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from: Secretary-General of the European Commission,
signed by Mr Jordi AYET PUIGARNAU, Director

date of receipt: 7 February 2012

to: General Secretariat of the Council

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Subject: **Draft COMMISSION REGULATION (EU) No .../.. of XXX** 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

Delegations will find attached Commission document D018675/02.

Encl.: D018675/02



EUROPEAN COMMISSION

Brussels, XXX
[...](2011) XXX draft
D018675/02

COMMISSION REGULATION (EU) No .../..

of XXX

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 .../..

of XXX

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 Agency¹, 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 726/2004², and in particular Article 49(3) thereof,

Whereas:

- (1) Regulation (EU) No 1235/2010 of the European Parliament and of the Council³ 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 use⁴ which has been amended by Directive 2010/84/EU⁵ 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 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 Council⁶ so that any infringement of those obligations may be subject to the financial penalties provided for in Regulation (EC) No 658/2007.

¹ OJ L 136, 30.4.2004, p. 1.

² OJ L 378, 27.12.2006, p. 1.

³ OJ L 348, 31.12.2010, p. 1.

⁴ OJ L 311, 28.11.2001, p. 67.

⁵ OJ L 348, 31.12.2010, p. 74.

⁶ OJ L 155, 15.6.2007, p. 10.

- (2) Regulation (EC) No 1901/2006, as amended by Regulation (EC) No 1902/2006⁷, provides that the Commission may impose financial penalties for infringement of its 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) 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) 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:

⁷ OJ L 378, 27.12.2006, p. 20.

"Article 1

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:

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), (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. the obligation to provide, at the request of the Agency, any data demonstrating that the risk-benefit balance remains favourable, as provided for in Article 16(4) and Article 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 accordance with Article 21 of Regulation (EC) No 726/2004 read together with Article 104 of Directive 2001/83/EC;
12. the obligation to submit, at the request of the Agency, a copy of the pharmacovigilance system master file, as provided for in Article 16(4) 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;
24. the obligation to comply with the time-limits for initiating or completing measures specified in the Agency's decision on deferral following the initial marketing authorisation of the medicinal product concerned and in accordance with the definitive opinion referred to in Article 25(5) of Regulation (EC) 1901/2006;
25. the obligation to place the medicinal product on the market within two years of the date on which the paediatric indication is authorised, as provided for in Article 33 of Regulation (EC) No 1901/2006;
26. the obligation to transfer the marketing authorisation or to allow a third party to use documentation contained in the marketing authorisation dossier, as provided for in the first subparagraph of Article 35 of Regulation (EC) No 1901/2006;
27. the obligation to submit paediatric studies to the Agency, including the obligation to enter information into the European database on third country clinical trials, as provided for in Article 41(1) and (2), Article 45(1) and Article 46(1) of Regulation (EC) 1901/2006;
28. the obligation to submit an annual report to the Agency as provided for in Article 34(4) of Regulation (EC) No 1901/2006 and to inform the Agency in accordance with the second subparagraph of Article 35 of that Regulation."

Article 2

For infringements that started before 2 July 2012, this Regulation shall apply to the part of the infringement that takes place after that date.

Article 3

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

It shall apply from 2 July 2012.

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

Done at Brussels,

For the Commission
José Manuel BARROSO
The President