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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

(OJ L 155, 15.6.2007, p. 10)

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**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 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.

⁽¹⁾ OJ L 136, 30.4.2004, p. 1. Regulation as amended by Regulation (EC) No 1901/2006 (OJ L 378, 27.12.2006, p. 1).

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- (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 ⁽¹⁾ 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 ⁽²⁾ 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.

⁽¹⁾ OJ L 311, 28.11.2001, p. 1. Directive as amended by Directive 2004/28/EC (OJ L 136, 30.4.2004, p. 58).

⁽²⁾ OJ L 311, 28.11.2001, p. 67. Directive as last amended by Regulation (EC) No 1901/2006.

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- (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

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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) ► **C1** 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;

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- (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) ► **C1** 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;

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- (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) No 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) No 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.

▼ B*Article 2***Complementarity of procedures**

For the purposes of the initiation and conduct of the infringement procedure provided for in Chapter II, the Agency and the Commission shall take into account any infringement procedure by a Member State against the same marketing authorisation holder and based on the same legal grounds and the same facts.

*Article 3***Cooperation by the competent authorities of the Member States**

1. The competent authorities of the Member States shall cooperate with the Agency and the Commission to enable them to carry out their duties under this Regulation.

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2. Information provided by the national competent authorities in response to a request from the Agency or the Commission under this Regulation shall be used by the Agency and the Commission only for the following purposes:

- (a) as evidence for the purposes of applying this Regulation;
- (b) for carrying out the tasks entrusted to them for the authorisation and supervision of medicinal products under Regulation (EC) No 726/2004.

*Article 4***Burden of proof**

In any infringement procedure under this Regulation, the burden of proving an infringement shall rest on the Commission.

CHAPTER II

INFRINGEMENT PROCEDURE

SECTION 1

Inquiry

Subsection 1

Initiation of procedure*Article 5***Initiation of the infringement procedure**

1. The Agency may initiate the infringement procedure on its own initiative or following a request from the Commission or a Member State.

The Agency shall inform the Commission that it intends to initiate the infringement procedure.

2. The Agency shall initiate the infringement procedure only after informing the Member States.

*Article 6***Request for information**

Prior to initiating an infringement procedure, the Agency may request from the marketing authorisation holder concerned any information relating to the alleged infringement.

The Agency shall state the purpose of the request and the fact that it is made under this Regulation, and indicate a time-limit for the submission of the reply by the marketing authorisation holder, which shall be at least four weeks.

Where the request is in response to a request from a Member State under Article 5(1), that Member State shall be informed by the Agency.

▼B*Article 7***Notification**

The Agency shall send written notification of the initiation of an infringement procedure to the marketing authorisation holder concerned, to the Member States and to the Commission.

The notification shall set out the allegations against the marketing authorisation holder, specifying the provision allegedly infringed, and the evidence on which those allegations are founded.

It shall give notice to the marketing authorisation holder that fines or periodic penalty payments may be imposed.

Subsection 2**Measures of inquiry***Article 8***Requests by the Agency**

1. The Agency may request the marketing authorisation holder to provide written or oral explanations, or particulars or documents.

Requests shall be addressed in writing to the marketing authorisation holder. The Agency shall state the legal basis and the purpose of the request, fix a time-limit by which the information is to be provided, which shall be at least four weeks, and inform the marketing authorisation holder of the fines provided for in Article 19(1)(a) and (b) for failing to comply with the request or for supplying incorrect or misleading information.

2. The Agency may request national competent authorities to cooperate in the investigation in the following ways:

- (a) by performing any of the tasks entrusted to the supervisory authorities by Articles 19(1) and 44(1) of Regulation (EC) No 726/2004;
- (b) by performing inspections or other supervisory measures in accordance with Articles 111 to 115 of Directive 2001/83/EC and Articles 80, 81 and 82 of Directive 2001/82/EC.

Requests shall be addressed in writing and shall state the legal basis and the purpose of the request. The time-limit for the submission of the reply or the conduct of the measure of inquiry shall be determined by agreement between the Agency and the national competent authority to which the request is addressed, having regard to the specific circumstances of the case.

3. The Agency may ask any natural or legal persons to provide information relating to the alleged infringement.

Requests shall be addressed in writing and shall state the legal basis and the purpose of the request, and shall fix a time-limit by which the information should be provided, which shall be at least four weeks.

▼B*Article 9***Right to be heard**

Before adoption of the report provided for in Article 10, the Agency shall invite the marketing authorisation holder to submit written observations.

It shall do so in writing, indicating a time-limit for the submission of those observations, which shall be at least four weeks.

