance therein of unsolicited ***material actively*** distributed to the general public or members thereof. ***Those websites shall not contain web-TV.***	Internet websites registered in accordance with paragraph 1 shall not allow the identification of members of the general public which have access to those websites ***without their explicit prior consent,*** or the appearance therein of unsolicited ***content*** distributed to the general public or members thereof. ***Internet websites may provide video content if it is useful for promoting the safe and effective use of the medicine.***

Justification

(*i) Depending on the design of the website, patients regularly visiting the site might wish to register/identify themselves in order to access information previously searched or to access information faster; this, however, could be done only with their explicit prior consent. (ii) For certain medicinal products (e.g. inhalers) other material and tools, for example a short film, is helpful to demonstrate the correct use of a medicinal product*.

Amendment 62

Proposal for a directive – amending act
Article 1 – point 5
Directive 2001/83/EC
Article 100 h – paragraph 2 – subparagraph 2 a (new)

Text proposed by the Commission	*Amendment*
	The registered websites shall display a notification at the top of each website page informing the public that the information contained therein is developed by a named marketing authorisation holder. A link to the EudraPharm database on medicinal products shall also be included in that notification.

Justification

The users of Internet sites containing information on prescription medicines must be clearly informed that such information has been developed by a marketing authorisation holder. The link to the EudraPharm database will ensure that users have direct and easy access to comparable information on prescription medicines provided by a non-commercial source, ensuring greater transparency.

Amendment 63

Proposal for a directive - amending act
Article 1 – point 5
Directive 2001/83/EC
Article 100 h – paragraph 3

Text proposed by the Commission	*Amendment*
3. The Member State where the Internet website has been registered shall be responsible for the monitoring of the contents ***disseminated*** on that website.	3. The Member State where the Internet website has been registered shall be responsible for the monitoring of the contents ***relating to medicinal products subject to medical prescription made available*** on that website.

Justification

The precision is important as much of the website's content could be unrelated to prescription medicinal products.

Amendment 64

Proposal for a directive - amending act
Article 1 – point 5
Directive 2001/83/EC
Article 100 h – paragraph 4 – point a

Text proposed by the Commission	*Amendment*
(a) If a Member State has reasons for doubts as to whether the translation of the reproduced information is correct, it may require a marketing authorisation holder to provide for a certified translation of the information disseminated on the Internet	(a) If a Member State has reasons for doubts as to whether the translation of the reproduced information is correct, it may require a marketing authorisation holder to provide for a certified translation of the ***authority-approved*** information

website registered with the national competent authority of another Member State.

disseminated on the Internet website registered with the national competent authority of another Member State.

Amendment 65

Proposal for a directive - amending act
Article 1 – point 5
Directive 2001/83/EC
Article 100 h – paragraph 4 – point b

Text proposed by the Commission	*Amendment*
(b) If a Member State has reasons for doubts as to whether the information ***disseminated*** on an Internet website registered with the national competent authorities of another Member State complies with the requirements of this Title, it shall inform that Member State of the reasons for its doubts. The Member States concerned shall use their best endeavours to reach agreement on the action to be taken. If they fail to reach an agreement within two months, the case shall be referred to the Pharmaceutical Committee set up by Decision 75/320/EEC. Any necessary measures may only be adopted after an opinion has been delivered by that Committee. Member States shall take account of opinions delivered by the Pharmaceutical Committee and shall inform the Committee of how its opinion has been taken into account.	(b) If a Member State has reasons for doubts as to whether the ***authority-approved*** information ***made available*** on an Internet website registered with the national competent authorities of another Member State complies with the requirements of this Title, it shall inform that Member State of the reasons for its doubts. The Member States concerned shall use their best endeavours to reach agreement on the action to be taken. If they fail to reach an agreement within two months, the case shall be referred to the Pharmaceutical Committee set up by Decision 75/320/EEC. Any necessary measures may only be adopted after an opinion has been delivered by that Committee. Member States shall take account of opinions delivered by the Pharmaceutical Committee and shall inform the Committee of how its opinion has been taken into account.

Amendment 66

Proposal for a directive – amending act
Article 1 – point 5
Directive 2001/83/EC
Article 100 h – paragraph 5

Text proposed by the Commission	*Amendment*
5. Member States shall ***allow*** marketing authorisation holders which have registered Internet websites in accordance with paragraphs 1 to 4 to include a ***statement therein to*** the ***effect*** that the ***site has been registered*** and is subject to monitoring in ***accordance with this Directive***. The statement shall identify the national competent authority monitoring the website concerned. It shall also specify that the fact that the website is monitored does not necessarily mean that all the information on the website has been subject to prior approval.	5. Member States shall ***require*** marketing authorisation holders which have registered Internet websites in accordance with paragraphs 1 to 4 to include a ***message at*** the ***top of each website page informing the public*** that ***information contained therein is developed by*** the ***marketing authorisation holder*** and is ***therefore*** subject to monitoring in ***order to avoid advertising of prescription medicines***. The statement shall ***clearly*** identify the national competent authority monitoring the website concerned ***and the marketing authorisation holder responsible for the website***. It shall also specify that the fact that the website is monitored does not necessarily mean that all the information on the website has been subject to prior approval ***and include a link to the EudraPharm database specifying that validated information is available there***.

Justification

The fact that the website is registered and monitored in accordance with a Directive offers no added value for users, but can be misused. It is important that the users are clearly informed that the website is "monitored in order to avoid advertising of prescription medicines" because the general public is not well aware of the notion of vested interests. The link to the Eudrapharm database will ensure that users have direct and easy access to comparable information on prescription medicines provided by a non-commercial source.

Amendment 67

Proposal for a directive - amending act
Article 1 – point 5
Directive 2001/83/EC
Article 100 i – paragraph 1 – subparagraph 1 a (new)

Text proposed by the Commission	*Amendment*
	Member States shall provide for the possibility to publish the name of a marketing authorisation holder

responsible for disseminating non-compliant information on a medicinal product.

Justification

This is an effective and dissuasive measure that would contribute to ensure the compliance with the legislation.

Amendment 68

Proposal for a directive – amending act
Article 1 – point 5
Directive 2001/83/EC
Article 100i – paragraph 1 – subparagraph 1 b (new)

Text proposed by the Commission	*Amendment*
	The level of penalties shall be determined at Community level.

Justification

It should not be a matter for Member States to determine the level of penalties. Setting of penalties by the Community provides more legal clarity and ensures that the sanctions have a clear deterrent effect in the event of violations.

Amendment 69

Proposal for a directive - amending act
Article 1 – point 5
Directive 2001/83/EC
Article 100 i – paragraph 2 a (new)

Text proposed by the Commission	*Amendment*
	2a. Member States shall ensure that marketing authorisation holders are represented and heard in any consideration of a case in which they are accused of non-compliance with the provisions set out in this Title. The marketing authorisation holders shall have the right to appeal to a judicial or other body against any decision. During

	the appeal procedure the dissemination of information shall be suspended until a contrary decision is taken by the responsible body.

Justification

This amendment aims to ensure greater efficiency and transparency in the process. Market authorization holders should be given the right to defend themselves in case they consider that the charges of non-compliance are unfounded. In order to protect the general public from information that would possibly not respect the provisions of this Title, it is necessary that the dissemination is suspended right after the decision of the competent authority. It should be resumed only in case the body responsible for analysing the marketing authorization holder's appeal decides so.

Amendment 70

Proposal for a directive - amending act
Article 1 – point 5
Directive 2001/83/EC
Article 100 j – point a

Text proposed by the Commission	*Amendment*
a) keep available for the authorities or bodies responsible for monitoring information on medicinal products, a sample of all information ***disseminated*** in accordance with this Title and information on its volume of ***dissemination***, together with a statement indicating the persons to whom it is addressed, the method of ***dissemination*** and the date of first ***dissemination***,	a) keep available for the ***competent*** authorities or bodies responsible for monitoring information on medicinal products ***that have approved the information in advance***, a sample of all information ***made available*** in accordance with this Title and information on its volume of ***provision***, together with a statement indicating the persons to whom it is addressed, the method of ***provision*** and the date of first ***provision***,

Amendment 71

Proposal for a directive – amending act
Article 1 – point 5
Directive 2001/83/EC
Article 100 j – point c

Text proposed by the Commission	*Amendment*
c) ***supply*** the authorities or bodies responsible for monitoring information on medicinal products with the information and assistance they require to carry out their responsibilities;	c) ***provide*** the authorities or bodies responsible for monitoring information on medicinal products with the information***, the financial resources*** and assistance they require to carry out their responsibilities;

Justification

The competent authorities should be given the appropriate financial resources in order to fulfil their tasks.

Amendment 72

Proposal for a directive – amending act
Article 1 – point 5 (new)
Directive 2001/83/EC
Article 100 j – point c a (new)

Text proposed by the Commission	*Amendment*
	ca) put in place complaint-handling systems and efficient redress mechanisms to deal with consumer complaints and to ensure fair compensation of victims.

Justification

Misleading information on prescription medicine can have serious consequences for public health. A complaint and redress system to protect consumers and provide them the tools to enforce their rights and seek compensation in case of misleading information needs to be added.

Amendment 73

Proposal for a directive – amending act
Article 1 – point 5
Directive 2001/83/EC
Article 100k

Text proposed by the Commission	*Amendment*
Information on homeopathic medicinal products referred to in Article 14(1) that have been classified as prescription-only shall be subject to the provisions of this Title.	Information on homeopathic medicinal products referred to in Article 14(1) that have been classified as prescription-only shall be subject to the provisions of this Title. ***The same shall apply to information on herbal medicinal products or any other compounds or therapies that have been classified as prescription-only.***

Amendment 74

Proposal for a directive – amending act
Article 1 - point 5
Directive 2001/83/EC
Article 100 k a (new)

Text proposed by the Commission	*Amendment*
	Article 100ka
	Consultation with independent patient, health and consumer organisations
	The Commission shall consult independent patient, health and consumer organisations on issues relating to the implementation of this Directive and its application by the Member States.

Justification

In order to make patients' voice heard on issues related to the implementation and application of this Directive, the Commission should consult the patients' organisations.

Amendment 75

Proposal for a directive – amending act
Article 1 - point 5
Directive 2001/83/EC
Article 100 k b (new)

Text proposed by the Commission	*Amendment*
	Article 100kb
	Exercise of the delegation
	1. The power to adopt delegated acts referred to in Articles 100d (4) and 100f (2) shall be conferred on the Commission for a period of 5 years following the entry into force of this Directive. The Commission shall draw up a report in respect of the delegated power at the latest 6 months before the end of the 5 year period. The delegation of power shall be automatically extended for periods of an identical duration, unless the European Parliament and the Council revoke it in accordance with Article 100kc.
	2. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.
	3. The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in Articles 100kc and 100kd.

Justification

Pursuant to Article 290 of the Treaty on the Functioning of the European Union, detailed provisions on the delegation of powers have to be set out in the Directive.

