Ref. Ares(2011)407433 - 12/04/2011

EUROPEAN COMMISSION
HEALTH AND CONSUMERS DIRECTORATE-GENERAL

Public Health and Risk Assessment
Pharmaceuticals

Brussels,
SANCO/C.8/FS/cg/a.5.001(2011)298037

AMENDMENT OF COMMISSION REGULATION (EC) NO 658/2007 CONCERNING FINANCIAL PENALTIES FOR INFRINGEMENTS COMMITTED BY MARKETING AUTHORISATION HOLDERS OF CENTRALLY AUTHORISED MEDICINAL PRODUCTS

THE CONCEPT PAPER SUBMITTED FOR PUBLIC CONSULTATION

A. INTRODUCTION

The European Commission is planning to put forward, a limited and targeted amendment to Commission Regulation (EC) No 658/2007[1] concerning financial penalties for certain obligations in connection with centrally authorised medicinal products in the human and in the veterinary sector.

The purpose of this amendment is two-fold. Firstly, to fulfil the mandate given by the legislator in the Paediatric Regulation (EC) No 1901/2006 and secondly, to adapt Commission Regulation (EC) No 658/2007 to the modifications introduced by the new pharmacovigilance legislation in the human sector.

Article 49 of the Paediatric Regulation (EC) No 1901/2006 empowers the Commission to impose financial penalties for infringement of the provisions of that Regulation or the implementing measures adopted pursuant to it. The maximum amounts as well as the conditions and methods for collection of these penalties shall be laid down in a Commission Regulation.

As Commission Regulation (EC) No 658/2007 already provides a framework for financial penalties against marketing authorisation holders of centrally authorised products, the mandate of Article 49 may best fulfilled by extending the scope of the existing Regulation.

At the same time, due to the new pharmacovigilance regime introduced by Regulation (EU) No 1235/2010 and Directive 2010/84/EU the current system was substantively modified with the aim of improving the legal framework of the European Union on the pharmacovigilance of medicinal products for human use. Those amendments have to be reflected in the subject-matter and scope of

[1] OJ L 155, 15.6.2007, p. 10.

Commission Regulation (EC) No 658/2007 in order to allow its application once the new rules enter into force in July 2012.

The purpose of this consultation paper is to describe the scope of the amendments the Commission is currently considering and to seek views and feedback from stakeholders on those issues.

This concept paper is now being put out for public consultation. Replies or comments should be submitted by 30 May 2011 at the latest. Practical information about the consultation is set out at the end of the paper.

B. SCOPE OF THE CONSULTATION

The existing Commission Regulation (EC) No 658/2007 sets out a common framework for imposing financial penalties in order to ensure the enforcement of obligations connected with marketing authorisations for centrally authorised products. Those rules outline amongst other things the details of the infringement procedure including the inquiry to be conducted by the European Medicines Agency (EMA) to establish the facts. They take into account due process and the rights of defence of any marketing authorisation holder concerned by such procedure.

In order to incorporate infringements of the Paediatric Regulation as well as the amendments introduced by the pharmacovigilance provisions, it is not necessary to modify the substantive procedural provisions of the exiting Commission Regulation. Instead, it is sufficient to adapt the scope of the Regulation to the legislative changes since its adoption.

As a consequence, the Commission has currently no intention to modify the principal framework established by Regulation (EC) No 658/2007, but to simply adjust its scope to the requirements of the Paediatric Regulation and the new pharmacovigilance legislation. It means that amendments will basically concern Article 1 of Commission Regulation (EC) No 658/2007.

C. CONSULTATION TOPICS

1. INCORPORATING THE NEW PHARMACOVIGLANCE RULES AND THE PAEDIATRIC REGULATION

Article 1 of Commission Regulation (EC) No 658/2007 lists obligation in respect of which an infringement may lead to the initiation of an infringement procedure under the terms of the Regulation. Neither the Paediatric Regulation nor the new pharmacovigilance provisions are covered by the existing list of obligations.

1.1. Paediatric Regulation

The Paediatric Regulation introduces a system of obligations and rewards to stimulate research as regards the use of medicinal products in the paediatric population and to increase the availability of authorised products that are suitably adapted to the needs of children. According to its Article 49(3) the Commission may impose financial penalties for infringements of the

provisions of the Paediatric Regulation, as far as it concerns products that are centrally authorised.

