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

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**2008/0256(COD)**

4.3.2010

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## **DRAFT 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

### ***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 interinstitutional decision-making procedures' (COM)2009)0665),
  - having regard to Article 294(3), Article 114 and Article 168(4)c) of the Treaty on the functioning of the EU,
  - having regard to the opinion of 10 June 2009 of the European Economic and Social Committee<sup>1</sup> and the opinion of 7 October 2009 of the Committee of the Regions<sup>2</sup>,
  - 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 (A7-0000/2010),
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.

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<sup>1</sup> OJ C 306, 16.12.2009, p. 19.

<sup>2</sup> OJ C

## Amendment 1

### Proposal for a directive – amending act Recital 3

#### *Text proposed by the Commission*

(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.

#### *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 **as regards 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, which is detrimental to patients with chronic diseases from some Member States, should be redressed.**

Or. en

## Amendment 2

### Proposal for a directive – amending act Recital 5

#### *Text proposed by the Commission*

(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

#### *Amendment*

(5) Those disparities in the interpretation of the Community rules **on providing information to patients and the public at large**, and between national provisions on information have a negative impact on the uniform application of Community rules on **providing information to patients and the public at large**, and on the effectiveness of

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.

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.

Or. en

#### *Justification*

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

### **Amendment 3**

#### **Proposal for a directive – amending act Recital 7**

##### *Text proposed by the Commission*

(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.

##### *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 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.**

Or. en

#### *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 4

### Proposal for a directive – amending act Recital 8

#### *Text proposed by the Commission*

(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.

#### *Amendment*

(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. 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 **making available** of specific information on medicinal products by marketing authorisation holders to the general public **in the context of a wider "information to patients" strategy**. The ban on advertising to the general public for prescription-only medicinal products should be maintained. **The provisions of this Directive concerning the making available of information by marketing authorisation holders are without prejudice to the relationship between patients and their doctors and should contribute to ensuring that patients are better informed. The quality and accuracy of information should be increased with a view to better informing patients and therefore to achieving better health outcomes for patients.**

Or. en

#### *Justification*

*(i) It has to be emphasised that the new provisions do not mean to replace the patient-doctor relationship just to support it; it is in line with Article 100d, paragraph 2, point b of the Commission proposal. Better informed patients are more likely to continue necessary*

*treatments and better understand decisions related to their treatment. (ii) Information by the marketing authorisation holder on prescription-only medicines should be part of a wider information and health-literacy strategy.*

## **Amendment 5**

### **Proposal for a directive – amending act Recital 9**

#### *Text proposed by the Commission*

(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.

#### *Amendment*

(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 ***by the marketing authorisation holder***, 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.***

Or. en

#### *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 6

### Proposal for a directive – amending act Recital 12

#### *Text proposed by the Commission*

(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.

#### *Amendment*

(12) Information to the general public on prescription-only medicinal products should only be **made available by the marketing authorisation holder** through specific channels of communication 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 by the marketing authorisation holder** via television, radio, **or newspapers, magazines and similar publications**, patients are not protected against such unsolicited information and such **making available of information** should therefore not be allowed.

Or. en

#### *Justification*

*(i) The amendment, in terms of replacing "disseminate" by "make available" applies throughout the text. Adopting it will necessitate corresponding changes throughout including replacing the "the noun dissemination" by "making available". (ii) Information by the marketing authorisation holder should be made available to those who are seeking such information themselves; i.e. the "pull principle" should apply. Where information is made available by the pharmaceutical company via newspapers, magazines and similar publications, patients are not protected from unsolicited information, therefore such publications should not be allowed.*

## Amendment 7

### Proposal for a directive – amending act Recital 15

#### *Text proposed by the Commission*

(15) As this Directive introduces for the first time harmonised rules on the provision of information on medicinal

#### *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.

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

Or. en

#### *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 8**

##### **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.***

Or. en

#### *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 9

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

*Text proposed by the Commission*

*Amendment*

***(15b) The Commission should consult patient organisations on issues relating to the implementation of this Directive and its application by the Member States.***

Or. en

*Justification*

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

## Amendment 10

### 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 VIIIa."

- information ***that meets the quality criteria and that is made available*** by the marketing authorisation holder to the general public on medicinal products subject to medical prescription, which is subject to the provisions of Title VIIIa."

Or. en

*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 11

### Proposal for a directive – amending act

#### Article 1 - point 2

Directive 2001/83/EC

Article 88 - paragraph 4

#### *Text proposed by the Commission*

"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.";

#### *Amendment*

"4. The prohibition set out in paragraph 1 shall not apply to vaccination campaigns and other **information** campaigns in the interest of public health, **such as information campaigns on rare diseases**, carried out by the industry and approved by the competent authorities of the Member States.";

Or. en

#### *Justification*

*There is a need to clarify type of campaigns that are allowed. These should be informational rather than promotional and they should address diseases that there might be limited available knowledge about that is accessible to patients such as rare diseases. A disease affecting fewer than 5 people in 10 000 is considered rare. In the EU it is estimated that 6-8% of the population is suffering from altogether 5-8000 distinct rare diseases. Pharmaceutical companies, thanks to their extensive research, have a vast knowledge on these diseases. In order to improve the knowledge of patients and the general public of rare diseases, industry should be allowed to provide information about them.*

## Amendment 12

### Proposal for a directive – amending act

#### Article 1 - point 5

Directive 2001/83/EC

Article 100 a - paragraph 1

#### *Text proposed by the Commission*

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

#### *Amendment*

1. 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 to the general public or members thereof on authorised medicinal

provisions of this Title. Such information shall not be considered advertising for the purposes of the application of Title VIII.