Amendment 76

Proposal for a directive – amending act
Article 1 - point 5
Directive 2001/83/EC
Article 100 k c (new)

Text proposed by the Commission	*Amendment*
	Article 100kc
	Revocation of the delegation
	1. The delegation of power referred to in Articles 100d(4) and 100f(2) may be revoked at any time by the European Parliament or by the Council.
	2.The institution which has commenced an internal procedure for deciding whether to revoke the delegation of power shall endeavour to inform the other institution and the Commission within a reasonable time before the final decision is taken, indicating the delegated powers which could be subject to revocation and possible reasons for a revocation.
	3. The decision of revocation shall put an end to the delegation of the power specified in that decision. It shall take effect immediately or at a later date specified therein. It shall not affect the validity of the delegated acts already in force. It shall be published in the Official Journal of the European Union.

Justification

Pursuant to Article 290 of the Treaty on the Functioning of the European Union, detailed provisions on the delegation of powers have to be set out in the Directive.

Amendment 77

Proposal for a directive – amending act
Article 1 - point 5
Directive 2001/83/EC
Article 100 k d (new)

Text proposed by the Commission	*Amendment*
	Article 100kd
	Objections to delegated acts
	1. The European Parliament or the Council may object to a delegated act within a period of three months from the date of notification.
	At the initiative of the European Parliament or the Council this period shall be extended by one month.
	2. If, on expiry of the period referred to in paragraph 1, neither the European Parliament nor the Council has objected to the delegated act it shall be published in the Official Journal of the European Union and shall enter into force at the date stated therein.
	The delegated act may be published in the Official Journal of the European Union and enter into force before the expiry of that period if the European Parliament and the Council have both informed the Commission of their intention not to raise objections.
	3. If either the European Parliament or the Council objects to the delegated act within the period referred to in paragraph 1, it shall not enter into force. In accordance with Article 296 of the Treaty on the Functioning of the European Union, the institution which objects shall state the reasons for objecting to the delegated act.

Justification

Pursuant to Article 290 of the Treaty on the Functioning of the European Union, detailed

provisions on the delegation of powers have to be set out in the Directive.

Amendment 78

Proposal for a directive - amending act
Article 1 – point 5
Directive 2001/83/EC
Article 100 l

Text proposed by the Commission	*Amendment*
By [insert specific date five years from the entry into force of amending directive] at the latest, the Commission shall publish a report on the experience acquired in the implementation of this Title and shall also assess the need for a review thereof. The Commission shall submit this report to the European Parliament and to the Council.	By [insert specific date five years from the entry into force of amending directive] at the latest, the Commission shall publish a report on the experience acquired in the implementation of this Title ***after consulting independent patient, health and consumer organisations*** and ***the members of health care professions and*** shall also assess the need for a review thereof. The Commission shall submit this report to the European Parliament and to the Council.

Amendment 79

Proposal for a directive – amending act
Article 1 - point 4a (new)
Directive 2001/83/EC
Article 100 la (new)

Text proposed by the Commission	*Amendment*
	Article 100 la (new)
	Notwithstanding the provisions of this Title on information by the marketing authorisation holder, Member States shall ensure that objective, unbiased information is available to the general public and members thereof on
	(a) medicinal products placed on the market on the territory of that Member State. Such information shall include, but shall not be limited to, the most recent summary of product characteristics and

labelling and package leaflet of the medicinal product as approved by the competent authorities during the course of marketing authorisation and its renewal, and the most recent, publicly accessible version of the assessment report as drawn up by the competent authorities, and updates thereof;

(b) the diseases and health conditions which are to be treated with the medicinal product referred to in point a); and

(c) the prevention of such diseases and conditions.

Such information shall be made available both in electronic and printed form and in a format accessible for people with disabilities.

The information shall be made available through the following channels:

(a) dedicated websites set up by the Member State or by a body assigned by the Member State, and monitored by the competent national authority or by a body assigned by the competent national authority;

(b) printed materials made available to the general public;

(c) written answers to request for information of a member of the general public.

The Commission shall facilitate the sharing of best practices between Member States and shall adopt guidelines.

By ... the Commission shall present a report to the European Parliament and the Council on the progress made by the Member States in applying this Article.

**** OJ: Insert the date three years from the entry into force of the directive***

Justification

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 directive of the European Parliament and of the Council amending, as regards information to the general public on medicinal products subject to medical prescription, Directive 2001/83/EC on the Community code relating to medicinal products for human use
(COM(2008)0663 – C6-0516/2008 – 2008/0256(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:

By presenting this Directive, 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 definition of health-related publications and in relation to penalties. These issues are 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 directive – amending act
Recital 4

Text proposed by the Commission	*Amendment*
(4) Experience gained from the application of the current legal framework has also shown that certain restrictions on the possibilities of pharmaceutical companies to provide information result from the fact that the distinction between the notions of advertising and information is not interpreted consistently across the Community.	(4) Experience gained from the application of the current legal framework has also shown that certain restrictions on the possibilities of pharmaceutical companies to provide information result from the fact that the distinction between the notions of advertising and information is not interpreted consistently across the Community. ***As a result citizens in certain Member States may be denied the right to have access, in their own language, to high-quality, non-promotional information on medicines.***

Justification

It is a fundamental principle in a democratic society that citizens have a right to access information, including on prescription medicines.

Amendment 2

Proposal for a directive – amending act
Recital 8

Text proposed by the Commission	*Amendment*
(8) National competent authorities and health care professionals should remain important sources of information on medicinal product for the general public. Member States should facilitate the access of citizens to high-quality information through appropriate channels. Marketing authorisation holders may be a valuable source of non promotional information on their medicinal products. This Directive should therefore establish a legal framework for the dissemination of specific information on medicinal products by marketing authorisation holders to the general public. The ban on advertising to the general public for prescription-only medicinal products should be maintained.	(8) National competent authorities and health care professionals should remain important sources of information on medicinal product for the general public. Member States should facilitate the access of citizens to high-quality information through appropriate channels. Marketing authorisation holders may be a valuable source of non promotional information on their medicinal products. This Directive should therefore establish a legal framework for the dissemination of specific information on medicinal products by marketing authorisation holders to the general public. ***Establishing the necessary legal framework for marketing authorisation holders will enhance legal certainty for the pharmaceutical industry in relation to the provision to the general public of specific types of information on their medicines.*** The ban on advertising to the general public for prescription-only medicinal products should be maintained.

Amendment 3

Proposal for a directive – amending act
Recital 9

Text proposed by the Commission	*Amendment*
(9) In accordance with the principle of proportionality, it is appropriate to limit the scope of this Directive to prescription-only medicinal products, as current Community rules allow the advertising to the general public of medicinal products not subject to prescription, under certain conditions.	(9) In accordance with the principle of proportionality, it is appropriate to limit the scope of this Directive to prescription-only medicinal products, as current Community rules allow the advertising to the general public of medicinal products not subject to prescription, under certain conditions. ***This Directive requires Member States to permit, through certain channels and***

subject to appropriate monitoring, the provision by a marketing authorisation holder of certain information on authorised medicines subject to prescription to the public. Communications that do not fall within Title VIIIa should be permitted, provided that they do not constitute advertising.

Justification

Clarification of the scope of the proposed Directive. It is important that new legislation does not inadvertently prohibit certain communications, e.g. responses to healthcare professionals' enquiries on unlicensed uses.

Amendment 4

Proposal for a directive – amending act
Recital 10

Text proposed by the Commission	*Amendment*
(10) Provisions should be established to ensure that only high-quality non-promotional information about the benefits and the risks of medicinal products subject to medical prescription may be ***disseminated***. The information should take into account patients needs and expectations in order to empower patients, allow informed choices and enhance the rational use of medicinal products. ***Therefore, any*** information to the general public on prescription-only medicinal products should comply with a set of quality criteria.	(10) Provisions should be established to ensure that only high-quality non-promotional information about the benefits and the risks of ***authorised*** medicinal products subject to medical prescription may be ***made available***. The information should take into account patients needs and expectations in order to empower patients, allow informed choices and enhance the rational use of medicinal products. ***Providing EU citizens with more high quality information on medicines will enable them to make more rational and appropriate use of medicines, which will lead not only to better informed citizens but also to healthier societies. To achieve this***, information to the general public on ***authorised*** prescription-only medicinal products should comply with a set of quality criteria. *(Replacing the term 'disseminated' with 'made available' applies throughout the text. Adopting this amendment will necessitate corresponding changes*

throughout.)

Justification

The recitals should also reflect the stated objective of the proposal to enable citizens to make proper (more rational and safer) use of medicines and to enhance adherence to prescribed treatments. According to WHO data, more than 50% of EU citizens use their medicines inappropriately. The scope of this directive is restricted to authorised medicinal products. The information should not be disseminated but made available to members of the public who require it. This implies that members of the public would play an active part in obtaining this information.

Amendment 5

Proposal for a directive – amending act
Recital 11

Text proposed by the Commission	*Amendment*
(11) In order to further ensure that marketing authorisation holders disseminate only high-quality information and to distinguish non-promotional information from advertising, the types of information which may be disseminated should be defined. It is appropriate to allow marketing authorisation holders to disseminate the contents of the approved summaries of product characteristics and package leaflet, information that is compatible with those documents without going beyond their key elements***, and other well-defined medicinal product-related information***.	(11) In order to further ensure that marketing authorisation holders disseminate only high-quality information and to distinguish non-promotional information from advertising, the types of information which may be disseminated should be defined. It is appropriate to allow marketing authorisation holders to disseminate the contents of the approved summaries of product characteristics and package leaflet, information that is compatible with those documents without going beyond their key elements.

Amendment 6

Proposal for a directive – amending act
Recital 13

Text proposed by the Commission	*Amendment*
(13) The Internet is of major importance with regard to the provision of information to patients and its importance is increasing. The Internet allows almost unlimited access to information disregarding national	(13) The Internet is of major importance with regard to the provision of information to patients and its importance is increasing. The Internet allows almost unlimited access to information disregarding national

boundaries. Specific rules on the monitoring of websites should be established to take account of the cross-border nature of information provided over the Internet and to allow cooperation between the Member States.	boundaries. Specific rules on the monitoring of websites ***that are directed specifically at EU citizens*** should be established to take account of the cross-border nature of information provided over the Internet and to allow cooperation between the Member States.

Justification

Clarification as this Directive only covers websites aimed at EU citizens. It does not cover websites that are aimed outside the EU nor those aimed at a global audience, irrespective of whether the information was generated or the server was based in the EU.

Amendment 7

Proposal for a directive – amending act
Article 1 – point -1 (new)
Directive 2001/83/EC
Article 86 – paragraph 1 – indent 1 a (new)

Text proposed by the Commission	*Amendment*
	(-1) In Article 86(1), the following indent shall be inserted after the first indent:
	"- drawing the general public's attention to a specific medicinal product, using therapeutic indications or signs and symptoms,"

Justification

Suggesting medicinal products on the basis of signs and symptoms of diseases may encourage self-diagnosis, self-medication and the unnecessary taking of medicinal products. Action should be taken to prevent this.

Amendment 8

Proposal for a directive – amending act
Article 1 – point 1
Directive 2001/83/EC
Article 86 – paragraph 2 – indent 1 a (new)

Text proposed by the Commission	*Amendment*
	- correspondence, possibly accompanied by all material of a non-promotional nature, needed to answer a specific question about a particular medicinal product;

Justification

It is essential that 'correspondence, possibly accompanied by all material of a non-promotional nature, needed to answer a specific question about a particular medicinal product' is neither advertising within the meaning of Title VIII nor information within the meaning of Title VIIIa. The legal situation should not change from the status quo.

