Commission Regulation (EC) No 658/2007 of 14 June 2007 concerning financial penalties for infringement of certain obligations in connection with marketing authorisations granted under Regulation (EC) No 726/2004 of the European Parliament and of the Council

COMMISSION REGULATION (EC) No 658/2007

of 14 June 2007

concerning financial penalties for infringement of certain obligations in connection with marketing authorisations granted under Regulation (EC) No 726/2004 of the European Parliament and of the Council

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to 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[(1)], and in particular the first subparagraph of Article 84(3) thereof,

Whereas:

(1) In order to ensure the enforcement of certain obligations connected with marketing authorisations for medicinal products granted in accordance with Regulation (EC) No 726/2004, Article 84 of that Regulation empowers the Commission, at the request of the European Medicines Agency, hereinafter 'the Agency', to impose financial penalties on the holders of marketing authorisations.

(2) Infringements of obligations laid down in connection with marketing authorisations granted in accordance with Regulation (EC) No 726/2004 which may lead to the application of a financial penalty should concern the content of a marketing authorisation and post-marketing requirements linked to a marketing authorisation, including the requirements of Community law relating to pharmacovigilance and market surveillance.

(3) Moreover, in view of the provision made by Article 84(1) of Regulation (EC) No 726/2004, under which the Member States are to determine the penalties to be applied for infringement of the provisions of that Regulation or the Regulations adopted pursuant to it and to take the necessary measures for their implementation, action at Community level should be taken only in cases where the interests of the Community are involved. In that way, the effective enforcement of Regulation (EC) No 726/2004 would be ensured by an appropriate management of the resources available at Community and national level.

(4) As a result of the system of parallel powers in relation to supervision and enforcement by the Community and the Member States with regard to marketing authorisations granted in accordance with Regulation (EC) No 726/2004, the provisions of this Regulation can

Changes to legislation: *There are outstanding changes not yet made to Commission Regulation (EC) No 658/2007. Any changes that have already been made to the legislation appear in the content and are referenced with annotations. (See end of Document for details) View outstanding changes*

be effectively enforced only in a framework of close cooperation, in accordance with Article 10 of the Treaty, between the Member States, the Agency and the Commission. For that purpose it is necessary to set up arrangements for consultation and cooperation between them.

(5) It is appropriate that, for the purposes of the initiation and conduct of the infringement procedure and the quantification of financial penalties, the Agency and the Commission should take into account any procedure by a Member State against the same marketing authorisation holder and based on the same legal grounds and the same facts.

(6) In order to ensure the effective conduct of the inquiry stage of alleged infringements, the Agency and the Commission should have recourse to the competent authorities of the Member States, designated as the supervisory authorities of medicinal products authorised through the centralised procedure by Regulation (EC) No 726/2004, to carry out the necessary measures of inquiry and to obtain information relating to infringements falling within the scope of this Regulation. To that end, it is appropriate that the supervisory authorities conduct the inspection and surveillance activities for which they are competent in accordance with the provisions of Regulation (EC) No 726/2004, Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to veterinary medicinal products[(2)] and Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use[(3)] and their implementing provisions.

(7) The obligations connected with marketing authorisations granted in accordance with Regulation (EC) No 726/2004 falling within the scope of this Regulation should be enforceable by means of two types of financial penalties: fines and periodic penalty payments. Maximum amounts for both categories should be established.

(8) The decision to initiate an infringement procedure under this Regulation should be taken by the Agency, which should first inform the Commission and the Member States. In the course of an inquiry, the Agency should be empowered to require such information to be supplied as is necessary to detect any infringement. It should also be able to rely on the cooperation of national competent authorities. Any supervisory powers entrusted to the Agency by Community law as regards marketing authorisations for medicinal products granted in accordance with Regulation (EC) No 726/2004 may be used by it in the course of the investigation of an infringement.

(9) The decisions by the Commission imposing penalties should be based on the inquiry by the Agency, the observations of the marketing authorisation holder subject to the infringement procedure and, where appropriate, other information submitted to it. Any supervisory powers entrusted to the Commission by Community law as regards marketing authorisations for medicinal products granted in accordance with Regulation (EC) No 726/2004 may be used by it in the course of the decision-making stage of an infringement procedure.