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 identified as such.***

Or. en

#### *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 13**

##### **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.***

Or. en

## 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 14

#### Proposal for a directive – amending act

##### Article 1 - point 5

Directive 2001/83/EC

Article 100 b

#### *Text proposed by the Commission*

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:

**(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.

**(b)** information which does not go beyond the elements of the summary of product

#### *Amendment*

**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 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. **This information should be made available both in electronic and printed form, and in a format accessible to people with disabilities.**

**2. The following types of information on authorised medicinal products subject to medical prescription may be made available by the marketing authorisation holder to the general public or members thereof:**

**(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;

*(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;*

*(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.*

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 way *that is comprehensible to the general public or members thereof without compromising the quality and reliability of the information;*

*(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 relating, for example, to pack changes or adverse-reaction warnings;*

*(c) 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. Such information shall be vetted by the Agency prior to its being made available in accordance with Article 20b(1) of Regulation EC (No) 726/2004;*

*(d) 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.*

*(Cross-reference: repositioning and amending Article 100b; points b)-d) of the proposal)*

Or. en

#### *Justification*

*The Directive should be made patient-centred and therefore as a minimum requirement, the SPC, the package leaflet, and the publicly accessible version of the assessment report has to be made available to the general public.*

*Apart from the essential information made available pursuant to the first subparagraph of Article 100b, more detailed information may be made available for patients. (i) It has to be*

*further emphasised that information should be presented in layman language while its quality is preserved. (ii) Medicines undoubtedly have an impact on the environment. Environmental information presented to the patients should be helped for them and point them towards right environmental practices instead of discouraging them from taking the medicine. (iii) For the sake of clarity it has to be emphasised that information made available pursuant to point (c) is subject to prior vetting by the EMA in accordance with Article 20b (1) of Regulation EC (No) 726/2004. (iv) 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 can not be obliged to make such test and trial documentation available; they, however, should be allowed to make that documentation public if they wish so.*

## **Amendment 15**

### **Proposal for a directive – amending act**

#### **Article 1 - point 5**

Directive 2001/83/EC

Article 100 c - introductory part

#### *Text proposed by the Commission*

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:

#### *Amendment*

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:

Or. en

#### *Justification*

*Information should be made available to those who are seeking such information themselves; i.e. the “pull principle” should apply. Where information is provided by the pharmaceutical company via newspapers, magazines and similar publications, patients are not protected from unsolicited information, therefore such publication should not be allowed.*

## Amendment 16

### Proposal for a directive – amending act

#### Article 1 - point 5

Directive 2001/83/EC

Article 100 c - 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;***

***deleted***

Or. en

#### *Justification*

*Information should be made available to those who are seeking such information themselves; i.e. the “pull principle” should apply. Where information is provided by the pharmaceutical company via health-related publications, patients are not protected from unsolicited information therefore such publication should not be allowed.*

## Amendment 17

### 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 mail address or e-mail address allowing members of the general public to send comments to, ***or request for further information from,*** the marketing authorisation holder.

Or. en

#### *Justification*

*Patients should be given the opportunity to contact the pharmaceutical company for further complementary information.*

## Amendment 18

### 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;***

Or. en

#### *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 19

### 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).

Or. en

*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 20**

**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.***

Or. en

*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 21**

**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

2. After consulting the Member States, ***patient organisations and healthcare professionals***, the Commission shall draw

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.

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.

Or. en

#### *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 22**

##### **Proposal for a directive – amending act**

##### **Article 1 - point 5**

Directive 2001/83/EC

Article 100 h - paragraph 1 - subparagraph 2

#### *Text proposed by the Commission*

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.

#### *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 ***registered by the marketing authorisation holder in accordance with the provisions of the first subparagraph*** throughout the Community if the contents are identical.

Or. en

### *Justification*

*In order to comply with the 'pull principle' and to make sure that information on prescription-only medicines does not appear on any other non-related website, the possibility to make medicine-related information available should be limited to the dedicated websites which are registered and maintained by the pharmaceutical companies in accordance with Article 100h, paragraph 1, subparagraph 1.*

### **Amendment 23**

#### **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*

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.**

#### *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 **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 the safe and effective use of the medicine.**

Or. en

### *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 24**

### **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 patient organisations***

***The Commission shall consult patient organisations on issues relating to the implementation of this Directive and its application by the Member States.***

Or. en

#### *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 25**

### **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 powers 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 make a report in respect of the delegated powers at the latest 6 months before the end of the 5***

*year period. The delegation of powers shall be automatically extended for periods of an identical duration, unless the European Parliament 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 powers to adopt delegated acts are conferred on the Commission subject to the conditions laid down in Articles 100kc and 100kd.*

Or. en

#### *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 26**

#### **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 powers 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 powers 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 powers 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.*

Or. en

#### *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 27**

#### **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 that period, 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.*

***3. If the European Parliament or the Council objects to a delegated act, it shall not enter into force. The institution which objects shall state the reasons for objecting to the delegated act.***

Or. en

*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.*

## 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 than 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.