COUNCIL OF THE EUROPEAN UNION

Brussels, 4 June 2008

9920/08

Interinstitutional File: 2008/0045 (COD)

MI 164
SAN 105
AGRILEG 87
ECO 64
ENT 106
CODEC 656

NOTE

From :	General Secretariat of the Council
to :	COUNCIL
No. Cion prop. :	7529/08 MI 94 SAN 44 AGRILEG 40 ECO 39 ENT 53 CODEC 356
Subject :	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 - Information from the Presidency

Delegations will find a Progress report prepared by the Presidency in the Annex to this note. This Progress report is intended for the meeting of the Council (EPSCO) on 10 June 2008.

ANNEX

PRESIDENCY PROGRESS REPORT
on the

PROPOSAL FOR A DIRECTIVE OF THE EUROPEAN PARLIAMENT AND THE COUNCIL

AMENDING DIRECTIVE 2001/82/EC AND DIRECTIVE 2001/83/EC AS REGARDS VARIATIONS TO THE TERMS OF MARKETING AUTHORISATIONS FOR MEDICINAL PRODUCTS

I. INTRODUCTION

1. The Commission submitted its 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 on 4 March 2008. The proposal is based on Article 95 of the Treaty.

2. The European Parliament is expected to give its first-reading opinion in October 2008.

3. The requirements for the granting of an initial marketing authorisation for medicinal products for human and veterinary use are fully harmonised at Community level.

4. After a marketing authorisation for a medicinal product has been granted and the product has been placed on the market, a need to change the marketing authorisation might arise resulting from *e.g.* changes in the production process, changes to the packaging or a change of address of the manufacturer. The procedures for such variations of the marketing authorisation are, however, not fully harmonised.

5. The legal bases for variations are laid down in Article 39 of Directive 2001/82/EC[1], Article 35 of Directive 2001/83/EC[2] and Articles 16 and 41 of Regulation (EC) No 726/2004[3]. Variations are governed either by national provisions or by Community rules laid down in the "Variations Regulations" Commission Regulations (EC) No 1084/2003 and No 1085/2003[4]. Today, changes to marketing authorisations for medicinal products which have been granted at a national level by a Member State competent authority under a national procedure and which do not fall under mutual recognition are not covered by the Variations Regulations. Such marketing authorisations are in the following called "purely national authorisations", although they are granted in accordance with provisions of Community legislation.

6. A marketing authorisation holder applying for a variation of the authorisation therefore has to follow different procedures and meet different requirements depending on under which procedures the initial marketing authorisation was granted.

7. The main objective of the proposed Directive is therefore to amend the legal bases for variations in Directives 2001/82/EC and 2001/83/EC in order to empower the Commission to extend the scope of the corresponding Variations Regulation, namely Regulation (EC) No 1084/2003, to cover also changes to "purely national authorisations".

---

1 OJ L 311, 28.11.2001, p. 1. Directive as last amended by Directive 2004/28/EC (OJ L 136, 30.4.2004, p. 58).

2 OJ L 311, 28.11.2001, p. 67. Directive as last amended by Regulation (EC) No 1394/2007 (OJ L 324, 10.12.2007, p. 121).

3 OJ L 136, 30.4.2004, p. 1. Regulation as last amended by Regulation (EC) No 1394/2007 (OJ L 324, 10.12.2007, p. 121).

4 OJ L 159, 27.6.2003, p.1 and OJ L 159, 27.6.2003, p. 24 respectively.

8. In addition, the proposal contains elements which align the provisions of Directive 2001/82/EC concerning implementing powers conferred on the Commission with the novelties of the Comitology Decision[5]. The elements of this alignment are similar to those already agreed for Directive 2001/83/EC[6].

II. PARALLEL AND FUTURE LEGISLATIVE WORK

9. In parallel, the Commission, in the Standing Committees for Human and Veterinary Medicinal Products, has presented amendments to the Commission Regulation on variations to marketing authorizations that aim to align and simplify the provisions on variations for medicinal products authorised through the centralised procedure (Regulation (EC) No 726/2004) and medicinal products authorised through a mutual recognition procedure (Directives 2001/82/EC and 2001/83/EC).

10. As part of its ongoing work on simplification of Community legislation, the Commission has stated an intention to present further amendments to the Commission Regulation on variations that would align also the provisions for variations of "purely national authorisations" with those now under discussion in the Standing Committees. The changes to the legal bases effectuated through the proposed Directive are a prerequisite for such an alignment. This additional alignment would ensure that all medicinal products, regardless of the procedure under which they have been authorised, would be subject to the same criteria for the evaluation, approval and administrative treatment of variations.

III. STATE OF PLAY

11. The Working Party on Pharmaceuticals and Medical devices has started a detailed examination of the proposal in order to identify important issues for further consideration, and has discussed all articles of the proposal. The Commission has informed the Working Party on the progress taking place in the parallel procedure in the Standing Committees.

---

5 Council Decision 2006/512/EC OJ L200, 22.7.2006, p.11-13.
6 Directive 2008/29/EC OJ L81 20.3.2008, p. 51.

12. The Danish, Maltese and United Kingdom delegations have entered Parliamentary scrutiny reservations.

13. Following the first reading of the text, there is broad agreement on most elements of the proposal. Most delegations tend to accept the text as it stands, one delegation however has a reservation of substance on the concept behind the proposal. This delegation, subject to further scrutiny, holds that harmonized rules for variations of "purely national marketing authorisations" might not contribute to an overall simplification of the legislation as compared to its present system. Other delegations have not yet reacted to this. Clearly, this question needs to be further examined in forthcoming meetings.

14. Some delegations said that they expect to encounter some legal problems when preparing for implementation of the Directive. One delegation entered a general reservation and some other delegations entered a scrutiny reservation on Article 3 of the Proposal and suggested a prolongation of the transposition period. In addition, a few delegations have made technical remarks on the proposal.

IV. CONCLUSIONS

15. Progress has been made on the Proposal, and on most technical points agreement in the Council is foreseeable. The Working Party will pursue the examination of the proposal, in particular as concerns the content of the reservations raised.