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

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.