Amendment 9

Proposal for a directive – amending act
Article 1 – point 1
Directive 2001/83/EC
Article 86 – paragraph 2 – indent 2

Text proposed by the Commission	*Amendment*
- factual, informative announcements and reference material relating, for example, to pack changes, adverse-reaction warnings as part of general drug precautions, trade catalogues ***and*** price lists, provided ***they*** include no product claims;	- factual, informative announcements and reference material relating ***to a medicinal product***, for example, ***relating*** to pack changes, adverse-reaction warnings as part of general drug precautions, trade catalogues**,** price lists ***and reimbursement***, provided ***that such announcements and reference material*** include no product ***promotional*** claims;

Justification

Clarification of scope of the Directive. Companies should be allowed to continue to provide certain information. For instance, stock market rules require that companies keep investors fully informed of significant developments and employees must be kept informed of business developments. 'Product claim' could be taken to mean any statement about the properties of a product, positive and negative, and might inadvertently prohibit statements about adverse reactions and warnings.

Amendment 10

Proposal for a directive – amending act
Article 1 – point 2
Directive 2001/83/EC
Article 88 – paragraph 4

Text proposed by the Commission	*Amendment*
4. The prohibition set out in paragraph 1 shall not apply to vaccination campaigns and other campaigns in the interest of public health carried out by the industry and approved by the competent authorities of the Member States.	4. The prohibition set out in paragraph 1 shall not apply to vaccination campaigns and other campaigns in the interest of public health carried out by the industry and approved by the competent authorities of the Member States***, which shall ensure that such campaigns are not intended to serve as advertising, provided that these campaigns are carried out exclusively for medically necessary purposes***.

Justification

These campaigns should be carried out exclusively for medically necessary purposes and should not be misused for the purposes of advertising.

Amendment 11

Proposal for a directive – amending act
Article 1 – point 5
Directive 2001/83/EC
Article 100a – paragraph 1

Text proposed by the Commission	*Amendment*
1. Member States shall allow the marketing authorisation holder to disseminate***, either directly or indirectly through a third party,*** information to the general public or members thereof on authorised medicinal products subject to medical prescription provided that it is in accordance with the provisions of this Title. Such information shall not be considered advertising for the purposes of the application of Title VIII.	1. Member States shall allow the marketing authorisation holder to disseminate information to the general public or members thereof on authorised medicinal products subject to medical prescription provided that it is in accordance with the provisions of this Title ***and provided that the medicinal products meet the conditions under which they may be marketed***. Such information shall not be considered advertising for the purposes of the application of Title VIII ***but it shall require prior authorisation by the Member State, after having checked that such information complies with the***

requirements for marketing authorisation for the medicinal product. The information concerned may not contain any data on development studies for medicinal products, new prospects for their use or properties under investigation, or any other information which may create distortions or endow the medicinal product with properties or uses other than those contained in the current marketing authorisation for the medicinal product in question.

Justification

Member State authorisation is needed, since up to now there has been no legally useable definition of information as distinct from advertising. It is important that only the marketing authorisation holder should be able to make information on the medicinal product available to the public in order to prevent problems in attributing responsibility in the event of an infringement of the regulations.

Amendment 12

Proposal for a directive – amending act
Article 1 – point 5
Directive 2001/83/EC
Article 100a – paragraph 2 – point a

Text proposed by the Commission	*Amendment*
(a) information relating to human health or diseases, provided that there is no reference, even indirect, to medicinal products;	(a) information relating to human health or diseases, provided that ***it is based on objective, realistic data supplied by the competent bodies and*** there is no reference, even indirect, to medicinal products;

Amendment 13

Proposal for a directive – amending act
Article 1 – point 5
Directive 2001/83/EC
Article 100a – paragraph 2 – point b

Text proposed by the Commission	*Amendment*
(b) material provided by the marketing authorisation holder to healthcare professionals for distribution to patients.	(b) material provided by the marketing authorisation holder to healthcare professionals for distribution to patients***, which must be explicitly authorised by the Member States, taking account of what was authorised in the technical summary***.

Amendment 14

Proposal for a directive – amending act
Article 1 – point 5
Directive 2001/83/EC
Article 100a – paragraph 2 – point b a (new)

Text proposed by the Commission	*Amendment*
	(ba) factual, informative, non-promotional announcements and reference material relating to a medicinal product, for example, relating to pack changes, adverse reaction warnings as part of general drug precautions, trade catalogues, prices lists and reimbursement, provided that such announcements and reference material do not intend to promote an individual medicinal product.

Justification

Clarification of scope, e.g. stock market rules require that companies keep investors fully informed of significant developments and employees must be kept informed of business developments. It is necessary to specify this to allow appropriate provision of such information.

Amendment 15

Proposal for a directive – amending act
Article 1 – point 5
Directive 2001/83/EC
Article 100b – point a

Text proposed by the Commission	*Amendment*
(a) the summary of product characteristics, labelling and package leaflet of the medicinal product, as approved by the competent authorities, ***and*** the publicly accessible version of the assessment report drawn up by the competent authorities;	(a) the summary of product characteristics, labelling and package leaflet of the medicinal product, as approved by the competent authorities, the publicly accessible version of the assessment report drawn up by the competent authorities ***and other available statements and documents published by the competent authorities***;

Justification

The EPAR (European Product Assessment Report) and other documents published by the competent authorities include detailed information, which is of interest to certain patients.

Amendment 16

Proposal for a directive – amending act
Article 1 – point 5
Directive 2001/83/EC
Article 100b – point b

Text proposed by the Commission	*Amendment*
(b) information which does not go beyond the elements of the summary of product characteristics, labelling and the package leaflet of the medicinal product, and the publicly accessible version of the assessment report drawn up by the competent authorities, but presents them in a different way;	(b) information which does not go beyond the elements of the summary of product characteristics, labelling and the package leaflet of the medicinal product, and the publicly accessible version of the assessment report drawn up by the competent authorities, but presents them in a different way***, provided that it clearly contains an accurate representation of the risks and benefits of the medicinal product***; ***this publicly accessible version may not constitute a substantial change in the characteristics, properties, effects and reactions that the medicinal product might have;***

Justification

It is beneficial for information to be presented in a simplified manner addressed to the general public, since this makes it easier to understand. Nevertheless, this simplification may entail a change in the context of the information that may lead to a false understanding of the

benefits and risks of the medicinal product, and this should be prevented.

Amendment 17

Proposal for a directive – amending act
Article 1 – point 5
Directive 2001/83/EC
Article 100b – point c

Text proposed by the Commission	*Amendment*
(c) information on the environmental impact of the medicinal product, prices and factual, informative announcements and reference material relating, for example, to pack changes or adverse-reaction warnings;	(c) information on the environmental impact of the medicinal product, prices and factual, informative announcements and reference material relating, for example, to pack changes***, reimbursement*** or adverse-reaction warnings;

Justification

It would be useful to include reimbursement status in the list as an example of factual information that should be permitted under this clause.

Amendment 18

Proposal for a directive – amending act
Article 1 – point 5
Directive 2001/83/EC
Article 100b – point d

Text proposed by the Commission	*Amendment*
(d) medicinal product-related 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.	(d) medicinal product-related 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. ***This information must have been evaluated in advance by the Member State, and such studies must be included in the registration dossier for the medicinal product. Scientific studies may not be submitted if they were carried out without complying with the legal requirements in force for clinical trials.***

	Scientific studies may also not be submitted if they relate to properties of the medicinal product or a use of that product other than those for which it is currently authorised in the Member State.

Amendment 19

Proposal for a directive – amending act
Article 1 – point 5
Directive 2001/83/EC
Article 100c – introductory part

Text proposed by the Commission	*Amendment*
Information on authorised medicinal products subject to medical prescription disseminated by the marketing authorisation holder to the general public or members thereof shall not be made available on television ***or*** radio. It shall only be made available through the following channels:	Information on authorised medicinal products subject to medical prescription disseminated by the marketing authorisation holder to the general public or members thereof shall not be made available on television***,*** radio ***or any other instrument of dissemination to the general public, including Internet radio or television channels, or in general newspapers and magazines or in the form of inserts or supplements to them***. It shall only be made available through the following channels:

Amendment 20

Proposal for a directive – amending act
Article 1 – point 5
Directive 2001/83/EC
Article 100c – point a

Text proposed by the Commission	*Amendment*
(a) ***health-related publications as defined by the Member State of publication***, to the exclusion of unsolicited material actively distributed to the general public or members thereof;	(a) ***technical and scientific magazines in the field of health, or magazines addressed to the general public whose main content is in the field of health, brochures, leaflets and other categories of printed information***, to the exclusion of unsolicited material actively distributed to the general public or members thereof;

health-related publications shall mean those certified as such by the Member State, so that consumers can clearly identify those publications as having been endorsed and authorised by the Member State;

Justification

A definição de "publicações na área da saúde" é pouco clara e levará a interpretações divergentes nos diferentes Estados-Membros, perdendo-se a oportunidade de harmonização que confere mais segurança jurídica à indústria e uniformidade de acesso à informação entre os cidadãos europeus. Várias formas de material impresso continuam a ser importantes canais de informação, sobretudo para pessoas que não têm acesso ao conteúdo informativo disponibilizado pela internet. É contudo importante salvaguardar que estes canais apenas são permitidos para veicular informação sobre medicamentos se existir da parte do público uma procura voluntária e activa de tais publicações.

Amendment 21

Proposal for a directive – amending act
Article 1 – point 5
Directive 2001/83/EC
Article 100c – point b

Text proposed by the Commission	*Amendment*
(b) internet websites on medicinal products, to the exclusion of unsolicited material actively distributed to the general public or members thereof;	(b) internet websites on medicinal products, ***explicitly authorised and regarded as such by the Member State,*** to the exclusion of unsolicited material actively distributed to the general public or members thereof; ***for this purpose, the Member States shall establish a system for authorising, supervising and monitoring Internet sites which may present the information referred to in this article; furthermore, an early warning system shall be set up among the Member States to combat Internet sites which violate the provisions of this Directive; an additional authorisation and monitoring system shall be established for the distribution of unsolicited material;***

Amendment 22

Proposal for a directive – amending act
Article 1 – point 5
Directive 2001/83/EC
Article 100c – point c

Text proposed by the Commission	*Amendment*
(c) written answers to requests for information *of* a member of the general public.	(c) written ***and oral*** answers***, provided that the latter are duly recorded,*** to requests for information *from* a member of the general public***; these answers shall in all cases correspond to the package leaflet or technical summary for the authorised medicinal product and shall refer the requestor to the Member State's health authority and to medical or pharmaceutical healthcare staff, giving an explicit indication in the answer that it is no substitute for mandatory intervention by the above healthcare professionals; furthermore, all these written and oral answers shall also be forwarded to the competent health authorities in the Member State for periodic supervision***.

Amendment 23

Proposal for a directive – amending act
Article 1 – point 5
Directive 2001/83/EC
Article 100d – paragraph 1 – point b

Text proposed by the Commission	*Amendment*
(b) it must ***take into account the general needs and expectations of patients***;	(b) it must ***be geared to the patient, to better meet his or her needs***;

Justification

This wording better reflects the objectives of the proposal: to provide patients with the information they need in a form which is more easily understood.

