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 (Text with EEA relevance)

TITLE V

GENERAL AND FINAL PROVISIONS

Article 81

1 All decisions to grant, refuse, vary, suspend, withdraw or revoke a marketing authorisation which are taken in accordance with this Regulation shall state in detail the reasons on which they are based. Such decisions shall be notified to the party concerned.

2 An authorisation to place a medicinal product governed by this Regulation on the market shall not be granted, refused, varied, suspended, withdrawn or revoked except through the procedures and on the grounds set out in this Regulation.

Article 82

1 Only one authorisation may be granted to an applicant for a specific medicinal product.

However, the Commission shall authorise the same applicant to submit more than one application to the Agency for that medicinal product when there are objective verifiable reasons relating to public health regarding the availability of medicinal products to health-care professionals and/or patients, or for co-marketing reasons.

2 As regards medicinal products for human use, Article 98(3) of Directive 2001/83/EC shall apply to medicinal products authorised under this Regulation.

3 Without prejudice to the unique, Community nature of the content of the documents referred to in Article 9(4)(a), (b), (c) and (d) and in Article 34(4)(a) to (e), this Regulation shall not prohibit the use of two or more commercial designs for a given medicinal product covered by a single authorisation.

Article 83

1 By way of exemption from Article 6 of Directive 2001/83/EC Member States may make a medicinal product for human use belonging to the categories referred to in Article 3(1) and (2) of this Regulation available for compassionate use.

2 For the purposes of this Article, ‘compassionate use’ shall mean making a medicinal product belonging to the categories referred to in Article 3(1) and (2) available for compassionate reasons to a group of patients with a chronically or seriously debilitating disease or whose disease is considered to be life-threatening, and who can not be treated satisfactorily by an authorised medicinal product. The medicinal product concerned must either be the subject of an application for a marketing authorisation in accordance with Article 6 of this Regulation or must be undergoing clinical trials.

3 When a Member State makes use of the possibility provided for in paragraph 1 it shall notify the Agency.

4 When compassionate use is envisaged, the Committee for Medicinal Products for Human Use, after consulting the manufacturer or the applicant, may adopt opinions on the conditions for use, the conditions for distribution and the patients targeted. The opinions shall be updated on a regular basis.

5 Member States shall take account of any available opinions.

6 The Agency shall keep an up-to-date list of the opinions adopted in accordance with paragraph 4, which shall be published on its website. Article 24(1) and Article 25 shall apply *mutatis mutandis*.

7 The opinions referred to in paragraph 4 shall not affect the civil or criminal liability of the manufacturer or of the applicant for marketing authorisation.

8 Where a compassionate use programme has been set up, the applicant shall ensure that patients taking part also have access to the new medicinal product during the period between authorisation and placing on the market.

9 This Article shall be without prejudice to Directive 2001/20/EC and to Article 5 of Directive 2001/83/EC.

Article 84

1 Without prejudice to the Protocol on the Privileges and Immunities of the European Communities, each Member State shall determine the penalties to be applied for infringement of the provisions of this Regulation or the regulations adopted pursuant to it and shall take all measures necessary for their implementation. The penalties shall be effective, proportionate and dissuasive.

Member States shall inform the Commission of these provisions no later than 31 December 2004. They shall notify any subsequent alterations as soon as possible.

2 Member States shall inform the Commission immediately of any litigation instituted for infringement of this Regulation.

3 At the Agency's request, the Commission may impose financial penalties on the holders of marketing authorisations granted under this Regulation if they fail to observe certain obligations laid down in connection with the authorisations. The maximum amounts as well as the conditions and methods for collection of these penalties shall be laid down in accordance with the procedure referred to in Article 87(2).

The Commission shall publish the names of the marketing authorisation holders involved and the amounts of and reasons for the financial penalties imposed.

Article 85

This Regulation shall not affect the competences vested in the European Food Safety Authority created by Regulation (EC) No 178/2002[(1)].

Article 86

At least every ten years, the Commission shall publish a general report on the experience acquired as a result of the operation of the procedures laid down in this Regulation, in Chapter 4 of Title III of Directive 2001/83/EC and in Chapter 4 of Title III of Directive 2001/82/EC.

Article 87

1 The Commission shall be assisted by the Standing Committee on Medicinal Products for Human Use set up by Article 121 of Directive 2001/83/EC and by the Standing Committee on Veterinary Medicinal Products set up by Article 89 of Directive 2001/82/EC.

2 Where reference is made to this paragraph, Articles 5 and 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

The period laid down in Article 5(6) of Decision 1999/468/EC shall be set at three months.

3 Where reference is made to this paragraph, Articles 4 and 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

The period laid down in Article 4(3) of Decision 1999/468/EC shall be set at one month.

4 The committees shall adopt their Rules of Procedure.

Article 88

Regulation (EEC) No 2309/93/EC is hereby repealed.

References to the repealed Regulation shall be construed as references to this Regulation.

Article 89

The periods of protection provided for in Articles 14(11) and 39(10) shall not apply to reference medicinal products for which an application for authorisation has been submitted before the date referred to in Article 90, second paragraph.

Article 90

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

By way of derogation from the first paragraph, Titles I, II, III and V shall apply from 20 November 2005 and point 3, fifth and sixth indent of the Annex shall apply from 20 May 2008.

(**1**) Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (OJ L 31, 1.2.2002, p. 1).

Status:
Point in time view as at 26/01/2007.

Changes to legislation:
There are currently no known outstanding effects for the Regulation (EC) No 726/2004 of the European Parliament and of the Council, TITLE V.