MINISTERIAL DECISION No. 11475 EFA 2388
(GG B' 1165/25.06.2008)

"Submission of an application with the OBI for a six-month extension of the duration of the supplementary protection certificate for paediatric pharmaceuticals"

THE MINISTERS
OF THE NATIONAL ECONOMY –
OF DEVELOPMENT –
AND OF HEALTH AND SOCIAL SOLIDARITY

Having taken into consideration:

1. The provisions of Article 1 and 2, para. 1 (g) and (i) of Law 1338/1983 'Implementation of Community law' (Government Gazette 34 A') as this was amended by Article 6, para. 1 of Law 1440/1984 'Participation of Greece in the capital, reserves, and provisions of the European Investment Bank, and in the capital of the European Coal and Steel Community and the EURATOM Supply Organisation' (Government Gazette 70 A'), in combination with the provisions of Article 1 of Law 1965/1991 (Government Gazette A 146).
2. Law 945/1979 on "Ratification of the Treaty of accession of Greece to the European Economic Community" (Government Gazette A 170/27.7.1979).
3. The provisions of Article 1 par 2 of Law 1733/1987 'Transfer of technology, inventions, and technological innovation, and setting up of an Atomic Energy Commission' (Government Gazette A 171/22.9.1987).
4. The provisions of the second Article of Law 2077/1992 'Ratification of the Treaty on the European Union and the respective protocols and declarations included in the final act" (Government Gazette A 136).
5. The provisions of Articles 11 and 12 of Presidential Decree 77/88 'Provisions on the implementation of the Convention on the granting of European patents', which was ratified by Law 1607/1987 (Government Gazette 33/A/25-2-1988).
6. Presidential Decree no. 248/89 "Organization of General Secretariat for Research and Technology" (Government Gazette A 116/10.5.1989), as amended by Presidential Decree no. 179/92 (Government Gazette A 81/26.5.1992), Presidential Decree no. 147/94 (Government Gazette A 99/4.7.1994) and Presidential Decree no. 128/97 (Government Gazette A 115/9.6.1997).
7. Presidential Decree no 27/1996 "Merger of the Ministries of Tourism, Industry, Energy and Technology and Commerce into the Ministry of Development" (Government Gazette A 19/1.2.1996) and Presidential Decree no. 122/2004 "Re-establishment of the Ministry of Tourism" (Government Gazette A 85/17.3.2004).
8. The provisions of article 90 of the Code ratified by the first article of Presidential Decree no. 63/2005 "Codification of Law on Government and Government Bodies" (Government Gazette A 98/22.4.2005).
9. Presidential decree no. 206/2007 "Appointment of Ministers and Deputy Ministers" (Government Gazette A 232/19.9.2007).
10. Regulation (EEC) 1768/92 of the Council of 18 June 1992 (EU No. L 182/1 of 2 July 1992).
11. 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 (EU no. L378/1 of 27 December 2006).
12. 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 (EU No. L 136, 30.04.2004).
13. 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 (EU no. L311, 28.11.2001) as amended of late with Directive 2004/27/EC (EU L 136, 30.4.2004).
14. The fact that no charge on the state budget is created by the provisions of the present decision.
15. The minutes of meeting no. 14/13.11.2007 of OBI's BoD, we have determined:

PART ONE

GENERAL PROVISIONS

Article 1
Purpose

The purpose of this decision is to determine the procedure for the granting of a six-month extension of the duration of the supplementary protection certificate referred to in Article 13 paragraphs 1 and 2 of the Regulation (EEC) 1768/1992 for paediatric pharmaceuticals as products that are protected by a supplementary protection certificate based on Regulation (EEC) no. 1768/1992 or the patent certificate that fulfils the pre-requisites for granting a supplementary protection certificate.