Amendment 24

Proposal for a directive – amending act
Article 1 – point 5
Directive 2001/83/EC
Article 100d – paragraph 1 – point c

Text proposed by the Commission	*Amendment*
(c) it must be based on evidence, be verifiable and include a statement on the level of evidence;	(*Does not affect the English version)*

Justification

(Does not affect the English version.)

Amendment 25

Proposal for a directive – amending act
Article 1 – point 5
Directive 2001/83/EC
Article 100d – paragraph 1 – point f

Text proposed by the Commission	*Amendment*
(f) it must be understandable for the general public ***or*** members thereof;	(f) it must be understandable ***and perfectly legible*** for the general public ***and*** members thereof***, paying particular attention to elderly people***;

Amendment 26

Proposal for a directive – amending act
Article 1 – point 5
Directive 2001/83/EC
Article 100d – paragraph 1 – point h a (new)

Text proposed by the Commission	*Amendment*
	(ha) it must be presented in such a way as to ensure that the dosage of the medicinal product is perfectly understandable, paying particular attention to those medicinal products whose correct administration is complex. This information shall indicate:

(i) the exact dosage to be taken;

(ii) the way in which it is to be measured and the instruments to be used for this purpose;

(iii) the interval of time between each dose;

(iv) the adjustment of the dosage to the weight and age of the individual patient.

Amendment 27

Proposal for a directive – amending act
Article 1 – point 5
Directive 2001/83/EC
Article 100d – paragraph 2 – point b

Text proposed by the Commission	*Amendment*
(b) a statement indicating that the information is intended to support, not to replace, the relationship between patient and health professionals and that a health professional should be contacted if the patient requires clarification on the information provided;	(b) a statement indicating that the information is intended to support, not to replace, the relationship between patient and health professionals and that a health professional should be contacted if the patient requires clarification ***or further information*** on the information provided;

Justification

To clarify in the statement that a health professional should be contacted if a patient requires further information. The health professional may however not be in a position to answer specific questions relating to the information provided by the manufacturer.

Amendment 28

Proposal for a directive – amending act
Article 1 – point 5
Directive 2001/83/EC
Article 100d – paragraph 2 – point c

Text proposed by the Commission	*Amendment*
(c) a statement indicating that the information is disseminated by a marketing authorisation holder;	(c) a statement indicating that the information is disseminated by a marketing authorisation holder ***and naming the***

holder;

Justification

This information is clearer and more easily understood, since many readers may find the term 'marketing authorisation holder' confusing.

Amendment 29

Proposal for a directive – amending act
Article 1 – point 5
Directive 2001/83/EC
Article 100d – paragraph 2 – point d

Text proposed by the Commission	*Amendment*
(d) a mail address or e-mail address allowing members of the general public to send comments to the marketing authorisation holder.	(d) a mail address or e-mail address allowing members of the general public to send comments to the marketing authorisation holder***; comments sent by private individuals and the replies from marketing authorisation holders shall be duly recorded and monitored***.

Amendment 30

Proposal for a directive – amending act
Article 1 – point 5
Directive 2001/83/EC
Article 100d – paragraph 2 – point d a (new)

Text proposed by the Commission	*Amendment*
	(da) the text of the current package leaflet or an indication as to where that text may be found. In the case of Internet sites under the control of marketing authorisation holders that are directed specifically at citizens of one or more Member States, they shall contain the summary of product characteristics and the package leaflet of the medicinal products concerned in the official languages of the Member States where they are authorised if the information on medicinal products is presented in those

languages.

Justification

It is important that the reader is able to access the current package leaflet text. The requirement for Internet websites is better dealt with under this paragraph than as a monitoring requirement for Member States.

Amendment 31

Proposal for a directive – amending act
Article 1 – point 5
Directive 2001/83/EC
Article 100d – paragraph 3 – point a

Text proposed by the Commission	*Amendment*
(a) comparisons between medicinal products;	(a) comparisons between medicinal products***, except where such comparisons are included in officially approved documents, such as the summary of product characteristics***;

Justification

Comparisons exist in the Summary of Product Characteristics (SmPC) and package leaflets of some medicines. To exclude those existing comparisons would in effect require that information provided by marketing authorisation holders is incomplete. This could also prejudice the approval process.

Amendment 32

Proposal for a directive – amending act
Article 1 – point 5
Directive 2001/83/EC
Article 100e – paragraph 1

Text proposed by the Commission	*Amendment*
1. Member States shall ensure that marketing authorisation holders' Internet websites for the dissemination of information on medicinal products subject to medical prescription reproduce the summary of product characteristics and the package leaflet of the medicinal products	1. Member States shall ensure that marketing authorisation holders' Internet websites for the dissemination of information on medicinal products subject to medical prescription reproduce the summary of product characteristics and the package leaflet of the medicinal products

concerned in the official ***languages*** of the Member ***States*** where they are authorised.	concerned in the official ***language*** of the Member ***State*** where they are authorised ***and for which the website is intended.***

Justification

It should be clarified that the summary of product characteristics and the package leaflet of a medicinal product subject to medical prescription should only be reproduced in the official language of the Member State where the information is published and where the website is intended for. For example, if the website is intended for the German market the summary of product characteristics and the package leaflet need to be published in German language only. The current wording is unclear in this regard.

Amendment 33

Proposal for a directive – amending act
Article 1 – point 5
Directive 2001/83/EC
Article 100e – paragraph 2 a (new)

Text proposed by the Commission	*Amendment*
	2a. The state or regional/local authorities responsible for health administration shall set up a telephone helpline providing individual advice to patients, staffed by healthcare professionals, that may be consulted on the interpretation of the information contained in the leaflet, and on compatibility with other medicinal products or with the patient's case history.

Amendment 34

Proposal for a directive – amending act
Article 1 – point 5
Directive 2001/83/EC
Article 100f – paragraph 2 a (new)

Text proposed by the Commission	*Amendment*
	2a. A harmonised procedure shall be established to determine the bases on which information provided on Internet websites and information points is regulated, in such a way as to guarantee

	the reliability of the data presented and its compliance with the authorisation and registration of the medicinal product, providing a guarantee for consumers that the site or information concerned is accurate and based on facts. A certification or qualification system shall be applied with respect to authorised sites. A list shall also be kept of Internet web pages and information points authorised to provide the information referred to in this Directive. That list shall be kept up-to-date and shall be accessible to consumers.

Amendment 35

Proposal for a directive – amending act
Article 1 – point 5
Directive 2001/83/EC
Article 100g – paragraph 2

Text proposed by the Commission	*Amendment*
2. After consulting the Member States, the Commission shall draw up guidelines concerning information allowed under this Title and containing a code of conduct for marketing authorisation holders providing information to the general public or members thereof on authorised medicinal products subject to medical prescription. The Commission shall draw up these guidelines on the entry into force of this directive and update them regularly on the basis of the experience gained.	2. After consulting the Member States ***and other stakeholders***, the Commission shall draw up guidelines concerning information allowed under this Title and containing a code of conduct for marketing authorisation holders providing information to the general public or members thereof on authorised medicinal products subject to medical prescription. The Commission shall draw up these guidelines on the entry into force of this directive and update them regularly on the basis of the experience gained.

Justification

Other stakeholders such as patients, healthcare professionals and the industry should be consulted in drawing up the code and guidelines.

Amendment 36

Proposal for a directive – amending act
Article 1 – point 5
Directive 2001/83/EC
Article 100h – paragraph 1 – subparagraph 1

Text proposed by the Commission	*Amendment*
1. Member States shall ensure that marketing authorisation holders register Internet websites containing information on medicinal products with the national competent authorities of the Member State of the country code Top Level Domain used by the website concerned, prior to making it available to the general public. Where the website does not use a country code Top Level Domain, the marketing authorisation holder shall select the Member State of registration.	1. Member States shall ensure that marketing authorisation holders register Internet websites containing information on medicinal products with the national competent authorities of the Member State of the country code Top Level Domain used by the website concerned, prior to making it available to the general public. Where the website does not use a country code Top Level Domain, the marketing authorisation holder shall select the Member State of registration. ***This information shall comply with the requirements laid down in this Directive and shall be in accordance with the registration dossier for the medicinal product.***

Amendment 37

Proposal for a directive – amending act
Article 1 – point 5
Directive 2001/83/EC
Article 100h – paragraph 2 – subparagraph 2

Text proposed by the Commission	*Amendment*
Internet websites registered in accordance with paragraph 1 shall not allow the identification of members of the general public which have access to those websites or the appearance therein of unsolicited material actively distributed to the general public or members thereof. Those websites shall not ***contain web-TV***.	Internet websites registered in accordance with paragraph 1 shall not allow the identification of members of the general public which have access to those websites or the appearance therein of unsolicited material actively distributed to the general public or members thereof. Those websites shall not ***disseminate video material or any other digital information format unless it is authorised by the respective authority.***

Amendment 38

Proposal for a directive – amending act
Article 1 – point 5
Directive 2001/83/EC
Article 100h – paragraph 3

Text proposed by the Commission	*Amendment*
3. The Member State where the Internet website has been registered shall be responsible for the monitoring of the contents disseminated on that website.	3. The Member State where the Internet website has been registered shall be responsible for the monitoring of the contents disseminated on that website ***in relation to medicinal products subject to medical prescription***.

Justification

This additional precision is important, since much of the information contained on the Internet web pages may not relate to medicinal products.

Amendment 39

Proposal for a directive – amending act
Article 1 – point 5
Directive 2001/83/EC
Article 100h – paragraph 5

Text proposed by the Commission	*Amendment*
5. Member States shall ***allow*** marketing authorisation holders which have registered Internet websites in accordance with paragraphs 1 to 4 ***to*** include a statement therein to the effect that the site has been registered and is subject to monitoring in accordance with this Directive**.** The statement shall identify the national competent authority monitoring the website concerned**.** It shall also specify that the fact that the website is monitored does not necessarily mean that all the information on the website has been subject to prior approval.	5. Member States shall ***require that:***
	(a) marketing authorisation holders which have registered Internet websites in accordance with paragraphs 1 to 4 include

a statement therein to the effect that the site has been registered and is subject to monitoring in accordance with this Directive***;*** the statement shall identify the national competent authority monitoring the website concerned ***and*** shall also specify that the fact that the website is monitored does not necessarily mean that all the information on the website has been subject to prior approval***;***

(b) registered Internet websites include on each of their pages, in a prominent position, a hyperlink to the web page of the Eudravigilance database, together with an explanatory note informing users that this is the official database developed by the European Medicines Agency.

Justification

Os utilizadores de sítios de internet contendo informação sobre medicamentos sujeitos a receita médica devem ser inequivocamente informados sobre o facto de o sítio de internet estar sujeito a monitorização por parte de uma autoridade do medicamento, mas de que isso não constitui garantia de que toda a informação tenha sido validada. A ligação à base de dados Eudrapharma assegura que os utilizadores das páginas de internet contendo informação sobre medicamentos desenvolvidas por fontes comerciais tenham acesso fácil e directo a informação comparável aprovada por uma autoridade do medicamento (nacional ou europeia), assegurando uma maior transparência sobre a qualidade da informação.

