

Opinion of the European Economic and Social Committee 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) 663 final — 2008/0256 (COD)

(2009/C 306/04)

On 23 January 2009, the Council of the European Union decided to consult the European Economic and Social Committee, under Article 95 of the Treaty establishing the European Community, 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'

The Section for the Single Market, Production and Consumption, which was responsible for preparing the Committee's work on the subject, adopted its opinion on 19 May 2009. The rapporteur was Ms HEINISCH.

At its 454th plenary session, held on 10/11 June (meeting of 10 June), the European Economic and Social Committee adopted the following opinion by 94 votes with 4 abstentions.

1. Conclusions and recommendations

1.1 The Committee takes note of the plan to improve information to the public on prescription-only medicines and wishes to express its reservations about individual points in the proposal for a directive. A harmonised legal framework would help to ensure legal certainty and clarity within the Community. The EESC has doubts about the proposal for a Directive COM(2008) 663 final, which would authorise the pharmaceutical industry to communicate directly with patients.

1.2 With the same aim in mind, the EESC considers that the significant variations from one Member State to another in rules on the legal status of medicines with regard to prescription and dispensing are an obstacle to good, understandable information on medicines. Accordingly, the EESC calls on the Commission to continue working towards harmonisation of the setting of rules on the prescription and dispensing of medicines.

1.3 Every citizen (patient) has the right to comprehensive and comprehensible information in their own language. This also applies to online information about prescription-only medicines. This information should relate to the illness in question, i.e. the information on the medicine concerned should also give patients an explanation of the illness it may be used to treat⁽¹⁾. In view of demographic changes, it is particularly important to provide older patients with the means of accessing information⁽²⁾.

⁽¹⁾ See the EESC opinion on the Proposal for a Directive of the European Parliament and of the Council on the application of patients' rights in cross-border healthcare, OJ C 175, 28.7.2009, p. 116.

⁽²⁾ See the EESC opinion on Taking into account the needs of older people, OJ C 77, 31.3.2009, p. 115.

1.4 The EESC recommends setting up an independent body to provide information alongside market authorisation holders. Such a body would be able to provide information on medicines from different manufacturers used in a particular indication. The EESC therefore urges that the proposal for a directive be amended accordingly to advocate such independent bodies.

1.5 Under Article 100h(1) of the proposed directive, websites have to be registered in advance with the national competent authorities. This would ensure that public concerns, including in relation to online material, can be more easily and effectively met.

1.6 It is difficult to distinguish between advertising and information in a given case, as the dividing line between these two areas is often blurred. The EESC considers that the directive should define authorised information on the basis of quality criteria on independent, comparative and comprehensible information, without waiting for the Commission to draw up 'guidelines'.

1.7 The EESC urges that information on non-interventional scientific studies not be considered as information which can be disseminated to the public, and that the relevant sections of the proposal be deleted.

1.8 'Health-related publications' are not an appropriate means of disseminating information on prescription-only medicines. This could constitute 'push' information, whereas the scope of the directive should be confined to information which patients are actively looking for. The option of disseminating information by means of 'health-related publications' should therefore be deleted from the proposal for a Directive.

Conversely, websites can be an appropriate information channel, but the new Article 100c (b) must specify that it is referring to websites exclusively devoted to medicines and approved by the European agency and the national agencies.

1.9 The proposal for a Directive also reflects the need to make officially approved information more readable, especially in the package leaflet. The EESC strongly supports such efforts, also outside the context of proposal under discussion. Patients must be given full and comprehensible information, especially concerning the side-effects of medicines and patient lifestyle factors. Doctors and healthcare professionals should also be given further training in this regard.

1.10 The EESC calls on the Member States to set up an industry-independent online portal, soon after the entry into force of the Directive, which can be used to disseminate information on prescription-only medicines. For this to happen, conferences and forums must be organised in the Member States in cooperation with patient organisations and social security bodies including complementary sickness insurance bodies.

1.11 The directorates-general are advised to inform patients of the possibilities and dangers of online options for finding information on medicines.

1.12 The EESC endorses the methods for monitoring information set out in Article 100g. Wherever prior checks on information appear necessary, they should be carried out. However, if the content of the publication has already been approved by the competent authorities or if there is a different mechanism in place to ensure equally adequate and effective monitoring, no prior checks are needed. Member States must have scope to decide whether a mechanism is in place in their territories to ensure equally adequate and effective monitoring. Article 100g thus regulates the issue in a balanced way.

