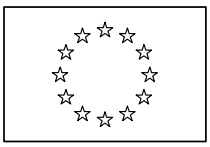

COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 22.12.2006
COM(2006) 919 final

2006/0295 (COD)

Proposal for a

DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

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

(presented by the Commission)

2006/0295 (COD)

Proposal for a

DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL 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

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[1],

Having regard to the opinion of the European Economic and Social Committee[2],

Having regard to the opinion of the Committee of the Regions[3],

Acting in accordance with the procedure laid down in Article 251 of the Treaty[4],

Whereas:

(1) Directive 2001/83/EC of the European Parliament and of the Council[5] provides that certain measures should 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[6].

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

(3) In accordance with the joint statement of the European Parliament, the Council and the Commission[7] on Decision 2006/512/EC, instruments which are already in force must be adjusted in accordance with the applicable procedures. The statement comprises a list of instruments to be adapted as a priority, including Directive 2001/83/EC.

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1 OJ C […], […], p. […].
2 OJ C […], […], p. […].
3 OJ C […], […], p. […].
4 OJ C […], […], p. […].
5 OJ L 311, 28.11.2001, p. 67-128
6 OJ L 184, 17.7.1999, p. 23. Decision as amended by Decision 2006/512/EC (OJ L 200, 22.7.2006, p. 11).
7 OJ C 255, 21.10.2006, p. 1.

(4) In particular, power should be conferred on the Commission to adapt certain provisions and annexes, to adopt arrangements and principles and guidelines, and to lay down specific conditions of application. Since these measures are of general scope and are designed to amend/delete non-essential elements of Directive 2001/83/EC and/or to supplement this Directive by the addition of new non-essential elements, they should 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 procedures only, they do not require transposition by the Member States. Therefore it is not necessary to establish provisions for this purpose,

HAVE ADOPTED THIS DIRECTIVE:

Article 1

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

1) The second subparagraph of Article 14(1) is replaced by the following:

"If new scientific evidence so warrants, the Commission may amend the third indent of the first subparagraph. This 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) The third subparagraph of Article 35(1) is replaced by the following:

"These arrangements shall be adopted by the Commission in the form of an implementing regulation. This 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) The second subparagraph of Article 46(f) is 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 shall be established by a Directive adopted by the Commission. This 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) is replaced by the following:

"The Commission shall be empowered to adapt paragraph 1 to take account of scientific and technical progress. This 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) The first subparagraph of Article 47 is 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. This 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) is replaced by the following:

"The Commission may amend paragraph 6 in view of experience gained through its operation. This 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) Article 108 is replaced by the following:

"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. This 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)."

8) Article 120 is replaced by the following:

"The Commission shall adopt any changes which are necessary in order to adapt Annex I to take account of scientific and technical progress. These 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 121 is amended as follows:

a) The following paragraph 2a is inserted:

"2a. Where reference is made to this paragraph, Article 5a(1) to (4) and Article 7 of Decision No 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof".

(b) Paragraph 4 is deleted.

Article 2

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

Article 3

This Directive is addressed to the Member States.

Done at Brussels,

For the European Parliament
President

For the Council
President