Amendment 40

Proposal for a directive – amending act
Article 1 – point 5
Directive 2001/83/EC
Article 100i – paragraph 1 – subparagraph 1 a (new)

Text proposed by the Commission	*Amendment*
	The level of penalties shall be determined at Community level.

Justification

It should not be a matter for Member States to determine the level of penalties. Setting of penalties by the Community provides more legal clarity and ensures that the sanctions have a clear deterrent effect in the event of violations.

Amendment 41

Proposal for a directive – amending act
Article 1 – point 5
Directive 2001/83/EC
Article 100i – paragraph 2 a (new)

Text proposed by the Commission	*Amendment*
	2a. Member States shall ensure that marketing authorisations holders are represented and heard in any consideration of a case in which they are accused of non-compliance with the provisions set out in this Title. Marketing authorisation holders may appeal any decision in such a case to a judicial or other competent body.

Justification

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

Amendment 42

Proposal for a directive – amending act
Article 1 – point 5
Directive 2001/83/EC
Article 100k

Text proposed by the Commission	*Amendment*
Information on homeopathic medicinal products referred to in Article 14(1) that have been classified as prescription-only shall be subject to the provisions of this Title.	Information on homeopathic medicinal products referred to in Article 14(1) that have been classified as prescription-only shall be subject to the provisions of this Title. ***The same shall apply to information on herbal medicinal products or any other compounds or therapies that have been classified as prescription-only.***

PROCEDURE

Title	Information on medicinal products subject to medical prescription (amendment of Directive 2001/83/EC)
References	COM(2008)0663 – C6-0516/2008 – 2008/0256(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 –: 6 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, Claude Turmes, 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

18.5.2010

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 directive of the European Parliament and of the Council amending, as regards information to the general public on medicinal products subject to medical prescription, Directive 2001/83/EC on the Community code relating to medicinal products for human use
(COM(2008)0663 – C6-0516/2008 – 2008/0256(COD))

Rapporteur: Cristian Silviu Buşoi

SHORT JUSTIFICATION

The proposal for a directive of the European Parliament and of the Council amending, as regards information to the general public on medicinal products subject to medicinal prescription, Directive 2001/83/EC on the Community code relating to medicinal products for human use (COM (2008)0663 final) aims to provide for a clear legal framework for consumer information on prescription-only medicines with a view of promoting better patient choices when deciding on possible treatments. There are still disparities in the interpretation of the Community rules on advertising and information to patients. Whereas limitations on advertisement will not be changed, consumers across Europe do not have the same degree of access to independent quality information on medicinal products.

Information to patients should fulfil the following main characteristics:

1. Reliability: Information to patients should be based on the latest scientific knowledge with clear references made to its source;

2. Independence: It has to be clear who provides and who finances the information so that consumers can identify potential conflicts of interest;

3. It should be consumer friendly and patient-oriented: Information should be comprehensible and easily available taking into account the particular needs of consumers (age, cultural differences, and availability in all European languages).

The proposed piece of legislation introduces a legal framework for the dissemination of information on prescription-only medicines to the general public. The question arises which role the pharmaceutical industry should play in providing direct information to patients. Pharmaceutical companies have valuable health information from their clinical studies. They can be a valuable source for consumer information. However, pharmaceutical companies cannot be seen as independent providers of health information because of an inherent conflict of interest. Hence, they are not to be considered as an exclusive source of information.

The distinction between information and advertisement is not clear. Consumers require comprehensive quality sources for health information (especially on the internet) to evaluate their options and form an informed opinion.

The EudraPharm Database could provide for a useful tool to provide information to patients. The resources of the EMEA (European Medicines Agency) could be further explored.

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 directive – amending act
Recital 2

Text proposed by the Commission	*Amendment*
(2) In the area of information, Directive 2001/83/EC lays down detailed rules on the documents to be annexed to the marketing authorisation and intended for information purposes: the summary of product characteristics (distributed to health-care professionals) and the package leaflet (inserted in the product's packaging when it is dispensed to the patient). On the other hand, as regards the ***dissemination*** of information from the marketing authorisation holder to the general public, the Directive only provides that certain information activities are not covered by the rules on advertising, without providing for a harmonised framework on the	(2) In the area of information, Directive 2001/83/EC lays down detailed rules on the documents to be annexed to the marketing authorisation and intended for information purposes: the summary of product characteristics (distributed to health-care professionals) and the package leaflet (inserted in the product's packaging when it is dispensed to the patient). On the other hand, as regards the ***making available*** of information from the marketing authorisation holder to ***patients and*** the general public, the Directive only provides that certain information activities are not covered by the rules on advertising, without providing for a harmonised

contents and the quality of *non promotional* information on medicinal products or on the channels through which this information may be ***disseminated***.	framework on the contents and the quality of *non-promotional* information on medicinal products or on the channels through which this information may be ***made available***. *(This amendment applies throughout the text. Adopting it will necessitate corresponding changes throughout.)*

Justification

This directive must be patient-centred. Therefore non-promotional information on medicinal products must be made available to patients and 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 2

Proposal for a directive – amending act
Recital 4

Text proposed by the Commission	*Amendment*
(4) Experience gained from the application of the current legal framework has also shown that certain restrictions on the possibilities of pharmaceutical companies to ***provide*** information result from the fact that the distinction between the notions of advertising and information is not interpreted consistently across the Community.	(4) Experience gained from the application of the current legal framework has also shown that certain restrictions on the possibilities of pharmaceutical companies to ***make*** information ***available to patients and the general public*** result from the fact that the distinction between the notions of advertising and information is not interpreted consistently across the Community. *(This amendment applies throughout the text. Adopting it will necessitate corresponding changes throughout)*

Justification

This directive must be patient-centred. 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 3

Proposal for a directive – amending act
Recital 5

Text proposed by the Commission	*Amendment*
(5) Those disparities in the interpretation of the Community rules on advertising, and between national provisions on information have a negative impact on the uniform application of Community rules on advertising, and on the effectiveness of the provisions on product information contained in the summary of *products* characteristics and the package leaflet. Although those rules are fully harmonised to ensure the same level of protection of public health across the Community, this objective is undermined if widely divergent national rules on the ***dissemination*** of such key information are allowed.	(5) Those disparities in the interpretation of the Community rules on advertising, and between national provisions on information have a negative impact on the uniform application of Community rules on advertising, and on the effectiveness of the provisions on product information contained in the summary of *products'* characteristics and the package leaflet. Although those rules are fully harmonised to ensure the same level of protection of public health across the Community, this objective is undermined if widely divergent national rules on the ***making available*** of such key information are allowed. *(This amendment applies throughout the text. Adopting it will necessitate corresponding changes throughout)*

Justification

It is necessary to emphasise the fact that the main focus of this directive is about better informing patients and the general public on medicinal products, and not about advertising.

Amendment 4

Proposal for a directive – amending act
Recital 7

Text proposed by the Commission	*Amendment*
(7) In the light of the above and taking into account technological progress with regard to modern communication tools and the fact that patients throughout the European Union have become increasingly active as	(7) In the light of the above and taking into account technological progress with regard to modern communication tools and the fact that patients throughout the European Union have become increasingly active as

regards healthcare, it is necessary to amend the existing legislation in order to reduce differences in access to information and to allow for the availability of good-quality, objective, reliable and non promotional information on medicinal products.	regards healthcare, it is necessary to amend the existing legislation in order to reduce differences in access to information and to allow for the availability of good-quality, objective, reliable and non promotional information on medicinal products ***by placing emphasis on the interest of patients. They should have the right to easily access certain information such as a summary of product characteristics and the package leaflet in electronic and printed form. Certified and registered websites for independent, objective and non-promotional information are therefore necessary.***

Justification

Certified and registered websites will be a key channel for providing quality health information.

Amendment 5

Proposal for a directive – amending act
Recital 8

Text proposed by the Commission	*Amendment*
(8) National competent authorities and health care professionals should remain ***important*** sources of information on medicinal products for the general public. Member States should facilitate the access of citizens to high-quality information through appropriate channels. Marketing authorisation holders may be ***a valuable*** source of *non promotional* information on their medicinal products. This Directive should therefore establish a legal framework for the ***dissemination*** of specific information on medicinal products by marketing authorisation holders to the general public. The ban on advertising to the general public for prescription-only medicinal products should be maintained.	(8) National competent authorities and health care professionals should remain ***the main*** sources of information on medicinal products for the general public. Member States should facilitate the access of citizens to high-quality information through appropriate channels. ***Without prejudice to the importance of the role played by national competent authorities and healthcare professionals in better informing patients and the general public,*** marketing authorisation holders may be ***an additional*** source of *non-promotional* information on their medicinal products. This Directive should therefore establish a legal framework for the ***making available*** of specific information on medicinal products by marketing authorisation holders to the general public. The ban on

advertising to the general public for prescription-only medicinal products should be maintained.

Justification

It is important to underline that national competent authorities and healthcare professionals are the most important and the main sources of reliable and objective information on medicinal products for the patients and the general public. Marketing authorisation holders can provide complementary information but cannot substitute themselves for the national competent authorities and the health care professionals.

Amendment 6

Proposal for a directive – amending act
Recital 10

Text proposed by the Commission	*Amendment*
(10) Provisions should be established to ensure that only high-quality non-promotional information about the benefits and the risks of medicinal products subject to medical prescription may be ***disseminated***. The information should take into account *patients* needs and expectations in order to empower patients, allow informed choices and enhance the rational use of medicinal products. Therefore, any information to the general public on prescription-only medicinal products should comply with a set of quality criteria.	(10) Provisions should be established to ensure that only high-quality non-promotional information about the benefits and the risks of ***authorised*** medicinal products subject to medical prescription may be ***made available***. The information should take into account *patients'* needs and expectations in order to empower patients, allow informed choices and enhance the rational use of medicinal products. Therefore, any information to the general public on prescription-only medicinal products should comply with a set of quality criteria.

Amendment 7

Proposal for a directive – amending act
Recital 11

Text proposed by the Commission	*Amendment*
(11) In order to further ensure that marketing authorisation holders ***disseminate*** only high-quality information	(11) In order to further ensure that marketing authorisation holders ***make available*** only high-quality information

and to distinguish non-promotional information from advertising, the types of information which may be ***disseminated*** should be defined. It is appropriate to allow marketing authorisation holders to ***disseminate*** the contents of the approved summaries of product characteristics and package *leaflet*, information that is compatible with those documents without going beyond their key elements, and other well-defined medicinal product-related information.	and to distinguish non-promotional information from advertising, the types of information which may be ***made available*** should be defined. It is appropriate to allow marketing authorisation holders to ***make available*** the contents of the approved summaries of product characteristics and package *leaflets*, information that is compatible with those documents without going beyond their key elements, and other well-defined medicinal product-related information. *(This amendment applies throughout the text. Adopting it will necessitate corresponding changes throughout.)*

Justification

This directive must be patient-centred. Therefore non-promotional information on medicinal products must be made available by marketing authorisation holders to patients and to the general public according to the 'pull principle' whereby patients/the general 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 directive – amending act
Recital 12

Text proposed by the Commission	*Amendment*
(12) Information to the general public on prescription-only medicinal products should only be provided through specific channels of communication, including Internet and health-related publications, to ***avoid*** that the effectiveness of the prohibition on advertising is undermined by unsolicited provision of information to the public. Where information is ***disseminated*** via television or radio, patients are not protected against such unsolicited information and such ***dissemination*** should therefore ***not*** be ***allowed***.	(12) Information to the general public on prescription-only medicinal products should only be provided through specific channels of communication, including ***the*** Internet and health-related publications, to ***ensure*** that the effectiveness of the prohibition on advertising is ***not*** undermined by unsolicited provision of information to the public. Where information is ***made available*** via television or radio, patients are not protected against such unsolicited information and such ***making available*** should therefore be ***prohibited***.

