Directive 2008/29/EC of the European Parliament and of the Council of 11 March 2008 amending Directive 2001/83/EC on the Community code relating to medicinal products for human use, as regards the implementing powers conferred on the Commission

DIRECTIVE 2008/29/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

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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 2001/83/EC[(3)] of the European Parliament and of the Council provides that certain measures are to be adopted in accordance with Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission[(4)].

(2) Decision 1999/468/EC has been amended by Decision 2006/512/EC, which introduced the regulatory procedure with scrutiny for the adoption of measures of general scope and designed to amend non-essential elements of a basic instrument adopted in accordance with the procedure referred to in Article 251 of the Treaty, *inter alia*, by deleting some of those elements or by supplementing the instrument with new non-essential elements.

(3) In accordance with the statement by the European Parliament, the Council and the Commission[(5)] concerning Decision 2006/512/EC, for the regulatory procedure with scrutiny to be applicable to instruments adopted in accordance with the procedure referred to in Article 251 of the Treaty which are already in force, those instruments must be adjusted in accordance with the applicable procedures.

(4) The Commission should be empowered to adapt certain provisions and annexes, to adopt arrangements, principles and guidelines, and to lay down specific conditions of application. Since those measures are of general scope and are designed to amend non-essential elements of Directive 2001/83/EC, *inter alia*, by supplementing it with new non-essential elements, they must be adopted in accordance with the regulatory procedure with scrutiny provided for in Article 5a of Decision 1999/468/EC.

(5) Directive 2001/83/EC should therefore be amended accordingly.

(6) Since the amendments made to Directive 2001/83/EC by this Directive are technical in nature and concern committee procedure only, they do not need to be transposed by the Member States. It is therefore not necessary to lay down provisions to that effect,

HAVE ADOPTED THIS DIRECTIVE:

Article 1

Amendments

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

1. in Article 14(1), the second subparagraph shall be replaced by the following:

   If new scientific evidence so warrants, the Commission may amend the third indent of the first subparagraph. That measure, designed to amend non-essential elements of this Directive, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 121(2a).;

2. in Article 35(1), the third subparagraph shall be replaced by the following:

   These arrangements shall be adopted by the Commission 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. in Article 46(f), the second paragraph shall be replaced by the following:

   This point shall also be applicable to certain excipients, the list of which as well as the specific conditions of application of which shall be established by a Directive adopted by the Commission. 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).;

4. Article 46a(2) shall be replaced by the following:

2. The Commission shall be empowered to adapt paragraph 1 to take account of scientific and technical progress. That measure, designed to amend non-essential elements of this Directive, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 121(2a).;

5. in Article 47, the first paragraph shall be replaced by the following:

   The principles and guidelines of good manufacturing practices for medicinal products referred to in Article 46(f) shall be adopted in the form of a directive. 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).;

6. Article 104(7) shall be replaced by the following:

7. The Commission may amend paragraph 6 in view of experience gained through its operation. That measure, designed to amend non-essential elements of this

Directive, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 121(2a).;

7. in Article 107(2), the fourth subparagraph shall be replaced by the following:

> The decision on the final measures concerning the product shall be adopted in accordance with the management procedure referred to in Article 121(3).;

8. Article 108 shall be replaced by the following:

Article 108

The Commission shall adopt any amendments which may be necessary to update provisions of Articles 101 to 107 to take account of scientific and technical progress. Those measures, designed to amend non-essential elements of this Directive, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 121(2a).;

9. Article 120 shall be replaced by the following:

Article 120

The Commission shall adopt any changes which are necessary in order to adapt Annex I to take account of scientific and technical progress. Those measures, designed to amend non-essential elements of this Directive, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 121(2a).;

10. Article 121 shall be amended as follows:

(a) the following paragraph shall be inserted:

> 2a. Where reference is made to this paragraph, Article 5a(1) to (4) and Article 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.;

(b) paragraph 4 shall be replaced by the following:

> 4. The rules of procedure of the Standing Committee shall be made public.

Article 2

Entry into force

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

Article 3

Addressees

This Directive is addressed to the Member States.

Done at Strasbourg, 11 March 2008.

For the European Parliament

The President

H.-G. PÖTTERING

For the Council

The President

J. LENARČIČ

(**1**) OJ C 161, 13.7.2007, p. 45.

(**2**) Opinion of the European Parliament of 29 November 2007 (not yet published in the Official Journal) and Council Decision of 3 March 2008.

(**3**) 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).

(**4**) OJ L 184, 17.7.1999, p. 23. Decision as amended by Decision 2006/512/EC (OJ L 200, 22.7.2006, p. 11).

(**5**) OJ C 255, 21.10.2006, p. 1.