Opinion of the European Economic and Social Committee on the Proposal for a Regulation of the European Parliament and of the Council amending, as regards information to the general public on medicinal products for human use subject to medical prescription, Regulation (EC) No 726/2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency

COM(2008) 662 final — 2008/0255 (COD)

(2009/C 306/07)

On 12 February 2009 the Council decided to consult the European Economic and Social Committee, under Article 152 (1) of the Treaty establishing the European Community, on the

'Proposal for a Regulation of the European Parliament and of the Council amending, as regards information to the general public on medicinal products for human use subject to medical prescription, Regulation (EC) No 726/2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency'

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 Mr CEDRONE.

At its 454th plenary session on 10 and 11 June 2009 (meeting of 10 June), the European Economic and Social Committee adopted the following opinion by 91 votes with 3 abstentions.

1. **Conclusions and recommendations**

1.1 The Committee welcomes the proposed amendment of the regulation in question as it responds to the objectives of simplifying and harmonising information for patients.

However, the EESC considers that the significant variations from one Member State to another in rules on the legal status of prescription and dispensing of medicines are an obstacle to good, understandable information on medicines.

Accordingly, the EESC calls on the Commission to work towards harmonising the determination of the legal status of prescription and dispensing of medicines containing the same active ingredient(s), at the same dosage, for the same therapeutic indications, presented in the same way and under the various registered trade marks in existence in the Member States.

1.2 It has always supported legislative measures aimed at simplifying rules and extending them in a harmonised way to all EU Member States. As well as being advantageous to patients, this also benefits SMEs, which often find their hopes dampened by bureaucracy.

1.3 In order to achieve an ever-higher standard of information for patients, the EESC, in addition to the measures proposed by the Commission, proposes that the package leaflets that accompany every pharmaceutical product should contain information in a simple and direct visual form based on bands of colour for reporting for instance: benefits (green band), contraindications (yellow band), and possible risks (red band).

1.4 It would also be worthwhile having a list of generic medicines (pharmaceutical products with the same active ingredient whose patents have expired). This list could be put together by the Agency and supplied to pharmacies and all distribution centres open to patients.

1.5 Though aware that computer usage is not yet universal among the EU public, the EESC believes it would be useful to launch an additional procedure for providing patients with necessary information on medicines via the internet. This information, complementing rather than replacing that currently available, should be checked and should carry a label of Community recognition, in order to prevent abuses or misinformation.

1.6 While reiterating its call for continued development of the policy of streamlining bureaucratic procedures and patient information, the EESC calls on the Commission to table further legislative measures to cover all those areas of the pharmaceutical sector that still present difficulties in terms of non-harmonised application in individual Member States, as this impedes the achievement of full and free movement of medicinal products in the EU.

2. **Reasons for the current proposal**

2.1 The proposal in question amends current practice as provided for under Regulation (EC) No 726/2004 with regard solely to information for the general public on medicinal products for human use subject to medical prescription.

2.2 The amendments concern the rules on direct information for consumers on medicinal products subject to prescription and are aimed at securing the proper functioning of the internal market for medicinal products for human use. While amending the rules on information for the public on medicinal products for human use, the regulation also reaffirms the legislative ban on advertising, in line with the provisions of the Directive published in OJ L 311 of 28 November 2001 and the recent amendment set out in Directive 2008/29/EC.

2.3 The need to adjust the provisions of the existing regulation dates back to the Communication from the Commission to the European Parliament of 20 December 2007. That report on 'current practice with regard to information provision' noted that divergences in Member States' rules and practices regarding the provision of information had in some cases led to disparities and varying public access to relevant information.

3. **Gist of the current proposal**

3.1 Draft Regulation COM (2008) 662 final aims to:

— secure a high quality of information;

— ensure that information is provided through channels that address patients' needs;

— enable marketing authorisation holders to provide objective and non-promotional information in an understandable way.

3.2 The proposed amendments are aimed at filling the gaps in the current application of pharmaceutical legislation provided under Regulation (EC) No 726/2004 on information for the public on medicinal products for human use, more specifically:

— enabling marketing authorisation holders to provide the public with information, without prejudice to the prohibition on advertising;

— establishing high quality harmonised conditions on the content of information that marketing authorisation holders are allowed to disseminate;

— determining harmonised channels, in order to exclude unsolicited means of dissemination;

— obliging Member States to establish a monitoring system to be implemented only after information has been disseminated;

— stating that the information must be approved by the authorities responsible for granting marketing authorisations and must extend to information provided on web sites.