Justification

It is necessary to make clear that the television and the radio are not appropriate means to inform patients about medicinal products.

Amendment 9

Proposal for a directive – amending act
Recital 12 a (new)

Text proposed by the Commission	*Amendment*
	(12a) The internet is a major source of information for a growing number of patients. This trend is likely to increase in the coming years. In order to adapt to this development and to add to the growing importance of e-health, information on medicinal products should also be made available via national health websites. These websites should be monitored by competent authorities in the Member States. Member States in cooperation with stakeholders such as healthcare professionals or patient organisations should be responsible for managing these websites.

Justification

The Internet has become an important and powerful source of information. As misinformation obtained on the Internet can cause harm, there is an urgent need to respond to the needs of patients and set up officially validated health websites. In order to ensure that the information on these websites is independent and objective, Member States shall be responsible for controlling the information. Since the information should be patient-friendly, health care professionals and patient organisations should be involved in creating and managing the websites.

Amendment 10

Proposal for a directive – amending act
Recital 14

Text proposed by the Commission	*Amendment*
(14) Monitoring of information on prescription-only medicinal products should ensure that marketing authorisation holders only ***disseminate*** information which is in compliance with Directive 2001/83/EC. Member States should adopt rules establishing effective monitoring mechanisms and allowing effective enforcement in cases of non-compliance. Monitoring should be based on the control of information prior to ***its dissemination***, unless the substance of the information has already been agreed by the competent authorities or if there is a different mechanism in place to ensure ***an equivalent level of*** adequate ***and*** effective monitoring	(14) Monitoring of information on ***authorised*** prescription-only medicinal products ***under this Directive*** should ensure that marketing authorisation holders only ***make available*** information which is in compliance with Directive 2001/83/EC. Member States should adopt rules establishing effective monitoring mechanisms and allowing effective enforcement in cases of non-compliance. ***In cases of non-compliance, procedures should be put into place by means of which marketing authorisation holders can be represented and heard in the course of the consideration of their case.*** Monitoring should be based on the control of information prior to ***its being made available***, unless the substance of the information has already been agreed by the competent authorities or if there is a different mechanism in place to ensure adequate**,** effective ***and independent*** monitoring.

Justification

This amendment clarifies the scope of the directive by reinforcing that the provision of information on certain types or groups of medicines is not covered by this legislation.

For certain types of information the distinction between advertising and promotional information is more difficult to establish. Those types of information should therefore be subject to approval by the national competent authorities before its dissemination.

Independent monitoring mechanisms controlled by authorities should be in place even when another institute takes over the monitoring of the information.

Amendment 11

Proposal for a directive – amending act
Article 1 – point -1 (new)

Directive 2001/83/EC
Article 59 – paragraph 3 a (new)

Text proposed by the Commission	*Amendment*
	(-1) In Article 59 the following paragraph shall be inserted:
	"3a. The package leaflet shall correspond to the real needs of patients. To this end, patient organisations should be involved in developing and reviewing the information on medicinal products by national regulatory authorities and the European Medicines Agency. The package leaflet shall include a short paragraph which sets out the benefit and potential harm of a medicinal product as well as a short description of further information aiming at safe and effective use of a medicinal product."

Justification

Studies involving patients show that often the package leaflets are not read by most people (e.g. information in the wrong order, most important information does not stand out). Thus, patient leaflets should be developed in cooperation with patients' representatives, as proposed e.g. by the EMA Patient and Consumer Working Group in 2005. The EMA's work to improve the readability and patient-friendliness of the leaflet should be continued and should be followed as a model of good practice for national regulatory authorities.

Amendment 12

Proposal for a directive – amending act
Article 1 – point -1 a (new)
Directive 2001/83/EC
Article 86 – paragraph 1 – indent 1 a (new)

Text proposed by the Commission	*Amendment*
	(-1a) In paragraph 1 of Article 86, after the first indent, the following indent is inserted:
	"– drawing the attention of the general public to medicinal products by means of references to therapeutic indications or to

signs and symptoms,"

Amendment 13

Proposal for a directive – amending act
Article 1 – point 1
Directive 2001/83/EC
Article 86 **–** paragraph 2 **–** indent 2

Text proposed by the Commission	*Amendment*
- factual, informative announcements and reference material ***relating***, for example, to pack changes, adverse-reaction warnings as part of general drug precautions, trade catalogues ***and*** price lists, provided they include no ***product*** claims;	- factual, informative announcements**,** ***including announcements or statements such as those made to media organisations either in response to a direct enquiry or by dissemination of such information via conferences or written releases and announcements or reports to shareholders and/or regulators,*** and reference material ***on a medicinal product relating***, for example, to pack changes, adverse-reaction warnings as part of general drug precautions, trade catalogues, price lists ***and reimbursement***, provided they include no ***promotional*** claims ***relating to medicinal products***;

Justification

This amendment aims to clarify the scope of the directive. Companies should be allowed to continue to provide certain information. For instance, stock market rules require that companies keep investors fully informed of significant developments and employees must be kept informed of business developments.

Amendment 14

Proposal for a directive – amending act
Article 1 – point 1
Directive 2001/83/EC
Article 86 – paragraph 2 – indent 4

Text proposed by the Commission	*Amendment*
– information by the marketing	– information ***made available*** by the

authorisation holder to the general public on medicinal products subject to medical prescription, which is subject to the provisions of Title VIIIa.	marketing authorisation holder to the general public on medicinal products subject to medical prescription, which is subject to the provisions of Title VIII a.

Justification

This directive must be patient-centred. 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 15

Proposal for a directive – amending act
Article 1 – point 5
Directive 2001/83/EC
Article 100 a – paragraph 1

Text proposed by the Commission	*Amendment*
1. Member States shall allow the marketing authorisation holder to ***disseminate***, ***either directly or indirectly through a third party,*** information to the general public or members thereof on authorised medicinal products subject to medical prescription provided that it is in accordance with the provisions of this Title. Such information shall not be considered advertising for the purposes of the application of Title VIII.	1. ***Without prejudice to the importance of the role played by national competent authorities and healthcare professionals in better informing patients and the general public on authorised medicinal products subject to medical prescription,*** Member States shall allow the marketing authorisation holder to ***make available*** information to the general public or members thereof on authorised medicinal products subject to medical prescription provided that it is in accordance with the provisions of this Title. Such information shall not be considered advertising for the purposes of the application of Title VIII.

Justification

It is important to underline that national competent authorities and healthcare professionals are the most important and the main sources of reliable and objective information on medicinal products for the patients and the general public. Marketing authorisation holders can provide complementary information but cannot substitute themselves for national competent authorities and healthcare professionals.

Amendment 16

Proposal for a directive – amending act
Article 1 – point 5
Directive 2001/83/EC
Article 100 a – paragraph 1 a (new)

Text proposed by the Commission	*Amendment*
	1a. Information campaigns aimed at raising awareness among the general public and members thereof about the risks of falsified medicinal products should be organised. Such information campaigns may be conducted by national competent authorities in collaboration with industry, healthcare professionals and patient organisations.

Justification

In order to better protect human health, information campaigns about the risks of falsified medicines, initiated by national authorities, could be very useful and beneficial to patients. In order to increase the quality of these information campaigns and to ensure that they reach patients in an effective way, national authorities should take into consideration the expertise on the matter coming from the industry, health care professionals and patient organisations.

Amendment 17

Proposal for a directive – amending act
Article 1 – point 5
Directive 2001/83/EC
Article 100a **–** paragraph 2 **–** point b

Text proposed by the Commission	*Amendment*
(b) material provided by the marketing authorisation holder to healthcare professionals for distribution to patients.	***deleted***

Justification

Printed material provided to healthcare professionals for distribution to patients should respect the same criteria as the other means for disseminating information. It would be,

therefore, reasonable that this kind of material is also covered by this Title. Healthcare professionals might also be influenced by material containing advertising. There is no objective reason why material provided by companies to healthcare professionals for distribution to patients isn't subject to the provisions of this Title.

Amendment 18

Proposal for a directive – amending act
Article 1 – point 5
Directive 2001/83/EC
Article 100a – paragraph 2 – point b a (new)

Text proposed by the Commission	*Amendment*
	(ba) factual, informative announcements, including announcements or statements made to media organisations either in response to a direct enquiry or by dissemination of such information via conferences or written releases and announcements or reports to shareholders and/or regulators, and reference material on a medicinal product relating, for example, to pack changes, adverse-reaction warnings as part of general drug precautions, trade catalogues, price lists and reimbursement, provided they include no promotional claims relating to medicinal products;

Justification

This amendment is coherent with the amendment on article 86(2) and aims at clarifying the scope of the directive. Market authorization holders should be allowed to provide certain information. Stock market rules require that companies keep investors fully informed of significant developments and employees must be kept informed of business developments. It is necessary to specify this to allow appropriate provision of such information.

Amendment 19

Proposal for a directive – amending act
Article 1 – point 5
Directive 2001/83/EC
Article 100a – paragraph 2 – point b b (new)

Text proposed by the Commission	*Amendment*
	(bb) material provided to healthcare professionals for their own use.

Justification

It should be ensured that information provided to healthcare professionals for their own use is not covered by the Directive.

Amendment 20

Proposal for a directive – amending act
Article 1 – point 5
Directive 2001/83/EC
Article 100b – introductory part

Text proposed by the Commission	*Amendment*
The ***following types*** of ***information on*** authorised medicinal products subject to medical prescription ***may be disseminated by the marketing authorisation holder*** to the general public or members thereof:	***1.*** The ***marketing authorisation holder shall, in respect*** of authorised medicinal products subject to medical prescription***,*** ***make available*** to the general public or members thereof ***a summary of the product characteristics, labelling and package leaflet of the medicinal product, as approved by the competent authorities, and the publicly accessible version of the assessment report drawn up by the competent authorities. This information shall be made available both in electronic and in printed form and in a format accessible to people with disabilities.*** ***2. In addition, the following types of information may also be made available to the general public or members thereof by the marketing authorisation holder***:

Justification

The directive should be more patient-centred. Therefore, it should be emphasised that patients have a right to certain information. As a minimum requirement, patients should have the right to access the SPC, the package leaflet, and the publicly accessible version of the assessment report in printed as well as electronic form.

Amendment 21

Proposal for a directive – amending act
Article 1 – point 5
Directive 2001/83/EC
Article 100 b – point a

Text proposed by the Commission	*Amendment*
(a) the summary of product characteristics, labelling and package leaflet of the medicinal product, as approved by the competent authorities, and the publicly accessible version of the assessment report drawn up by the competent authorities;	***deleted***

Justification

In line with the amendment on Art. 100b(1), making a distinction between information to which patients have a right and which thus must be made available on the one hand, and on the other hand, information which may be made available as set out in Art. 100b(2).