1.13 Communication between patients and healthcare professionals — in particular doctors and pharmacists — must remain the top priority. Personalised advice from healthcare professionals is vital to ensuring that prescription-only medicines are used safely.

2. Introduction

2.1 The proposal for a Directive is intended to create a clear framework for provision of information by marketing authorisation holders about their prescription-only medicines to the general public with a view to enhancing the rational use of these medicines.

2.2 The aim is to ensure the high quality of information provided by coherent application of clearly defined standards across the Community.

2.3 The Directive is to allow the provision of information through channels that address the needs and capabilities of different types of patients.

2.4 Marketing authorisation holders are to be allowed to provide in an understandable way objective and non-promotional information about the benefits and the risks of their medicines.

2.5 The directive is also intended to make sure that monitoring and enforcement measures are in place to ensure that information providers comply with the quality criteria, while avoiding unnecessary bureaucracy.

3. Background

3.1 Directive 2001/83/EC on the Community code relating to medicinal products for human use⁽³⁾ provides for a harmonised framework for the advertising of medicines at Community level. This legislation prohibits the advertising to the general public of medicines subject to prescription. However, the Directive does not include detailed provisions on information on medicinal products, and only provides that certain information supply activities are exempted from the advertising provisions.

3.2 On the basis of Article 88a of Directive 2001/83/EC⁽⁴⁾, a Communication from the Commission to the European Parliament and the Council concerning the Report on current practices with regard to the provision of information to patients on medicinal products was adopted and submitted to the European Parliament and the Council on 20 December 2007⁽⁵⁾. The report notes that rules and practices on what information can be available vary significantly among Member States. While certain Member States apply very restrictive rules, others allow for several types of non-promotional information to be made available.

4. Commission proposal

4.1 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 envisages exempting certain types of information from the scope of the provisions on the advertising of medicines (Title VIII) and regulating information on prescription-only medicines in a new Title (VIIIa).

⁽³⁾ OJ L 311, 28.11.2001, p. 67, as last amended by Directive 2008/29/EC (OJ L 81, 20.3.2008, p. 51).

⁽⁴⁾ Introduced by Directive 2004/27/EC (OJ L 136, 30.4.2004, p. 34).

⁽⁵⁾ COM(2007) 862 final.

4.2 The types of information on authorised medicinal products subject to medical prescription which marketing authorisation holders may disseminate to the general public or members thereof are listed in Article 100b of the proposal for a Directive. These include the summary of product characteristics, labelling, and package leaflet of the medicinal product, as approved by the competent authorities. Medicinal product-related information on non-interventional scientific studies is also to be allowed.

4.3 Information may only be disseminated through health-related publications, internet websites on medicinal products, and written answers to requests for information of a member of the general public (Article 100c).

4.4 Article 100d sets out general quality standards for information and required content.

4.5 Article 100g sets out provisions for the monitoring of information. The methods used should be based on the control of information prior to its dissemination, unless the content of the information has already been approved by the competent authorities or an equivalent level of adequate and effective monitoring is ensured through a different mechanism.

4.6 Websites with information on prescription-only medicines are to be registered and may not contain web-TV.

5. General comments

5.1 The aim of improving information to the public on prescription-only medicines gives rise to numerous reservations in that it authorises the pharmaceutical industry to communicate directly with patients.

5.2 As well as rules on information provided to the general public, accompanying measures are needed, particularly in terms of ensuring that information is accessible and comprehensible. It is especially important to take account of demographic change, by also informing older people and other groups with particular information needs about possibilities for using the Internet in a way which is comprehensible to them.

5.3 However, after the directive is transposed, the problem also arises of differences between the status of particular medicines in the Member States. As a result, advertising of a medicine may be permitted in one Member State, while another Member State only allows information to be provided in accordance with the provisions of the Directive. Differences in the type and quality of information available in individual Member States will therefore remain.

5.4 The proposal for a Directive also responds to heightened EU public interest in information on existing medicines and treatment options. Patients have become responsible consumers of healthcare, increasingly seeking information about medicines and treatments. However, the image of the 'empowered consumer' is an idealised picture.