Article 2
Definitions

For the implementation of this decision, the following phrases shall have the following meanings:
a. “Regulation (EEC) 1768/92”: Regulation (EEC) 1768/92 of the Council of the European Union of 18 June 1992 'in relation to the introduction of a supplementary protection certificate for pharmaceuticals' (EU No. L 182/1 of 2 July 1992).
b. “Regulation (EC) no 1901/2006”: 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 (EU no. L378/1 of 27 December 2006).

c. “Regulation (EC) No 726/2004”: 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 (EU No. L 136, 30.04.2004).

d. “Directive 2001/83/EC”: 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 (EU no. L311, 28.11.2001) as amended lately with Directive 2004/27/EC (EU L 136, 30.4.2004).

e. “Ministerial Decision no. 14905/EFA 3058”: Ministerial Decision no. 14905/EFA 3058 regarding the submission of an application with the OBI for the granting of a supplementary protection certificate for pharmaceuticals (Government Gazette 1162 B of 30.12.1997).
f. “OBI”: the Industrial Property Organisation, which has its registered office in Athens (Article 1 of Law 1733/1987).
g. “Pharmaceutical”: any substance or compound which is prepared as having therapeutic or preventive properties within the meaning of Article 1, para 1 of Regulation (EEC) 1768/92.
h. “Patent”: the patent granted by the O.B.I. in accordance with Article 8 of Law 1733/87 (Government Gazette 171 A), or the European patent in force in Greece in accordance with Article 23 of Law 1733/87.
i. “Certificate”: the supplementary protection certificate, which is granted for pharmaceuticals from the OBI in accordance with the terms of Article 7 of Ministerial Decision no. 14905/EFA 3058.
j. “Marketing authorisation permit”: the marketing authorisation permit is issued for a pharmaceutical that is intended for human use, which exclusively covers therapeutic indications that are important for the paediatric population or its subtotal and which is issued in application of Regulation no. (EC) 1901/2006 and is governed by the provisions of Regulation (EC) no. 726/2004 or Directive 2001/83/EC.

PART TWO

BENEFICIARIES
APPLICATION PROCEDURE – APPLICATION CONTENT

Article 3
Right of application for extension

The right of applying for an extension of the duration of the supplementary protection certificate for pharmaceuticals, granted in accordance with Article 7 of Ministerial Decision no. 14905/EFA/3058, belongs to the certificate beneficiary as well as his general or special successors.

[Term (27), Regulation (EC) 1901/2006]

Article 4
Competent authority

The competent authority for the submission and approval of the extension for the duration of the certificate's validity shall be the Industrial Property Organisation (O.B.I.).
[Article 52 para. 4 a) Regulation (EC) 1901/2006]

Article 5
Application submission

1. For the extension of the duration of the protection certificate of Article 7 of the Ministerial Decision no. 14905/EFA/3058 and in application of Article 36 of Regulation (EC) 1901/2006, an application must be submitted to the OBI.
2. The application of paragraph 1, is submitted to the OBI either together with the application of a supplementary protection certificate for pharmaceuticals, or after having applied for a supplementary protection certificate and up until it is granted in accordance with Articles 5, 6 and 7 of the Ministerial Decision no. 14905/EFA/3058
(Article 52 para. 2(3) Regulation (EC) 1901/2006)

3. In the event that the OBI has already granted the certificate, in accordance with Article 7 of the Ministerial Decision no. 14905/EFA/3058, the application referred to in paragraph 1 is submitted to the OBI not later than two years before the expiry of the respective certificate.
(Article 52 para. 2(4) Regulation (EC) 1901/2006)

4. Notwithstanding paragraph 3 above, for five years following the entry into force of Regulation (EC) No 1901/2006, that is the 26th January 2012, the application for an extension of the duration of a certificate already granted shall be submitted not later than six months before the expiry of the certificate.
(Article 52 para. 2(5) Regulation (EC) 1901/2006)

Article 6
Application content

1. The application referred to in Article 5 above of the present decision is submitted in two copies and contains:
a) the particulars cited in Article 8 of Regulation (EEC) 1768/92.
b) a copy of the statement indicating compliance with an agreed completed paediatric investigation plan as referred to in Article 36(1) of Regulation (EC) No 1901/2006.