Amendment 22

Proposal for a directive – amending act
Article 1 – point 5
Directive 2001/83/EC
Article 100b – point b

Text proposed by the Commission	*Amendment*
(b) information which does not go beyond the elements of the summary of product characteristics, labelling and the package leaflet of the medicinal product, and the publicly accessible version of the assessment report drawn up by the competent authorities, but presents them in	***(a)*** information which does not go beyond the elements of the summary of product characteristics, labelling and the package leaflet of the medicinal product, and the publicly accessible version of the assessment report drawn up by the competent authorities, but presents them in

a ***different*** way;	a ***patient-friendly*** way ***that is comprehensible to the general public or members thereof without jeopardising the quality or reliability of the information made available, including its comprehensive and impartial nature***;

Justification

It should be clarified that putting information in a different way must enhance patients' ability to better understand the information, thus ensuring that it will be presented in a more patient-friendly way.

Amendment 23

Proposal for a directive – amending act
Article 1 – point 5
Directive 2001/83/EC
Article 100b – point c

Text proposed by the Commission	*Amendment*
(c) information ***on the environmental impact*** of ***the*** medicinal ***product***, prices and factual, informative announcements and reference material relating, for example, to pack changes or adverse-reaction warnings;	***(b)*** information ***relating to the disposal*** of ***unused*** medicinal ***products or waste derived from medicinal products***, ***as well as reference to any collection system in place; information on*** prices and factual, informative announcements and reference material ***on a medicinal product,*** relating, for example, to pack changes or adverse-reaction warnings;

Justification

Medicines have an impact on the environment. Therefore, such information, especially with regard to disposal and collection systems, is important to prevent any environmental harm.

Amendment 24

Proposal for a directive – amending act
Article 1 – point 5
Directive 2001/83/EC
Article 100b – point d

Text proposed by the Commission	*Amendment*
(d) medicinal product-related 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.	***deleted***

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 25

Proposal for a directive – amending act
Article 1 – point 5
Directive 2001/83/EC
Article 100b – point d a (new)

Text proposed by the Commission	*Amendment*
	(da) other information on medicinal products subject to medical prescription provided under this Title, such as information about the pharmaceutical and pre-clinical tests or clinical trials, that meets the criteria set out in Article 100d and does not promote any individual medicinal product.

Justification

Patients should be given the opportunity to get information about the pharmaceutical and pre-clinical tests and the clinical trials. Considering, however, the commercial sensitivity of

these tests and trials, pharmaceutical companies cannot be obliged to make such test and trial documentation available; they, however, should be allowed to make that documentation public if they so wish.

Amendment 26

Proposal for a directive – amending act
Article 1 – point 5
Directive 2001/83/EC
Article 100c – introductory part

Text proposed by the Commission	*Amendment*
Information on authorised medicinal products subject to medical prescription ***disseminated*** by the marketing authorisation holder to the general public or members thereof shall not be made available on television ***or*** radio. It shall only be made available through the following channels:	Information on authorised medicinal products subject to medical prescription ***made available*** by the marketing authorisation holder to the general public or members thereof shall not be made available on television***,*** radio ***or in the printed media***. It shall only be made available through the following channels:

Justification

The amendment aims at clarifying what is meant by printed media. Booklets, leaflets etc. should be allowed as channels for making information available to patients.

Amendment 27

Proposal for a directive – amending act
Article 1 – point 5
Directive 2001/83/EC
Article 100c – point a

Text proposed by the Commission	*Amendment*
(a) health-related publications as defined by the ***Member State of publication***, to the exclusion of unsolicited material actively distributed to the general public or members thereof;	(a) ***booklets, leaflets, and other categories of printed information, scientific and technical journals or magazines aimed at the general public with mainly health-related content, including*** health-related publications as defined by the ***Commission's guidelines concerning the information allowed***, to the exclusion of unsolicited material actively distributed to

the general public or members thereof;

Amendment 28

Proposal for a directive – amending act
Article 1 – point 5
Directive 2001/83/EC
Article 100c **–** point b

Text proposed by the Commission	*Amendment*
(b) internet websites on medicinal products, to the exclusion of unsolicited ***material actively distributed to the general public or members thereof***;	(b) ***marketing authorisation holders'*** internet websites ***and other electronic repositories containing information*** on medicinal products, to the exclusion of unsolicited ***distribution to citizens through mass communications such as e-mails and telephone text messages to multiple recipients***;

Justification

"other electronic repositories containing information": A necessary clarification to allow provision of high-quality non-promotional information through electronic repositories that are not strictly Internet websites. There are already electronic communication media that are not websites but through which information seekers can access reference information (eg reference text pages made available through TV sets or via telephone systems. The Internet is also becoming much more dynamic and is going beyond static websites. It is important that the directive is fit for the future.

Amendment 29

Proposal for a directive – amending act
Article 1 – point 5
Directive 2001/83/EC
Article 100 c – point c

Text proposed by the Commission	*Amendment*
(c) ***written*** answers to requests for information ***of*** a member of the general public.	(c) answers to requests for information ***from*** a member of the general public. ***Verbal questions must be recorded.***

Amendment 30

Proposal for a directive – amending act
Article 1 – point 5
Directive 2001/83/EC
Article 100c a (new)

Text proposed by the Commission	*Amendment*
	Article 100ca
	1. Member States shall ensure that the mandatory information as referred to in Article 100b(1) shall be made available through national health websites in the official language(s) of the Member State where the website is registered.
	Such websites shall be monitored by a competent authority of the Member State or by a body assigned by the competent authority in accordance with Article 100g.
	The websites shall be administered and managed in cooperation with stakeholders such as healthcare professionals and patient organisations.
	2. The information shall communicate both benefits and risks in a clear descriptive manner that is patient friendly and linked to the national medicinal products safety website.
	The websites shall provide patients with the mandatory information on all available medicinal products in that Member State both centrally approved by the European Medicines Agency and locally approved in that Member State.
	3. The websites should also include general information about medicinal and non-medicinal treatment of various diseases, including rare diseases, in order to promote a high level of public health.
	They may also contain other information as referred to in Article 100b(2) and as defined by the Commission's guidelines concerning information allowed.

4. Where deemed appropriate by the national competent authorities, they may also make available information on medicinal products and other relevant health information to the general public by way of agreements with internet service providers, who may make available public interest information in accordance with Article 21(4) of Directive 2009/136/EC of the European Parliament and of the Council of 25 November 2009 on universal service and users' rights relating to electronic communications networks and services[1].

In such a case, information shall be made available by the same means used for regular communications between the undertakings and their subscribers. Since information on medicinal products falls outside the scope of Article 21(4) of Directive 2009/136/EC, internet service providers may charge national authorities for making available such information.

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[1] OJ L 337, 18.12.2009, p. 11.

Justification

Patients increasingly use the Internet as a source of information. Yet, they are often directed towards US websites, which contain promotional claims, or other dubious websites. In order to provide patients with better information, national health portals should be developed. They should be seen as a means to complement the relationship between patients and health care professionals rather than replacing it. They should be managed by the competent authority of a Member State in cooperation with stakeholders such as patient organisations or health care professionals.

The public messages concerned in Directive 2009/136/EC relate to electronic communications services. However, information on medicines and broader health information might also be of public interest. Since this type of information falls outside the scope of the provisions in the USD, it is proposed that this framework should be used on the basis of voluntary agreements between ISPs and national authorities. This channel should be used only when national authorities consider it necessary and when it has an added value in terms of effectiveness compared to the other regular channels.

Amendment 31

Proposal for a directive – amending act
Article 1 – point 5
Directive 2001/83/EC
Article 100d – paragraph 1 – introductory part

Text proposed by the Commission	*Amendment*
1. The content and presentation of information on authorised medicinal products subject to medical prescription ***disseminated*** by the marketing authorisation holder to the general public or members thereof shall fulfil the following conditions:	1. The content and presentation of information on authorised medicinal products subject to medical prescription ***made available*** by the marketing authorisation holder to the general public or members thereof shall fulfil the following conditions:

Justification

Information should not be disseminated by the marketing authorization holder as it may imply an active role (push) in passing information to the public. Information may, however, be made available to the public by the marketing authorization holder: the public must have a proactive role in seeking such information (pull).

Amendment 32

Proposal for a directive – amending act
Article 1 – point 5
Directive 2001/83/EC
Article 100d – paragraph 1 – point b

Text proposed by the Commission	*Amendment*
(b) it must ***take into account the general needs and expectations of patient***s;	(b) it must ***be patient oriented to better meet their needs***;

Justification

Re-wording to better reflect one of the main objectives of the proposal, namely to provide information that patients want and that better meets their individual needs.

Amendment 33

Proposal for a directive – amending act
Article 1 – point 5
Directive 2001/83/EC
Article 100d **–** paragraph 2 **–** point c

Text proposed by the Commission	*Amendment*
(c) a statement indicating that the information is ***disseminated*** by a marketing authorisation holder;	(c) a statement indicating that the information is ***made available*** by ***or on behalf of*** a ***named*** marketing authorisation holder;

Justification

A third party may undertake dissemination on behalf of the Marketing Authorisation Holder.

Readers of the statement may not be familiar with the term "marketing authorisation holder". A statement bearing the name of the marketing authorisation holder is more meaningful and understandable.

Amendment 34

Proposal for a directive – amending act
Article 1 – point 5
Directive 2001/83/EC
Article 100d **–** paragraph 3 **–** point a

Text proposed by the Commission	*Amendment*
(a) comparisons between medicinal products;	(a) comparisons between medicinal products ***regarding their quality, safety and efficiency, if disseminated by marketing authorisation holders except: - where those comparisons are included in officially approved documents, such as the Summary of Product Characteristics; - where those comparisons are based on comparative scientific studies published by the relevant national authorities or the European Medicines Agency***;

Justification

Comparisons exist in the Summary of Product Characteristics (SmPC) and package leaflets of some medicines. To exclude those existing comparisons would in effect require that

information provided by marketing authorisation holders is incomplete. This could also prejudice the approval process. Comparative scientific studies on the quality, safety and efficiency of different medicinal products by independent National Authorities and the EMEA should not be discouraged as they can provide a valuable source for consumer information.

Amendment 35

Proposal for a directive – amending act
Article 1 – point 5
Directive 2001/83/EC
Article 100d – paragraph 3 – point b a (new)

Text proposed by the Commission	*Amendment*
	(ba) information on other medicinal products for which the pharmaceutical company is not the marketing authorisation holder.

Justification

Misinformation campaigns by third part companies on medicinal products which have obtained a marketing authorisation from competent authorities must be prohibited by any means. The prohibition should be extended to advertising and information to healthcare professionals. Misinformation campaigns from originator companies on generic medicines, for instance, towards the general public has been identified as one of the delaying strategies in the Preliminary Report of the Pharmaceutical Sector Inquiry.[1]

Amendment 36

Proposal for a directive – amending act
Article 1 – point 5
Directive 2001/83/EC
Article 100 g – paragraph 1 – subparagraph 3

Text proposed by the Commission	*Amendment*
The methods may include the voluntary control of information on medicinal products by ***self-regulatory or*** co-regulatory bodies and recourse to such bodies, if proceedings before such bodies are possible in addition to the judicial or	The methods may include the voluntary control of information on medicinal products by co-regulatory bodies and recourse to such bodies, if proceedings before such bodies are possible in addition to the judicial or administrative

[1] The preliminary report can be found following the link : http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/preliminary_report.pdf

administrative proceedings available in the Member States.	proceedings available in the Member States.