5.5 More and more people are searching online for information about medicines, including those which are available only on prescription. The growing importance of the Internet must be taken into account by approaching it as a key source of information which the public can use to find out about medicines. In this context, it should be noted that action is also needed to enable those social groups that have hitherto been less frequent users of the Internet to make better use of the possibilities this medium affords (see point 5.2).

5.6 Another reason that a framework had to be established in Community law for the provision of information on prescription-only medicines is the dubious quality of some of the information available online. We must ensure that high-quality information is made available. Article 100h(5) of the proposal requires registered websites to be clearly identified so that the public can distinguish them from suspect ones.

5.7 Since the information which market authorisation holders are allowed to disseminate on prescription-only medicines is to include the package leaflet, the EESC supports ongoing efforts — outside the context of the proposal under discussion here — to improve the readability of such leaflets. This can only happen if patient organisations are involved. The EESC recommends that a working group be set up to look into this issue.

5.8 The EESC recommends setting up an independent body to provide information alongside market authorisation holders. Such bodies could provide information on medicines from different market authorisation holders and, for instance, also present different medicines (especially generic medicines) available for a particular indication.

6. Specific comments

6.1 The EESC welcomes the continued ban on advertising prescription-only medicines to the public.

6.2 The proposal for a Directive is rightly based on the principle that officially approved information such as 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 should be classified not as advertising but as information. It should be permissible to make such information available to the general public.

6.3 If the presentation of the criteria set out in point 6.2 above differs from the officially approved form, compliance with the quality criteria set out in Article 100d must be ensured. Article 100b(b) should explicitly refer to the requirements of Article 100d, to ensure clarity. Presentation of officially approved information in a different form may be necessary due to the fact that at present officially approved information such as package leaflets and specialised information may sometimes be difficult for patients to understand. The EESC therefore reiterates that such information in the officially approved form must be made easier to read and more readily comprehensible (see point 5.7).

6.4 Information on non-interventional scientific studies should not be disseminated to the public. There are considerable doubts as to whether patients are capable of correctly evaluating information on non-interventional scientific studies and drawing the conclusions that are relevant for them, irrespective of the quality of such information. Information about such studies should continue to be provided by healthcare professionals on a case-by-case basis

6.5 'Health-related publications' are not an appropriate means of disseminating information on prescription-only medicines. Given that the term itself can be understood in different ways, it is doubtful whether it would be interpreted uniformly in the individual Member States. It may also be asked whether this method of disseminating information crosses the boundary between information sought by patients ('pull' information) to information actively disseminated to patients ('push' information), given that patients who buy health-related publications are not necessarily looking specifically for information on a particular medicine ⁽⁶⁾.

6.6 Under Article 100h(1) of the proposed directive, websites have to be registered in advance with the national competent authorities. This would ensure that public concerns, including in relation to online material, can be more easily and effectively met.

6.7 The costs of registration should not place an unreasonable administrative burden on either authorities or the industry.

6.8 It makes sense for information to include a statement indicating that a health professional should be contacted if the patient requires more detailed explanation of the information provided. While providing information on prescription-only medicines may meet patients' heightened need for information and reflect the changing profile of the 'informed' consumer, the information to be disseminated under the proposed directive cannot take the place of explanations provided by health professionals to individual patients.

6.9 The EESC endorses the methods for monitoring information set out in Article 100g. Wherever prior checks on information appear necessary, they should be carried out. If the content of the publication has already been approved by the competent authorities or if there is a different mechanism in place to ensure equally adequate and effective monitoring, no prior checks are needed. Member States must have scope to decide whether a mechanism is in place in their territories to ensure equally adequate and effective monitoring. Article 100g thus regulates the issue in a balanced way.

6.10 The EESC is wholeheartedly in favour of drawing up guidelines on information permitted under Title VIIIa, as provided for in Article 100g(2) of the proposed directive. These guidelines and the code of practice set out therein could clarify the distinction between unauthorised advertising and authorised information. This is necessary given the impossibility of a drawing an abstract distinction in a general definition.

6.11 The EESC endorses the ban on having web-TV on websites and on disseminating information by TV or radio.

Brussels, 10 June 2009.

The President
of the European Economic and Social Committee
Mario SEPI

⁽⁶⁾ Particularly in the case of 'health-related publications' which are actually newspaper supplements.