Directive 2009/53/EC of the European Parliament and of the Council of 18 June 2009 amending Directive 2001/82/EC and Directive 2001/83/EC, as regards variations to the terms of marketing authorisations for medicinal products (Text with EEA relevance)

DIRECTIVE 2009/53/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

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(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 95 thereof,

Having regard to the proposal from the Commission,

Having regard to the opinion of the European Economic and Social Committee[(1)],

Acting in accordance with the procedure laid down in Article 251 of the Treaty[(2)],

Whereas:

(1) Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to veterinary medicinal products[(3)], Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use[(4)] and Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency[(5)], lay down harmonised rules for the authorisation, supervision and pharmacovigilance of medicinal products within the Community.

(2) Under those rules, marketing authorisations may be granted in accordance with harmonised Community procedures. The terms of those marketing authorisations may subsequently be varied where, for instance, the production process or the address of the manufacturer has changed.

(3) Article 39 of Directive 2001/82/EC and Article 35 of Directive 2001/83/EC empower the Commission to adopt an implementing regulation as regards variations subsequently made to marketing authorisations granted in accordance with the provisions of Chapter 4 of Title III of Directive 2001/82/EC and Chapter 4 of Title III of Directive 2001/83/EC, respectively. The Commission therefore adopted Regulation (EC) No 1084/2003 of 3 June 2003 concerning the examination of variations to the terms of a marketing

authorisation for medicinal products for human use and veterinary medicinal products granted by a competent authority of a Member State[(6)].

(4) However, the majority of medicinal products for human or veterinary use currently on the market have been authorised under purely national procedures and, as such, fall outside the scope of Regulation (EC) No 1084/2003. Variations to marketing authorisations granted under purely national procedures are thus subject to national rules.

(5) Consequently, while the granting of all marketing authorisations for medicinal products is subject to harmonised rules within the Community, this is not the case for variations to the terms of marketing authorisations.

(6) For reasons of public health and legal consistency, and with a view to reducing the administrative burden and strengthening predictability for economic operators, variations to all types of marketing authorisations should be subject to harmonised rules.

(7) The rules on variations adopted by the Commission should pay particular attention to simplifying administrative procedures. To this effect, the Commission should provide, when adopting these rules, for the possibility of submitting a single application for one or more identical changes made to the terms of a number of marketing authorisations.

(8) In accordance with point 34 of the Interinstitutional Agreement on better law-making[(7)], Member States are encouraged to draw up, for themselves and in the interests of the Community, their own tables illustrating, as far as possible, the correlation between this Directive and the transposition measures, and to make them public.

(9) Directive 2001/82/EC and Directive 2001/83/EC should therefore be amended accordingly,

HAVE ADOPTED THIS DIRECTIVE:

(**1**) OJ C 27, 3.2.2009, p. 39.

(**2**) Opinion of the European Parliament of 22 October 2008 (not yet published in the Official Journal) and Council Decision of 28 May 2009.

(**3**) OJ L 311, 28.11.2001, p. 1.

(**4**) OJ L 311, 28.11.2001, p. 67.

(**5**) OJ L 136, 30.4.2004, p. 1.

(**6**) OJ L 159, 27.6.2003, p. 1.

(**7**) OJ C 321, 31.12.2003, p. 1.