Subsection 3

Report*Article 10***Content and time-limits**

1. The Agency shall provide the Commission, the Member States and the marketing authorisation holder with a report summarising its findings in the light of the inquiry carried out in accordance with this Section.
2. Where the Agency considers that the marketing authorisation holder has committed an infringement as referred to in Article 1, the report shall also include an assessment of the circumstances of the specific case in accordance with the criteria set out in Article 18(2) and a request to the Commission for application of financial penalties.
3. The Agency shall adopt its report no later than 18 months after notification of initiation of the procedure in accordance with Article 7 or one year after notification by the Commission of the return of the file in accordance with Article 15.

SECTION 2

Decision-making stage

Subsection 1

Procedure*Article 11***Statement of objections**

1. Where, following a request from the Agency pursuant to Article 10(2), the Commission decides to continue with the infringement procedure, it shall notify in writing to the marketing authorisation holder a statement of objections containing the following:
 - (a) the allegations against the marketing authorisation holder, including a precise indication of which provision has allegedly been infringed, and the evidence on which those allegations are founded;
 - (b) notice that fines or periodic penalty payments may be imposed.
2. Where, within 18 months of receiving the request from the Agency, the Commission has not notified a statement of objections, it shall provide the marketing authorisation holder with an explanatory statement.

▼B*Article 12***Right to reply**

1. When notifying the statement of objections, the Commission shall set a time-limit within which the marketing authorisation holder may submit to the Commission his written observations on the statement of objections.

That time-limit shall be at least four weeks.

The Commission shall not be obliged to take into account written observations received after the expiry of that time-limit.

2. The marketing authorisation holder may annex to his written observations, statements from other persons who may corroborate any aspect of those written observations.

*Article 13***Oral hearing**

1. Where the marketing authorisation holder so requests in his written observations, the Commission shall give him an opportunity to develop his arguments at an oral hearing.

The date for the oral hearing shall be set by the Commission.

2. Where necessary, the Commission may invite the national competent authorities or any other persons to take part in the oral hearing.

3. The oral hearing shall not be public. Each person may be heard separately or in the presence of other persons invited to attend, having regard to the legitimate interest of marketing authorisation holders and other persons in the protection of their business secrets and other confidential information.

*Article 14***Requests for information**

1. After receipt of a request from the Agency pursuant to Article 10(2) and before adoption of the decision referred to in Article 16, the Commission may at any time request the marketing authorisation holder to provide written or oral explanations, or particulars or documents, relating to the alleged infringement.

Requests shall be addressed in writing to the marketing authorisation holder. The Commission shall state the legal basis and the purpose of the request, fix a time-limit by which the information is to be provided, which shall be at least four weeks, and inform the marketing authorisation holder of the fines provided for in Article 19(1)(c) and (d) for failing to comply with the request or supplying incorrect or misleading information.

2. The Commission may request the Agency, the national competent authorities or any other natural or legal persons to provide information relating to the alleged infringement.

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Requests shall be addressed in writing and shall state the legal basis and the purpose of the request. Where the request is addressed to the Agency or a national competent authority, the time-limit by which the information is to be provided shall be determined by the Commission after consultation of the Agency or the national competent authority to which the request is addressed, having regard to the specific circumstances of the case. Where the request is addressed to other natural or legal persons, it shall fix a time-limit by which the information is to be provided, which shall be at least four weeks.

*Article 15***New period of inquiry**

1. Where, having regard to the report of the Agency, the observations of the marketing authorisation holder and, as the case may be, other information submitted to it, the Commission considers that additional information is needed in order to continue the procedure, it may return the case-file to the Agency for a new period of inquiry.

The Commission shall clearly indicate to the Agency the points of fact which it should further examine and, if appropriate, suggest possible measures of inquiry to that effect.

2. Subsections 2 and 3 of Section 1 shall apply to the conduct of the new period of inquiry.

Subsection 2**Decision and financial penalties***Article 16***Forms of financial penalty and maximum amounts**

1. Where, following the procedure provided for in Subsection 1, the Commission finds that the marketing authorisation holder has committed, intentionally or negligently, an infringement as referred to in Article 1, it may adopt a decision imposing a fine not exceeding 5 % of the holder's Community turnover in the preceding business year.

2. Where the marketing authorisation holder has not terminated the infringement, the Commission may, in the decision referred to in paragraph 1, impose periodic penalty payments per day not exceeding 2,5 % of the holder's average daily Community turnover in the preceding business year.

