Opinion of the European Economic and Social Committee on the 'Proposal for a Directive of the European Parliament and of the Council amending Directive 2001/82/EC and Directive 2001/83/EC as regards variations to the terms of marketing authorisations for medicinal products'

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On 3 April 2008 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 Directive 2001/82/EC and Directive 2001/83/EC as regards variations to the terms of marketing authorisations for medicinal products.

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 11 June 2008. The rapporteur was Mr Cedrone.

At its 446th plenary session, held on 9-10 July 2008 (meeting of 9 July), the European Economic and Social Committee adopted the following opinion by 127 votes with seven abstentions.

1. **Conclusions and recommendations**

1.1 The EESC approves the Proposal for a Directive amending Directive 2001/82/EC and Directive 2001/83/EC (COM (2008)123 final), recognising that these amendments ensure the harmonisation of the rules regulating all medicinal products regardless of the procedure under which marketing authorisation has been granted.

1.2 Applying the same criteria to all medicinal products ensures, in addition to the same quality, safety and efficacy criteria, a high level of public health protection, the efficient functioning of the internal market, and eliminates an unnecessary administrative and financial burden on businesses.

1.3 The EESC has always supported and continues to support the Commission's efforts to improve the safety of medicinal products, a fundamentally important factor in safeguarding human and animal health.

1.4 The EESC agrees that the Commission should be empowered to extend the scope of Regulation (EC) No 1084/2003 to post-authorisation variations, regardless of the procedure applied, thus avoiding any obstacles to the free movement of medicinal products; and emphasises the importance of future provisions the Commission will have to adopt.

1.5 The EESC once again emphasises its conviction that we must waste no time in completing the single market also in those sectors where this has not occurred or is only partial.

2. **Context**

2.1 In November 2001, the Commission presented sweeping regulatory reforms on medicinal products via two instruments, i.e. Directive 2001/82/EC on the Community code relating to veterinary medicinal products, and Directive 2001/83/EEC on the Community code relating to medicinal products for human use [1].

2.2 The abovementioned legislation was an extension of a profound reform initiated in 1993 through the creation of the European Medicines Agency (EMEA), as set out in Regulation (EEC) No 2309/93, and the implementation of new marketing authorisation procedures for pharmaceuticals [2].

2.3 Based on the principle of the free movement of goods, this regulation foresaw two procedures for marketing authorisation for medicinal products as of 1 January 1995:

a) A 'centralised' procedure for authorisations issued by the EMEA, applicable throughout the EU, compulsory for biotechnological medicinal products and optional for newly formulated pharmaceutical products.

b) A so-called 'decentralised' national procedure enabled authorisation by a competent national authority. This procedure made it possible to apply specific 'mutual recognition' rules for the marketing of medicinal products authorised by a specific Member State in other EU countries.

2.4 The purpose of these marketing authorisation procedures was to ensure a proper assessment of the benefit/risk ratio and to define high quality, safety and efficacy criteria for the precise purpose of safeguarding human and animal health in the EU.

[1] OJ L 311, 28.11.2001.
[2] OJ L 214, 24.8.1993.

2.5 Directive 2001/82/EC and Directive 2001/83/EC strengthen these essential guarantees, setting out specific provisions for pharmacovigilance in order to achieve a high level of public health protection, with more frequent monitoring as well as enhanced and more targeted notification criteria for undesirable side effects.

2.6 During the course of periodic checks on the functioning of the authorisation system for pharmaceutical products, the Commission identified problems relating to variations that could occur downstream of Member State authorisations, which account for over 80 % of total marketing authorisations for medicinal products.

2.7 These variations coming after national authorisation are addressed by Regulation (EC) No 1084/2003 and Regulation (EC) No 1085/2003, but the latter only cover manufacturing procedures, pharmaceutical packaging and intellectual property. They do not address fundamental issues such as, for instance, the inclusion of new therapeutic indications or methods of administration.

2.8 As a result, the post-authorisation procedures may in some cases vary in individual Member States, which can lead to different rules and classifications being applied to the same product. This may result in different levels of health protection being applied due to differences in the therapeutic classification or use of the same product, not to mention the fact that it could constitute a sometimes artificial obstacle to the intended freedom of movement of medicinal products within the EU.

3. **The Commission proposal**

3.1 In order to avoid the emergence of different conditions for the same pharmaceutical products, the Commission has decided to submit a proposal to amend Directive 2001/82/EC and Directive 2001/83/EC by requesting that the application of Regulation (EC) No 1084/2003, currently applicable to pharmaceuticals under the centralised procedure, be extended to all medicinal products regardless of the procedure under which they have been authorised.

3.2 The proposal under consideration falls within the scope of the simplification initiatives foreseen under Annex 2 of the Commission Legislative and Work Programme 2008. It consists solely in a legislative amendment to a number of articles in Directive 2001/82/EC and Directive 2001/83/EC concerning the application of Regulation (EC) No 1084/2003, which is thus extended to all medicinal products.

3.3 Prolonging the present situation would result in unnecessary administrative and financial burdens for businesses wishing to trade in several EU countries. These businesses are faced with the different rules applied by individual Member States and their respective administrative requirements, which, moreover, can create a de facto artificial obstacle to the principle of free trade.

3.4 The proposal is purely legal in nature and sets out to amend the legal basis of Regulation (EC) No 1084/2003 by empowering the Commission to amend the regulation's scope in order to ensure an effective harmonisation of authorisation rules.

3.5 The Commission emphasises that this legislative amendment was based on broad consultation with all stakeholders; and that the choice of a legal amendment — one of many options — was the one identified as best suited to achieving harmonisation in the post-authorisation phase, in keeping with high public health standards and legal consistency.

3.6 The proposed amendments to a set of articles are based on Article 95 of the EC Treaty, which provides for the use of the co-decision procedure, and is consistent with the principle of subsidiarity and the principle of proportionality.

4. **General comments**

4.1 The EESC approves the proposal to amend Directive 2001/82/EC and Directive 2001/83/EC, recognising that these amendments ensure the harmonisation of the rules regulating all medicinal products, a high level of public health protection and the efficient functioning of the internal market, whilst also eliminating unnecessary administrative and financial burdens for businesses.

4.2 As in previous opinions on this issue, the EESC supports and even encourages the Commission's efforts to improve the safety of medicinal products, a fundamentally important factor in safeguarding human and animal health.

4.3 The EESC is therefore in favour of harmonising the rules regulating all medicinal products regardless of authorisation procedures through a simple legislative amendment, thereby simultaneously eliminating any future obstacles to free trade in such products.

4.4 The EESC, while in favour of modifying the legal basis, awaits the legislative proposal currently being drafted, believing it to be of greater significance to the future of the pharmaceutical sector.

Brussels, 9 July 2008.

The President

of the European Economic and Social Committee

Dimitris DIMITRIADIS