Justification

It is necessary to have an appropriate monitoring system in order to avoid information misuse. Self-regulation does not appear a sufficiently coercive tool to reach this objective.

Amendment 37

Proposal for a directive – amending act
Article 1 – point 5
Directive 2001/83/EC
Article 100g **–** paragraph 2

Text proposed by the Commission	*Amendment*
2. After consulting the Member States, the Commission shall draw up guidelines concerning information allowed under this Title and containing a code of conduct for marketing authorisation holders providing information to the general public or members thereof on authorised medicinal products subject to medical prescription. The Commission shall draw up these guidelines on the entry into force of this directive and update them regularly on the basis of the experience gained.	2. After consulting the Member States ***and other stakeholders***, the Commission shall draw up guidelines concerning information allowed under this Title and containing a ***mandatory*** code of conduct for marketing authorisation holders providing information to the general public or members thereof on authorised medicinal products subject to medical prescription. The Commission shall draw up these guidelines on the entry into force of this directive and update them regularly on the basis of the experience gained.

Justification

Other stakeholders such as patients, healthcare professionals and the industry should be consulted in drawing up the code and guidelines. In order to make sure that marketing authorization holders abide by the rules established by the Commission in the code of conduct, it should be specified that the latter should be mandatory, not voluntary.

Amendment 38

Proposal for a directive – amending act
Article 1 – point 5
Directive 2001/83/EC
Article 100h – paragraph 1 – subparagraph 1

Text proposed by the Commission	*Amendment*
1. Member States shall ensure that marketing authorisation holders register Internet websites ***containing information on medicinal products with the national competent authorities of the Member State of the country code Top Level Domain used by the website concerned***, prior to making it available to the general public. Where the website does not use a country code Top Level Domain, the marketing authorisation holder shall select the Member State of registration.	1. Member States shall ensure that marketing authorisation holders register Internet websites ***under their control that are directed specifically at citizens of one or more Member States and that contain information on prescription-only medicines covered by this Title,*** prior to making it available to the general public. Where the website does not use a country code Top Level Domain, the marketing authorisation holder shall select the Member State of registration.

Justification

Necessary clarification as this Directive only covers websites that are under the control of the Marketing Authorisation Holder and aimed at EU citizens. It does not cover websites that are aimed outside the EU nor those aimed at a global audience, irrespective of whether the information was generated or the server was based in the EU. Also it does not cover business sites that contain corporate information including product sales figures and other product related business information.

Amendment 39

Proposal for a directive – amending act
Article 1 – point 5
Directive 2001/83/EC
Article 100h – paragraph 1 – subparagraph 2 a (new)

Text proposed by the Commission	*Amendment*
	After registration of the website, any amendments to the content relating to medicinal products subject to medical prescription shall be subject to monitoring in accordance with paragraph 3. Such changes shall not require re-registration

of the website.

Justification

If changes to the content of a website are made, these should be monitored by the Member State where the Internet website has been registered. A re-registration should not be required to avoid unnecessary bureaucracy.

Amendment 40

Proposal for a directive – amending act
Article 1 – point 5
Directive 2001/83/EC
Article 100h – paragraph 2

Text proposed by the Commission	*Amendment*
2. Internet websites registered in accordance with paragraph 1 shall not contain links to other marketing authorisation holder websites unless they have also been registered in accordance with that paragraph. Those websites shall identify the competent authority which granted the marketing authorisation and its website address.	2. Internet websites registered in accordance with paragraph 1 shall not contain links to other marketing authorisation holder websites ***containing information covered by this Title*** unless they have also been registered in accordance with that paragraph. Those websites shall identify the competent authority which granted the marketing authorisation and its website address.
Internet websites registered in accordance with paragraph 1 shall not allow the identification of members of the general public which have access to those websites or the appearance therein of unsolicited material actively distributed to the general public or members thereof. Those websites shall not contain ***web-TV***.	Internet websites registered in accordance with paragraph 1 shall not allow the ***automatic*** identification of members of the general public which have access to those websites or the appearance therein of unsolicited material actively distributed to the general public or members thereof. Those websites shall not contain ***video broadcast material***.

Justification

Web TV should be clarified to forbid video broadcasting in websites which is prone to enable disguised advertising. Links to other websites that the marketing authorization holder has that are not required to, and indeed could not be registered, must be permitted e.g. a corporate business website or general health information websites.
The Commission proposal also foresees that internet websites shall not allow the identification of members of the general public which have access to those websites. There is a risk that this would be interpreted too restrictively. Members of the general public should,

for example, be able to send a specific question to the Marketing Authorization Holder or request a copy of a brochure through a registered website. Patients may also wish to participate in a compliance programme, which, for example, would remind them how and when to take their medicines to increase efficient and rational use. In such cases, identification of persons should be possible, and only the automatic identification (against the will of the visitor of the site) should be prohibited.

Amendment 41

Proposal for a directive – amending act
Article 1 – point 5
Directive 2001/83/EC
Article 100 h – paragraph 2 – subparagraph 2 a (new)

Text proposed by the Commission	*Amendment*
	Without prejudice to this prohibition, websites registered in accordance with paragraph 1 can provide video content where they are aimed at supporting the safe and effective use of medicinal products in general and provided that it does not contain any promotional claims relating to medicinal products. Compliance with these two conditions shall be subject to monitoring in accordance with Article 100g.

Justification

Video content, to the exclusion of promotional video materials, can bring an added value when showing the correct use of different medicines or medical devices such as inhalers. These video materials should be subject to monitoring in accordance with Article 100g so that we can ensure that they are completely neutral and do not contain any product promotional claims.

Amendment 42

Proposal for a directive – amending act
Article 1 – point 5

Directive 2001/83/EC
Article 100 h – paragraph 2 – subparagraph 2 b (new)

Text proposed by the Commission	*Amendment*
	The registered websites shall display a notification at the top of each website page informing the public that the information contained therein is developed by a named marketing authorisation holder. A link to the EudraPharm database on medicinal products shall also be included in that notification.

Justification

The users of Internet sites containing information on prescription medicines must be clearly informed that such information has been developed by a marketing authorisation holder. The link to the EudraPharm database will ensure that users have direct and easy access to comparable information on prescription medicines provided by a non-commercial source, ensuring greater transparency.

Amendment 43

Proposal for a directive – amending act
Article 1 – point 5
Directive 2001/83/EC
Article 100h **–** paragraph 3

Text proposed by the Commission	*Amendment*
3. The Member State where the Internet website has been registered shall be responsible for the monitoring of the contents ***disseminated*** on that website.	3. The Member State where the Internet website has been registered shall be responsible for the monitoring of the contents***, relating to medicinal products subject to medical prescription, made available*** on that website.

Justification

The precision is important as much of the website's content could be unrelated to prescription medicinal products.

Amendment 44

Proposal for a directive – amending act
Article 1 – point 5
Directive 2001/83/EC
Article 100h – paragraph 5

Text proposed by the Commission	*Amendment*
5. Member States shall ***allow*** marketing authorisation holders which have registered Internet websites in accordance with paragraphs 1 to 4 to include a statement therein to the effect that the ***site*** has been registered and is subject to monitoring in accordance with this Directive. The statement shall identify the national competent authority monitoring the website concerned. It shall also specify that the fact that the website is monitored does not necessarily mean that all the information on the website has been subject to prior approval.	5. Member States shall ***require*** marketing authorisation holders which have registered Internet websites in accordance with paragraphs 1 to 4 to include a statement therein to the effect that the ***website*** has been registered and is subject to monitoring in accordance with this Directive. The statement shall identify the national competent authority monitoring the website concerned. It shall also specify that the fact that the website is monitored does not necessarily mean that all the information on the website has been subject to prior approval.

Justification

The general public has to be informed about the quality of the website they visit. It is, therefore, better that the availability of the statement about the registration and monitoring procedures is required not simply allowed. This is necessary to show the general public that they can trust the website.

Amendment 45

Proposal for a directive – amending act
Article 1 – point 5
Directive 2001/83/EC
Article 100i – paragraph 2 a (new)

Text proposed by the Commission	*Amendment*
	2a. Member States shall ensure that marketing authorisation holders are represented and heard in any consideration of a case in which they are accused of non-compliance with the provisions set out in this Title. The marketing authorisation holders shall

have the right to appeal any decision to a judicial or other body. During the appeal procedure the dissemination of information shall be suspended until a contrary decision is taken by the responsible body.

Justification

This amendment aims to ensure greater efficiency and transparency in the process. Market authorization holders should be given the right to defend themselves in case they consider that the charges of non-compliance are unfounded. In order to protect the general public from information that would possibly not respect the provisions of this Title, it is necessary that the dissemination is suspended right after the decision of the competent authority. It should be resumed only in case the body responsible for analysing the marketing authorization holder's appeal decides so.

PROCEDURE

Title	Information on medicinal products subject to medical prescription (amendment of Directive 2001/83/EC)
References	COM(2008)0663 – C6-0516/2008 – 2008/0256(COD)
Committee responsible	ENVI
Opinion by Date announced in plenary	IMCO 19.10.2009
Rapporteur Date appointed	Cristian Silviu Buşoi 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	+: 33 –: 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, Iliana Ivanova, Philippe Juvin, Sandra Kalniete, Alan Kelly, Eija-Riitta Korhola, Edvard Kožušník, Kurt Lechner, Toine Manders, Mitro Repo, Robert Rochefort, Heide Rühle, Andreas Schwab, Róża Gräfin Von Thun Und Hohenstein, Kyriacos Triantaphyllides, Bernadette Vergnaud, Barbara Weiler, Anja Weisgerber
Substitute(s) present for the final vote	Pascal Canfin, Cornelis de Jong, Frank Engel, Anna Hedh, Othmar Karas, Emma McClarkin, Marc Tarabella, Kerstin Westphal

PROCEDURE

Title	Information on medicinal products subject to medical prescription (amendment of Directive 2001/83/EC)
References	COM(2008)0663 – C6-0516/2008 – 2008/0256(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	+: 46 –: 1 0: 3
Members present for the final vote	János Áder, 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, Françoise Grossetête, Satu Hassi, Jolanta Emilia Hibner, Karin Kadenbach, Christa Klaß, Holger Krahmer, Jo Leinen, Peter Liese, Radvilė Morkūnaitė-Mikulėnienė, Gilles Pargneaux, Antonyia Parvanova, Mario Pirillo, Pavel Poc, Frédérique Ries, Oreste Rossi, Daciana Octavia Sârbu, Carl Schlyter, Horst Schnellhardt, Richard Seeber, Bogusław Sonik, Catherine Soullie, Salvatore Tatarella, Anja Weisgerber, Sabine Wils
Substitute(s) present for the final vote	Christofer Fjellner, Marisa Matias, Judith A. Merkies, Bill Newton Dunn, Michèle Rivasi, Thomas Ulmer, Marita Ulvskog, Kathleen Van Brempt
Substitute(s) under Rule 187(2) present for the final vote	Josefa Andrés Barea, Matthias Groote, Philippe Juvin, Alojz Peterle