

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

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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.

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- (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:

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- (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.](#)