Periodic penalty payments may be imposed for a period running from the date of notification of that decision until the infringement has been brought to an end.

3. For the purposes of paragraphs 1 and 2, the preceding business year refers to the business year preceding the date of the decision referred to in paragraph 1.

*Article 17***Decision**

1. The decision provided for in Article 16 shall be based exclusively on grounds on which the marketing authorisation holder has been able to comment.

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2. The Commission shall inform the marketing authorisation holder of the judicial remedies available.
3. The Commission shall communicate the adoption of the decision to the Agency and to the Member States.
4. When publishing details of its decision in accordance with the second subparagraph of Article 84(3) of Regulation (EC) No 726/2004, the Commission shall have regard to the legitimate interest of marketing authorisation holders and other persons in the protection of their business secrets.

*Article 18***Principles governing the application and quantification of financial penalties**

1. In determining whether to impose a financial penalty and in determining the appropriate financial penalty, the Commission shall be guided by the principles of effectiveness, proportionality and dissuasiveness.
2. In each case, the Commission shall take into consideration, where relevant, the following circumstances:
 - (a) the seriousness and the effects of the infringement, and, in particular, the following:
 - (i) the way in which the infringement adversely affects the rights, safety or well-being of patients;
 - (ii) its effects on animal health and welfare and the impact on animal owners;
 - (iii) whether it poses or could pose a risk to public health, animal health or the environment;
 - (iv) the gravity of the infringement in relation to public health, animal health and the environment;
 - (b) on the one hand, the good faith of the marketing authorisation holder in the interpretation and fulfilment of the obligations connected with marketing authorisations granted in accordance with Regulation (EC) No 726/2004 or, on the other hand, any evidence of wilful deceit on the part of the marketing authorisation holder;
 - (c) on the one hand, the degree of diligence and cooperation shown by the marketing authorisation holder in the detection of the infringement and the application of corrective action, or during the course of the infringement procedure or, on the other hand, any obstruction by the marketing authorisation holder of the detection of an infringement and the conduct of an infringement procedure, or any non-compliance by the marketing authorisation holder with requests made by the Agency, the Commission or a national competent authority in application of this Regulation;
 - (d) the turnover of the medicinal product concerned;
 - (e) the need to adopt provisional measures by the Commission or urgent action by a Member State in accordance with Articles 20 or 45 of Regulation (EC) No 726/2004 as a result of an infringement;
 - (f) the repetition, frequency or duration of the infringement by that marketing authorisation holder;

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- (g) prior sanctions, including penalties, imposed on the same marketing authorisation holder.

3. In determining the amount of the financial penalty, the Commission shall take into account any penalties already imposed on the marketing authorisation holder at national level on the basis of the same legal grounds and the same facts.

*SECTION 3**Non-cooperation**Article 19***Financial penalties**

1. The Commission may by decision impose on marketing authorisation holders fines not exceeding 0,5 % of their Community turnover in the preceding business year where, intentionally or negligently:

- (a) they do not comply with a measure of inquiry adopted pursuant to Article 8(1);
- (b) they supply incorrect or misleading information in response to a measure of inquiry adopted pursuant to Article 8(1);
- (c) they do not comply with a request for information pursuant to Article 14;
- (d) they supply incorrect or misleading information in response to a request for information pursuant to Article 14.

2. Where the non-cooperation of the marketing authorisation holder continues, the Commission may, in the decision referred to in paragraph 1, impose periodic penalty payments per day not exceeding 0,5 % of the holder's average daily Community turnover in the preceding business year.

Periodic penalty payments may be imposed for a period running from the date of notification of that decision until the non-cooperation has ceased.

3. For the purposes of paragraphs 1 and 2, the preceding business year refers to the business year preceding the date of the decision referred to in paragraph 1.

*Article 20***Procedure**

When the Commission intends to adopt a decision as referred to in Article 19(1), it shall first notify in writing the marketing authorisation holder, setting a time-limit within which the marketing authorisation holder may submit to the Commission his written observations. That time-limit shall be at least four weeks.

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The Commission shall not be obliged to take into account written observations received after the expiry of that time-limit.

CHAPTER III

ACCESS TO THE FILE, REPRESENTATION, CONFIDENTIALITY AND TEMPORAL PROVISIONS*Article 21***Access to the file**

Following notification under Article 7, the marketing authorisation holder shall have the right, on request, to access the documents and other materials compiled by the Agency and the Commission which serve as evidence of an alleged infringement.

Documents obtained through access to the file shall be used only for the purposes of judicial or administrative proceedings for the application of this Regulation.

