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

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**2008/0255(COD)**

10.3.2010

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## **DRAFT REPORT**

on the proposal for a regulation of the European Parliament and of the Council on amending, as regards information to the general public on medicinal products for human use subject to medical prescription, Regulation (EC) No 726/2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency (COM(2008)0662 – C6-0517/2008 – 2008/0255(COD))

Committee on the Environment, Public Health and Food Safety

Rapporteur: Christofer Fjellner

### ***Symbols for procedures***

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

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

### ***Amendments to a draft act***

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

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

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## DRAFT EUROPEAN PARLIAMENT LEGISLATIVE RESOLUTION

**on the proposal for a regulation of the European Parliament and of the Council on amending, as regards information to the general public on medicinal products for human use subject to medical prescription, Regulation (EC) No 726/2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency (COM(2008)0662 – C6-0517/2008 – 2008/0255(COD))**

**(Ordinary legislative procedure: first reading)**

*The European Parliament,*

- having regard to the Commission proposal to the European Parliament and the Council (COM(2008)0662),
  - having regard to Article 251(2) and Article 95 of the EC Treaty, pursuant to which the Commission submitted the proposal to Parliament (C6-517/2008),
  - having regard to the communication from the Commission to the European Parliament and the Council entitled: 'Consequences of the entry into force of the Treaty of Lisbon for ongoing interinstitutional decision-making procedures' (COM (2009)0665),
  - having regard to Article 294(3), Article 114 and Article 168(4)(c) of the Treaty on the Functioning of the EU,
  - having regard to the opinion of the Economic and Social Committee and the Committee of the Regions,
  - having regard to Rule 55 of its Rules of Procedure,
  - having regard to the report of the Committee on the Environment, Public Health and Food Safety and the opinions of the Committee on Industry, Research and Energy and the Committee on the Internal Market and Consumer Protection (A7-0000/2010),
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.

## Amendment 1

### Proposal for a regulation – amending act Recital 2

*Text proposed by the Commission*

(2) The introduction of a new Title VIIIa in Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on a Community code relating to medicinal products for human use addresses those concerns through various provisions intended to ensure the availability of good-quality, objective, reliable and non promotional information on medicinal products for human use subject to prescription.

*Amendment*

(2) The introduction of a new Title VIIIa in Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on a Community code relating to medicinal products for human use addresses those concerns through various provisions intended to ensure the availability of good-quality, objective, reliable and non promotional information on medicinal products for human use subject to prescription **and to place emphasis on the rights and interests of patients.**

Or. en

### *Justification*

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

## Amendment 2

### Proposal for a regulation – amending act Article 1 – point 1

Regulation (EC) No 726/2004

Article 20 b – paragraph 3

*Text proposed by the Commission*

(3) The Agency may object to the information submitted or parts thereof on grounds related to non-compliance with the provisions of Title VIIIa of Directive 2001/83/EC within **60 days** after receipt of the notification. If the Agency does not object within **60 days**, the information shall

*Amendment*

(3) The Agency may object to the information submitted or parts thereof on grounds related to non-compliance with the provisions of Title VIIIa of Directive 2001/83/EC within **20 days** after receipt of the notification. If the Agency does not object within **20 days**, the information shall

be deemed accepted and may be published.

be deemed accepted and may be published.

Or. en

*Justification*

*60 days is excessively long and can be to the detriment of patients particularly where product alerts are concerned. In order to ensure greater efficiency in the process, a more reasonable deadline should therefore be set for the Agency to object to the information.*

## 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.