(10) It is appropriate that decisions imposing penalties be based exclusively on objections on which the marketing authorisation holder concerned has been able to comment.

***Changes to legislation:** There are outstanding changes not yet made to Commission Regulation (EC) No 658/2007. Any changes that have already been made to the legislation appear in the content and are referenced with annotations. (See end of Document for details) View outstanding changes*

(11) The penalties imposed should be effective, proportionate and dissuasive, having regard to the circumstances of the specific case.

(12) It appears appropriate to provide for a specific procedure in cases where the Commission intends to impose a fine for failure by a marketing authorisation holder subject to an infringement procedure to comply with a request for information from the Agency or the Commission.

(13) When carrying out an infringement procedure, the Agency and the Commission must ensure the respect of the rights of defence and of the principle of confidentiality in accordance with the general principles of law, and the case-law of the Court of Justice of the European Communities. In particular, the marketing authorisation holder subject to the infringement procedure should have the right to be heard by the Agency during the inquiry stage and by the Commission once it has been notified a statement of objections, as well as to access the file compiled by the Agency and the Commission. While the Commission should be entitled to compel marketing authorisation holders to provide the necessary information and documents relating to a presumed infringement, the right to silence in situations where the holder would be compelled to provide answers which may involve an admission on its part of the existence of an infringement, as developed by the Court of Justice, should also be respected.

(14) For the purposes of ensuring legal certainty in the conduct of the infringement procedure, it is necessary to lay down detailed rules for the computation of time-limits and limitation periods for the imposition and enforcement of penalties.

(15) Decisions imposing penalties are to be enforced in accordance with Article 256 of the Treaty and are subject to review by the Court of Justice.

(16) This Regulation respects the fundamental rights and observes the principles recognised in particular by the Charter of Fundamental Rights of the European Union.

(17) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee for Medicinal Products for Human Use and the Standing Committee for Veterinary Medicinal Products,

HAS ADOPTED THIS REGULATION:

CHAPTER I

GENERAL PROVISIONS

I[F1] Article 1

Subject matter and scope

This Regulation lays down rules concerning the application of financial penalties to the holders of marketing authorisations, granted under Regulation (EC) No 726/2004, in respect of infringements of the following obligations, in cases where the infringement concerned may have significant public health implications in the Union, or where it has

Changes to legislation: *There are outstanding changes not yet made to Commission Regulation (EC) No 658/2007. Any changes that have already been made to the legislation appear in the content and are referenced with annotations. (See end of Document for details) View outstanding changes*

a Union dimension by taking place or having its effects in more than one Member State, or where interests of the Union are involved:

(1) the obligation to submit complete and accurate particulars and documents in an application for marketing authorisation under Regulation (EC) No 726/2004 submitted to the European Medicines Agency established by that Regulation, (hereinafter 'the Agency'), or in response to obligations laid down in that Regulation and Regulation (EC) No 1901/2006 to the extent that the infringement concerns a material particular;

(2) the obligation to comply with conditions or restrictions included in the marketing authorisation and concerning the supply or use of the medicinal product, as referred to in Article 9(4)(b), the second subparagraph of Article 10(1), Article 34(4)(c) and the second subparagraph of Article 35(1) of Regulation (EC) No 726/2004;

(3) the obligation to comply with conditions or restrictions included in the marketing authorisation with regard to the safe and effective use of the medicinal product as referred to in Article 9(4)(aa), (c), (ca), (cb) and (cc), Article 10(1), Article 34(4)(d) and Article 35(1) of Regulation (EC) No 726/2004 taking account of any deadlines set in accordance with the third subparagraph of Article 10(1) of Regulation (EC) No 726/2004;

(4) the obligation to introduce any necessary variation to the terms of the marketing authorisation to take account of technical and scientific progress and enable the medicinal products to be manufactured and checked by means of generally accepted scientific methods, as provided for in Article 16(1) and Article 41(1) of Regulation (EC) No 726/2004;

(5) the obligation to supply any new information which may entail a variation to the terms of the marketing authorisation, to notify any prohibition or restriction imposed by the competent authorities of any country in which the medicinal product is marketed, or to supply any information that may influence the evaluation of the risks and benefits of the product, as provided for in Article 16(2) and Article 41(4) of Regulation (EC) No 726/2004;