*Article 22***Legal representation**

The marketing authorisation holder shall have the right to legal representation during the infringement procedure.

*Article 23***Confidentiality and professional secrecy**

1. Without prejudice to the exchange and to the use of information foreseen in Article 3, an infringement procedure shall be carried out subject to the principles of confidentiality and of professional secrecy. The Agency and the Commission, their officials, servants and other persons working under their supervision shall not disclose information acquired or exchanged by them pursuant to this Regulation and of the kind covered by the obligation of professional secrecy and confidentiality.

2. Without prejudice to the right to access the case-file, the marketing authorisation holder shall not have access to business secrets, confidential information or internal documents held by the Agency, the Commission or a Member State.

3. Any person who submits information or observations pursuant to Articles 8, 9, 12 or 14 shall clearly identify any material considered to be confidential, giving reasons, and provide a separate non-confidential version by the date set by the Agency or the Commission.

4. Without prejudice to paragraph 3, the Agency and the Commission may require persons who submit information or observations pursuant to this Regulation to identify the documents or parts of documents which they consider to contain business secrets or other confidential information belonging to them.

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The Agency and the Commission may also require marketing authorisation holders and other persons to identify any part of a report by the Agency, of a statement of objections or of a decision adopted by the Commission which in their view contains business secrets.

The Agency and Commission may set a time-limit within which the marketing authorisation holder and other persons are to:

- (a) substantiate their claim for confidentiality with regard to each individual document or part of document;
- (b) provide the Commission with a non-confidential version of the documents, in which the confidential passages are deleted;
- (c) provide a concise description of each piece of deleted information.

The time-limit referred to in the third subparagraph shall be at least two weeks.

5. If the marketing authorisation holder or other persons fail to comply with paragraphs 3 and 4, the Commission may assume that the information or observations concerned do not contain confidential information.

*Article 24***Application of time-limits**

1. The time-limits laid down in this Regulation shall run from the day following receipt of a communication or delivery thereof by hand.

In the case of a communication from the marketing authorisation holder, it shall be sufficient for the purposes of the relevant time-limits for the communication to have been dispatched by registered post before the relevant time-limit has expired.

2. Where the time-limit falls to expire on a Saturday, Sunday or public holiday, it shall be extended up to the end of the following working day.

3. In setting the time-limits provided for in Articles 6, 8(1), 12(1) and 14(1), the Agency and the Commission, as the case may be, shall have regard both to the time required for preparation of the submission and to the urgency of the case.

4. Where appropriate and upon reasoned request made before the expiry of the original time-limit, time-limits may be extended.

*Article 25***Limitation periods for the imposition of financial penalties**

1. The right of the Commission to adopt a decision imposing a financial penalty pursuant to Article 16 shall expire after five years.

In the case of the financial penalties provided for in Article 19, the right of the Commission to adopt a decision imposing such a penalty shall expire after three years.

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Time shall begin to run on the day on which the infringement is committed. However, in the case of continuing or repeated infringements, time shall begin to run on the day on which the infringement ceases.

2. Any action taken by the Agency or the Commission for the purpose of the investigation or infringement procedure shall interrupt the limitation periods laid down in paragraph 1. The limitation period shall be interrupted with effect from the date on which the action is notified to the marketing authorisation holder.

3. Each interruption shall start time running afresh. However, the limitation period shall expire at the latest on the day on which a period equal to twice the limitation period has elapsed without the Commission having imposed a financial penalty. The period shall be extended by the time during which limitation is suspended pursuant to paragraph 4.

4. The limitation period for the imposition of financial penalties shall be suspended for as long as the decision of the Commission is the subject of proceedings pending before the Court of Justice of the European Communities.

*Article 26***Limitation periods for the collection of financial penalties**

1. The right to start a recovery procedure shall expire one year after the decision pursuant to Article 16 or Article 19 has become final.

2. The limitation period for the recovery of financial penalties shall be interrupted by any action of the Commission or of a Member State, acting at the request of the Commission, designed to enforce payment of the penalty.

3. Each interruption shall start time running afresh.

4. The limitation period for the recovery of financial penalties shall be suspended for so long as:

- (a) time to pay is allowed;
- (b) enforcement of payment is suspended pursuant to a decision of the Court of Justice of the European Communities.

CHAPTER IV

FINAL PROVISIONS*Article 27***Transitional provision**

In the case of infringements which began before its entry into force, this Regulation shall apply to the part of the infringement which takes place after that date.

*Article 28***Entry into force**

This Regulation shall enter into force on the 20th day following its publication in the *Official Journal of the European Union*.

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