THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Regulation (EC) No 726/2004, and in particular Article 14(7) thereof,

Whereas:

(1) [Initial capital…].

(2) The measures provided for in this Regulation are in accordance with the opinion of the […] Committee,

HAS ADOPTED THIS REGULATION:

Article 1

Purpose

This Regulation lays down the conditions and the procedure for granting a conditional marketing authorisation in accordance with Article 14(7) of Regulation (EC) No 726/2004.

Article 2

Scope

The following categories of medicinal products may benefit from a conditional marketing authorisation:

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1. Medicinal products for human use as defined in Articles 3(1) and 3(2) of Regulation (EC) No 726/2004 which aim at the treatment, prevention or medical diagnosis of chronically or seriously debilitating diseases or life-threatening diseases.


3. Medicinal products for human use to be used in emergency situations, in response to public health threats duly recognised either by the World Health Organisation or by the Community in the framework of Decision No 2119/98/EC of the European Parliament and of the Council of 24 September 1998³.

Article 3

Request for a conditional marketing authorisation

1. A request for a conditional marketing authorisation may be presented by the applicant at the time of the application referred to in Article 6 of Regulation (EC) No 726/2004 accompanied by a detailed justification.

2. The applicant may also request a conditional marketing authorisation during the assessment procedure conducted by the Committee for Medicinal Products for Human Use of the Agency referred to in Article 7 of Regulation (EC) No 726/2004. This request has to be accompanied by a detailed justification.

3. The Committee for Medicinal Products for Human Use may, during the assessment procedure of Article 7 of Regulation (EC) No 726/2004, propose a conditional marketing authorisation, after having consulted the applicant. This proposal has to be accompanied by detailed explanatory reasons and has to be communicated to the applicant.

4. The conditional marketing authorisation is applied without prejudice to the application for an accelerated assessment procedure in accordance with Article 14(9) of Regulation (EC) No 726/2004.

5. Any request to, or proposal by, the Committee for Medicinal Products for Human Use for a conditional marketing authorisation shall be made publicly available.

6. The Agency shall inform forthwith the Commission on the applications initiated to grant a conditional marketing authorisation.

Article 4

Criteria for the granting of a conditional marketing authorisation

1. A conditional marketing authorisation may be granted subject to the following conditions:

(a) The medicinal product falls within the scope of this Regulation.

(b) The applicant is able to demonstrate the public health interest of the medicinal product.

(c) The applicant is able to demonstrate the presumed positive benefit-risk balance of the medicinal product, based on scientific evidence and pending completion of further studies.


(e) The applicant is required to finalise the on-going studies or to conduct new studies necessary to verify that the benefit-risk balance is positive and to resolve remaining uncertainty in this regard. Any specific obligation and the timeframe for their completion are to be clearly specified in the conditional marketing authorisation. The obligations and the timeframe shall be made publicly available.

(f) The specific obligations and time frame for their completion will be reviewed annually by the Committee for Medicinal Products for Human Use. The conclusions of the Committee shall be made publicly available.

2. In the case of medicinal products referred to in Article 2(3) of this regulation, the Agency may exceptionally and temporarily waive the conditions laid down in paragraph (d).

Article 5

Procedure for the evaluation of the application

1. The Committee for Medicinal Products for Human Use shall consult one of the relevant scientific advisory groups, set up in accordance with Article 56(2) of Regulation (CE) No 726/2004, in relation to the specific obligations for the conditional marketing authorisation of the product.

2. Any additional study requested to demonstrate that the benefit-risk balance is positive shall not impose on the marketing authorisation holder more stringent requirements than those required for marketing authorisations granted in accordance with the procedure set out in Articles 9 to 11 of Regulation (EC) No 726/2004.

Article 6

Procedure for the renewal of the conditional marketing authorisation

1. The conditional marketing authorisation shall be valid for one year on a renewable basis.

2. Within the 12 months following the granting of the conditional marketing authorisation, the marketing authorisation holder shall apply for the renewal of the marketing authorisation. The Committee for Medicinal Products for Human Use shall assess the application, taking into account the specific obligations and the timeframe for fulfilment of the obligations referred to in Article 4, point e, and decide whether these need to be retained or if there is a need to modify the specific obligations or timeframes to be fulfilled for continuation of the conditional marketing authorisation or if the specific obligations are met and the benefit-risk balance of the medicinal product can be established and adopt an opinion accordingly.

3. If the timeframe foreseen for the fulfilment of the specific obligations is longer than one year, the Committee for Medicinal Products for Human Use shall assess the application for renewal on the basis of an interim report provided by the applicant which will contain the necessary information and data allowing the timeframe for fulfilment of the obligations as foreseen in the conditional marketing authorisation to be evaluated.

4. At any time, when the obligations referred to in Article 4, point e, are satisfied, the Committee for Medicinal Products for Human Use may adopt an opinion in the meaning of Article 9 of Regulation (EC) No 726/2004 and the procedure foreseen in Articles 10 and 11 of said Regulation will be applied. Article 14(1) and (2) will apply thereafter.

5. The conditional marketing authorisation shall be valid until the decision is adopted by the Commission in accordance with the procedure referred to in Articles 9 to 11 of Regulation (EC) No 726/2004.

6. If the marketing authorisation holder does not apply in due time for the renewal of the marketing authorisation, the marketing authorisation ceases to be valid at the expiry date.

Article 7

Information and package leaflets

Without prejudice to Title V, Labelling and Package leaflets, of Directive 2001/83/CE, the information included in the summary of product characteristics and package leaflet of the medicinal product authorised in accordance with this Regulation shall contain a clear mention of the fact that a conditional marketing authorisation has been granted and of the annual renewal of this authorisation.
Article 8

Fees for the renewal of the conditional authorisation

A renewal fee shall apply for examining information available at the time of the annual renewal of a conditional marketing authorisation. The amount of this renewal fee shall be a fifth of the fee referred to in Article 3(3) of Council Regulation (EC) No XX.

Article 9

Periodic safety update reports

1. By derogation to Article 24(3) of Regulation (EC) No 726/2004, the periodic safety update reports shall be submitted to the Agency and Member States immediately upon request or at least every six months after authorisation until the placing on the market and immediately upon request or at least every six months after the placing on the market.

2. Where in accordance with Article 6(4), the medicinal product is authorised through the procedure referred to in Articles 9 to 11 of Regulation (EC) No 726/2004, Article 24(3) shall apply.

Article 10

EMEA advice prior to marketing authorisation application

A potential applicant for a marketing authorisation may request the advice of the Agency on whether a specific medicinal product being developed for a specific therapeutic indication fulfils the criteria set out in Article 4(1) subsections a and b.

Article 11

Guidelines

The Agency shall develop guidelines on the procedures necessary to implement this Regulation and guidelines for the application of Article 4 points b, c and d. The guidelines shall be adopted after a favourable opinion of the Commission.

Article 12
General provisions

Unless otherwise provided for in this Regulation the provisions of Title II concerning the authorisation and supervision of medicinal products for human use of Regulation (CE) No 726/2004 shall apply.

The criteria and procedures provided for Regulation (EC) No 726/2004 shall apply by analogy.

Article 13

This Regulation shall enter into force on the [...] day following that of its publication in the Official Journal of the European Union. It shall apply from 20 November 2005.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, [...]