# Commission Regulation (EU) No 488/2012 of 8 June 2012 amending Regulation (EC) No 658/2007 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 (EU) No 488/2012

## of 8 June 2012

## amending Regulation (EC) No 658/2007 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 EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

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,

Having regard to Regulation (EC) No 1901/2006 of the European Parliament and of the Council of 12 December 2006 on medicinal products for paediatric use and amending Regulation (EEC) No 1768/92, Directive 2001/20/EC, Directive 2001/83/EC and Regulation (EC) No 726/2004[(2)], and in particular Article 49(3) thereof,

Whereas:

(1) Regulation (EU) No 1235/2010 of the European Parliament and of the Council[(3)] amended Regulation (EC) No 726/2004 as regards pharmacovigilance of medicinal products for human use in order to strengthen and rationalise the monitoring of the safety of medicines that have been placed on the market in the Union. The provisions of Regulation (EC) No 726/2004 are complemented by 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[(4)] which has been amended by Directive 2010/84/EU of the European Parliament and of the Council[(5)] as regards pharmacovigilance. In order to ensure the enforcement of the obligations relating to pharmacovigilance introduced by Regulation (EU) No 1235/2010 and Directive 2010/84/EU, it is necessary to adapt 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[(6)] so that any infringement of those obligations may be subject to the financial penalties provided for in Regulation (EC) No 658/2007.

(2) Regulation (EC) No 1901/2006, as amended by Regulation (EC) No 1902/2006[(7)], provides that the Commission may impose financial penalties for infringement of its

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provisions or the implementing measures adopted pursuant to it in relation to medicinal products authorised through the procedure laid down in Regulation (EC) No 726/2004. It also empowers the Commission to adopt measures concerning the maximum amounts of those penalties and the conditions and methods for their collection. Since Regulation (EC) No 658/2007 concerns financial penalties for infringement of certain obligations in connection with marketing authorisations granted under Regulation (EC) No 726/2004, it is appropriate, for reasons of consistency, to include in the scope of Regulation (EC) No 658/2007 the obligations provided for in Regulation (EC) No 1901/2006 whose infringement may give rise to financial penalties under that same Regulation.

(3) In view of the harmonised application of the obligations laid down in connection with marketing authorisations granted under Regulation (EC) No 726/2004 and of the need to ensure the effectiveness of those obligations, the interests of the Union are involved where those obligations are infringed. Moreover, pharmacovigilance rules are necessary for the protection of public health in order to prevent, detect and assess adverse reactions to medicinal products for human use placed on the Union market, as the full safety profile of medicinal products for human use can be known only after they have been placed on the market.

(4) Infringements in relation to veterinary medicinal products are not concerned by Regulation (EC) No 1901/2006 or the amendments as regards pharmacovigilance. The scope of Regulation (EC) No 658/2007 therefore does not need to be modified in this respect. However, in order to ensure consistency with the amended provisions and to improve clarity, it is appropriate to restructure certain provisions concerning veterinary medicinal products without altering the substance.

(5) The amended provisions shall apply as of the same date as the amendments by Regulation (EU) No 1235/2010 as regards pharmacovigilance.

(6) Regulation (EC) No 658/2007 should therefore be amended accordingly.

(7) 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:

*Article 1*

Article 1 of Regulation (EC) No 658/2007 is replaced by the following:

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

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(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;

(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