P6_TA-PROV(2008)0510

Variations to the terms of marketing authorisations for medicinal products ***I

European Parliament legislative resolution of 22 October 2008 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 (COM(2008)0123 – C6-0137/2008 – 2008/0045(COD))

(Codecision procedure: first reading)

The European Parliament,

– having regard to the Commission proposal to the European Parliament and the Council (COM(2008)0123),

– having regard to Articles 251(2) and 95 of the EC Treaty, pursuant to which the Commission submitted the proposal to Parliament (C6-0137/2008),

– having regard to Rule 51 of its Rules of Procedure,

– having regard to the report of the Committee on the Environment, Public Health and Food Safety and the opinion of the Committee on Agriculture and Rural Development (A6-0346/2008),

1. Approves the Commission proposal as amended;

2. Calls on the Commission to refer the matter to Parliament again if it intends to amend the proposal substantially or replace it with another text;

3. Instructs its President to forward its position to the Council and the Commission.

P6_TC1-COD(2008)0045

Position of the European Parliament adopted at first reading on 22 October 2008 with a view to the adoption of Directive *2008/.../EC* 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

(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],

Having regard to the opinion of the Committee of the Regions[2],

Acting in accordance with the procedure laid down in Article 251 of the Treaty[3],

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[4], 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[5] 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[6], 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

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1 OJ C

2 OJ C

3 *Position of the European Parliament of 22 October 2008.*

4 OJ L 311, 28.11.2001, p. 1.‖

5 OJ L 311, 28.11.2001, p. 67. ‖

6 OJ L 136, 30.4.2004, p. 1. ‖

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[1].

(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) It results therefrom that 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, legal consistency***, 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 foresee, when adopting these rules, certain possibilities of filing a single application for one or more identical changes to the terms of a number of marketing authorisations.

(8) In accordance with point 34 of the Interinstitutional Agreement on better law-making[2], 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,

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1 OJ L 159, 27.6.2003, p. 1.

2 ***OJ C 321, 31.12.2003, p. 1.***

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 27b *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) In Article 39(1), the second and third subparagraphs *shall be* deleted.

Article 2
Amendments to Directive 2001/83/EC

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

(1) The following Article 23b *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 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 121(2a).

3. When adopting these arrangements, the Commission shall make efforts to extend the possibility of submitting 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 that 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 ...[+] , the implementing regulation shall apply."

(2) In Article 35(1), the second and third subparagraphs *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 ...[+] at the latest. They shall forthwith communicate to the Commission the text of those provisions.

When Member States adopt those provisions, 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 [twentieth] day following that of its publication in the Official Journal of the European Union.

Article 5
Addressees

This Directive is addressed to the Member States.

Done at ‖

For the European Parliament
The President

For the Council
The President

[+] ***OJ: 18 months after the date of entry into force of this Directive.***
[+] OJ: ***18 months*** after *the date of* entry into force *of this Directive.*