(6) the obligation to keep product information up to date with current scientific knowledge, including the conclusions of the assessment and recommendations made public on the European medicines web-portal, as provided for in Article 16(3) of Regulation (EC) No 726/2004;

(7) **[**[X1]the obligation to provide, at the request of the Agency, any data demonstrating that the risk-benefit balance remains favourable, as provided for in Articles 16(3a) and 41(4) of Regulation (EC) No 726/2004;**]**

(8) the obligation to place the medicinal product on the market in accordance with the content of the summary of the product characteristics and the labelling and package leaflet as contained in the marketing authorisation;

(9) the obligation to comply with the conditions referred to in Article 14(7) and (8) of Regulation (EC) No 726/2004 or to introduce the specific procedures referred to in Article 39(7) of Regulation (EC) No 726/2004;

(10) the obligation to notify the Agency of the dates of actual marketing and of the date when the product ceases to be on the market, and to provide to the Agency data relating to the volume of sales and the volume of prescriptions of the product, as provided in Article 13(4) and Article 38(4) of Regulation (EC) No 726/2004;

***Changes to legislation:** There are outstanding changes not yet made to Commission Regulation (EC) No 658/2007. Any changes that have already been made to the legislation appear in the content and are referenced with annotations. (See end of Document for details) View outstanding changes*

(11) the obligation to operate a comprehensive pharmacovigilance system for the fulfilment of pharmacovigilance tasks, including the operation of a quality system, maintenance of a pharmacovigilance system master file and performance of regular audits, in accordance with Article 21 of Regulation (EC) No 726/2004 read together with Article 104 of Directive 2001/83/EC;

(12) **[**[X1]the obligation to submit, at the request of the Agency, a copy of the pharmacovigilance system master file, as provided for in Article 16(3a) of Regulation (EC) No 726/2004;**]**

(13) the obligation to operate a risk management system as provided for in Article 14a and Article 21(2) of Regulation (EC) No 726/2004 read together with Article 104(3) of Directive 2001/83/EC and Article 34(2) of Regulation (EC) No 1901/2006;

(14) the obligation to record and report suspected adverse reactions for medicinal products for human use, in accordance with Article 28(1) of Regulation (EC) No 726/2004 read together with Article 107 of Directive 2001/83/EC;

(15) the obligation to submit periodic safety update reports, in accordance with Article 28(2) of Regulation (EC) No 726/2004 read together with Article 107b of Directive 2001/83/EC;

(16) the obligation to conduct post-marketing studies, including post-authorisation safety studies and post-authorisation efficacy studies, and to submit them for review, as provided for in Article 10a of Regulation (EC) No 726/2004 and Article 34(2) of Regulation (EC) No 1901/2006;

(17) the obligation to record and report all suspected serious adverse reactions and adverse human reactions to a veterinary medicinal product as well as all suspected serious unexpected adverse reactions and human adverse reactions or suspected transmission of infectious agents, as provided for in Article 49(1) and (2) of Regulation (EC) No 726/2004;

(18) the obligation to record in detail all suspected adverse reactions and to submit these records in the form of periodic safety update reports, as provided for in Article 49(3) of Regulation (EC) No 726/2004;

(19) the obligation to notify the Agency prior or simultaneously to any communication of information on pharmacovigilance concerns to the general public, as provided for in Article 49(5) of Regulation (EC) No 726/2004;

(20) the obligation to collate and assess specific pharmacovigilance data, as provided for in the fourth paragraph of Article 51 of Regulation (EC) No 726/2004;

(21) the obligation to have permanently and continuously at disposal an appropriately qualified person responsible for pharmacovigilance, as provided for in Article 48 of Regulation (EC) No 726/2004;

(22) the obligation to detect residues in the case of veterinary medicinal products, as provided for in Article 41(2) and (3) of Regulation (EC) No 726/2004;

(23) the obligation to ensure that public announcements relating to information on pharmacovigilance concerns are presented objectively and are not misleading and to notify them to the Agency, as provided for in Article 22 of Regulation (EC) No 726/2004 read together with Article 106a(1) of Directive 2001/83/EC;