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

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)

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:

Article 1

Amendments to Directive 2001/82/EC

Directive 2001/82/EC is hereby amended as follows:

1. the following Article shall be inserted:

Article 27b

The Commission shall adopt appropriate arrangements for the examination of variations to the terms of marketing authorisations granted in accordance with this Directive.

The Commission shall adopt these arrangements in the form of an implementing regulation. That measure, designed to amend non-essential elements of this Directive, by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 89(2a).

2. the second and third subparagraphs of Article 39(1) shall be deleted.

Article 2

Amendments to Directive 2001/83/EC

Directive 2001/83/EC is hereby amended as follows:

1. the following Article shall be inserted:

Article 23b

1 The Commission shall adopt appropriate arrangements for the examination of variations to the terms of marketing authorisations granted in accordance with this Directive.

2 The Commission shall adopt the arrangements referred to in paragraph 1 in the form of an implementing regulation. That measure, designed to amend non-essential elements of this Directive, by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 121(2a).

3 When adopting the arrangements referred to in paragraph 1, the Commission shall make efforts to make it possible to submit a single application for one or more identical changes made to the terms of a number of marketing authorisations.

4 A Member State may continue to apply national provisions on variations applicable at the time of entry into force of the implementing regulation to marketing authorisations granted before 1 January 1998 to medicinal products authorised only in that Member State. Where a medicinal product subject to national provisions in accordance with this Article is subsequently granted a marketing authorisation in another Member State, the implementing regulation shall apply to that medicinal product from that date.

5 Where a Member State decides to continue to apply national provisions pursuant to paragraph 4, it shall notify the Commission thereof. If a notification has not been made by 20 January 2011, the implementing regulation shall apply.

2. the second and third subparagraphs of Article 35(1) shall be deleted.

Article 3

Transposition

1 Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by 20 January 2011 at the latest. They shall forthwith communicate to the Commission the text thereof.

When Member States adopt those measures, they shall contain a reference to this Directive or be accompanied by such a reference on the occasion of their official publication. Member States shall determine how such reference is to be made.

2 Member States shall communicate to the Commission the text of the main provisions of national law which they adopt in the field covered by this Directive.

Article 4

Entry into force

This Directive shall enter into force on the 20th day following its publication in the *Official Journal of the European Union*.

Article 5

Addressees

This Directive is addressed to the Member States.

Done at Brussels, 18 June 2009.

For the European Parliament

The President

H.-G. PÖTTERING

For the Council

The President

Š. FÜLE

(**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.