3.3 A new Title VIIIa is aimed at addressing disparities by ensuring harmonised, good quality, non-promotional information. The aim is to do away with the unjustified differences in the case of medicinal products authorised under Title II of Regulation (EC) No 726/2004, which provides for a single summary of product characteristics and applies Title VIIIa of Directive 2001/83/EC to those products.

3.4 By way of derogation from Article 100g(1) of Directive 2001/83/EC, medicinal product-related information referred to in Article 100b(d) of that Directive is to be vetted by the Agency prior to its dissemination (Article 20 b), COM(2008) 662 final).

3.5 Therefore, the tasks of the Agency provided for under Article 57 (1) will include a letter u), that of 'delivering opinions on information to the general public on medicinal products for human use subject to medical prescription'.

3.6 The third paragraph of Article 20b states that the Agency may object to the information submitted within 60 days of receipt of the notification. In the absence of opposition, the information may be published, in accordance with the principle of 'silence implies consent'.

4. **The Agency's tasks**

4.1 The Committee for Medicinal Products for Human Use (CMPH), which is part of the Agency, is responsible for preparing opinions on all matters regarding the evaluation of medicinal products for human use. All decisions on authorisations are taken on the basis of scientific criteria relating to the quality, safety and efficacy of the medicinal products concerned.

4.2 EMEA is made up of various committees, including the Committee for Medicinal Products for Human Use. The Agency's tasks are to:

— provide Member States and the Community institutions with scientific advice on all matters regarding the evaluation of the quality, safety and efficacy of medicinal products;

— coordinate both the scientific evaluation of medicines subject to the Community marketing authorisation procedure and the scientific resources put at its disposal by the Member States for the evaluation, supervision and pharmacovigilance of medicinal products;

— disseminate information on adverse reactions to medicines authorised in the EU by means of the Eudravigilance database, which can be consulted on a permanent basis by all Member States;

— create a public database on medicines.

4.3 The present EC regulation complements:

— Commission Regulation (EC) No 2049/2005 laying down rules regarding the payment of fees to, and the receipt of administrative assistance from, the European Medicines Agency by micro, small and medium-sized enterprises;

— Commission Regulation (EC) No 507/2006 on marketing authorisation for medicinal products for human use;

— Commission Regulation (EC) No 658/2007 concerning financial penalties for infringement of certain obligations in connection with marketing authorisations.

5. **Legal base, subsidiarity and proportionality**

5.1 According to the Commission, these modifications are in line with the EU's other policies and objectives. Meanwhile, the choice of Treaty Article 95 appears to be appropriate as that is the legal base for Community pharmaceutical legislation. In addition, the content of the proposed modifications responds to the requirements of Article 5 of that Treaty with regard to the principles of both subsidiarity and proportionality.

6. **General comments**

6.1 The EESC has always supported legislative measures aimed at simplifying rules and ensuring they are adopted in all EU Member States in a harmonised way.

6.2 It therefore welcomes the proposed amendment of the regulation in question as it responds to the objectives of simplifying and harmonising information for patients while also simplifying matters for business, starting with SMEs.

6.3 The EESC believes it would be worthwhile launching an IT-based procedure for checking information via the internet, complementing the provisions currently available. It would also be useful to improve the visual format of the leaflets that accompany all pharmaceutical products (see point 1.3).

6.4 The EESC calls on the Commission to table further legislative measures to cover all those areas of the pharmaceutical sector that still present difficulties in terms of non-harmonised application in individual Member States, not least regarding the issue of sale price and the legal status regarding prescription and dispensing, where this impedes the achievement of full and free movement of medicinal products in the EU.

6.5 The EESC would like to know why the amendment of Regulation (EC) 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' has required two separate but parallel legislative initiatives. The first Commission document (COM(2008) 664 final) provides for amendments regarding pharmacovigilance, while the second (COM(2008) 662 final) addresses information for the general public on medicinal products for human use subject to medical prescription.

6.6 The EESC takes a negative view of this compartmentalisation by the Commission, as two separate legislative measures constitute a waste of procedural resources and could cause delays in securing a single regulation.

Brussels, 10 June 2009.

The President
of the European Economic and European Committee
Mario SEPI