The following provisions and obligations could be covered by the infringement provisions:

- compliance with the time-limits for initiating or completing measures specified in a deferral decision, as referred to in Article 21(1) second subparagraph of Regulation (EC) 1901/2006;

- placing the product on the market within two years of the date on which the paediatric indication is authorised, as referred to in Article 33 of Regulation (EC) No 1901/2006;

- transferring the marketing authorisation or allowing a third party to use documentation contained in the marketing authorisation dossier, as referred to in the first subparagraph of Article 35 of Regulation (EC) No 1901/2006;

- submitting paediatric studies to the Agency, as referred to in Article 41(2), Article 45(1) and Article 46(1) of Regulation (EC) 1901/2006;

- information and reporting obligations as referred to in Article 34(2), second subparagraph, Article 34(4), Article 35, second subparagraph of Regulation (EC) No 1901/2006;

- operating a risk management system, as referred to in Article 34(2) of Regulation (EC) No 1901/2006;

- performing post-marketing studies and submitting them for review, as referred to in Article 34(2) of Regulation (EC) No 1901/2006.

Consultation item no. 1: Do you agree with this list? Please comment.

1.2. New pharmacovigilance legislation

The new pharmacovigilance legislation introduced by Regulation (EU) No 1235/2010 and Directive 2010/84/EU strengthens and rationalises the current system for monitoring the safety of medicines on the European market. It introduces new procedures, new obligations and modifies many particularities of the existing system. Those changes are covered only to a limited extent by the current scope of Commission Regulation (EC) No 658/2007. It is therefore necessary to adapt the scope of the Regulation with the following obligations that could be covered by the infringement provisions:

- operating a comprehensive pharmacovigilance system for the fulfilment of pharmacovigilance tasks, including the maintenance of a pharmacovigilance system master file, as referred to in Article 104 of Directive 2001/83/EC and Article 16(4) and Article 21 of Regulation (EC) No 726/2004;

- submitting at the request of the Agency a copy of the pharmacovigilance system master file, as referred to in Article 16(4) of Regulation (EC) No 726/2004;

- operating a risk management system, as referred to in Article 104 of Directive 2001/83/EC, Article 14a and Article 21(2) of Regulation (EC) No 726/2004;

- recording and reporting of suspected adverse reactions of human medicinal products, as referred to in Article 107 of Directive 2001/83/EC and Article 28(1) of Regulation (EC) No 726/2004;

- submitting periodic safety update reports, as referred to in Article 107b of Directive 2001/83/EC and Article 28(1) of Regulation (EC) No 726/2004;

- performing post-authorisation studies, including post-authorisation safety studies and post-authorisation efficacy studies, and submitting them for review, as referred to in Articles 9(4) and 10a of Regulation (EC) No 726/2004;

- communication of information relating to pharmacovigilance concerns to the general public, as referred to in Article 106a of Directive 2001/83/EC and Article 22 of Regulation (EC) No 726/2004;

Consultation item no. 2: Do you agree with this list? Please comment.

1.3. List of other obligations

The list of obligations whose infringement could lead to the imposition of a penalty pursuant to Article 1 of Regulation (EC) No 658/2007 have been reviewed to determine whether it needs any adaptation as a result of changes to EU legislation, some minor modifications in order to mirror editorial changes or the re-numbering of Articles due to the new pharmacovigilance rules should be introduced:

- 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 as specified in accordance with Article 10(1) third subparagraph of Regulation (EC) No 726/2004;

- recording and reporting in the case of veterinary medicinal products of suspected serious adverse reactions and human adverse reactions, suspected serious unexpected adverse reactions and human adverse reactions and transmission of infectious agents, as referred to in Articles 49(1) and 49(2) of Regulation (EC) No 726/2004;

Consultation item no. 3: Is the above catalogue complete?

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Stakeholders are invited to comment on this consultation paper, and especially on the boxed text, by 10 June 2011 at the latest. Responses should be sent preferably by e-mail to sanco-pharmaceuticals@ec.europa.eu, or by post to Directorate-General for Health and Consumers, Unit SANCO/C/8, BE-1049 Brussels. The subject of the letter/e-mail should refer to "Public Consultation on Commission Regulation (EC) 658/2007".

When sending your comments and responses, you should state whether you are a stakeholder association or a private individual. If you represent an association, please indicate clearly what type of association this is (patient, sponsor, investigator, hospital, IMP manufacturer, insurance company, etc.). If you represent a company, please state whether it falls within the EU definition of a small and medium-sized enterprise (i.e. less than €50 million annual turnover and fewer than 250 employees).

All comments and responses will be made publicly available on the 'public health' website[2] once the consultation period is over. If you do not wish your contribution to be made public please indicate this clearly and specifically in the documentation you send us (i.e. not just in the covering letter or e-mail). In this case, only an indication of the contributor will be disclosed.

Professional organisations are invited to register in the Union's Register for Interest Representatives (http://ec.europa.eu/transparency/regrin/) set up as part of the European Transparency Initiative to provide the Commission and the public at large with information about the objectives, funding and structures of interest representatives.

[2] http://ec.europa.eu/health/human-use/index_en.htm.