c) proof that the pharmaceutical in question has authorisations to place the product on the market of all other Member States, as referred to in Article 36(3) of Regulation (EC) No 1901/2006.
(Article 52 para. 3(a) Regulation (EC) 1901/2006)

d) if a certificate is pending before the OBI, reference on the application that has already been submitted.
e) If a certificate has already been granted, a copy of the certificate already granted by the OBI.
(Article 52 para 3(b) Regulation (EC) 1901/2006)

2. In addition to the details of paragraph 1 of the present Article, the application shall be annexed with documents legalising the person submitting them, in the case of a legal person and the receipt of the duty collected by the OBI with respect to submitting the application for extension of the certificate's duration.
3. Should the terms of paragraph 1 of the present article be fulfilled, the submission of the application is accepted. In this event, the application shall be deemed regular; it shall be given a submission date and entered into the OBI Reports Register.

4. As to the submission and drafting of documents before the O.B.I., Articles 2, 3, 4 and 9 of Ministerial Decision 15928/EFA/1253 (Government Gazette 778 B) and 19 of Presidential Decree 77/88 (Government Gazette 33 A) shall be implemented.

Article 7
Additional information

1. Within four months from regular submission and after written notice from the O.B.I., the applicant must submit to the O.B.I. any missing information and supporting documents in accordance with Article 6, paragraphs 1 and 2 of the present Joint Ministerial Decision. In this event, the application shall be deemed complete.
2. If after the lapse of the time-limit of paragraph 1 above of this article, the O.B.I. establishes that the data of the application have not been completed, the application shall be rejected.
(Article 52 para 5 Regulation (EC) 1901/2006)

PART THREE

CERTIFICATE - PUBLICATION

Article 8
Granting of a certificate

If the application is complete and regular in accordance with Articles 6 and 7 of this decision and if the product, which it concerns, fulfils the terms of Regulation (EEC) 1768/92, the O.B.I. shall grant the extension of duration of the certificate.
(Article 52 para 5 Regulation (EC) 1901/2006)

2. In the event where the application for extension has been submitted together with the application for a supplementary protection certificate for pharmaceuticals or where an application for a certificate is pending before the OBI, the certificate granted by the OBI shall contain an indication of the application for an extended duration of the certificate. The certificate for the extension of the duration of the certificate is granted separately.
(Article 52 para 4 (c) Regulation (EC) 1901/2006)

3. After the granting of the certificate, third parties may seek information and copies of the application and of the additional information, which have been submitted.

4. The O.B.I. shall, without fail, notify the National Pharmaceuticals Organisation of the granting of the certificate.

Article 9
Publication

The extension of the duration of the certificate shall be published in the Industrial Property Bulletin.

The publication of the certificate shall mandatorily refer the details of Article 11, para. 1 of Regulation (EEC) 1768/92.

In the event of the application is rejected by the O.B.I. in accordance with Article 7, para. 2 of the present Ministerial Decision, the act of rejection and the particulars of Article 9, para. 2 of Regulation (EEC) 1768/92 shall be published in the Industrial Property Bulletin with an indication that the application concerns the extension of the duration of the certificate.
(Article 52 para 6 Regulation (EC) 1901/2006)

PART FOUR

RIGHTS FROM THE EXTENSION OF THE CERTIFICATE – DURATION - DUTIES

Article 10
Right of content

The extension of the certificate shall give its holder, being a natural or legal person, the exclusive rights of Article 10 of Law 1733/87, which shall be implemented mutatis mutandis.

Article 11
Extension period

On implementation of Article 36 of Regulation (EC) No 1901/2006, the duration of the certificate shall be extended by six months after the expiry of the scheduled time-frame of the certificate in accordance with Article 13 of the Regulation (EC) 1768/1992.
(Article 52 para 7 Regulation (EC) 1901/2006)

Article 12
Revocation of an extension of the duration

The extension of the duration may be revoked if it was granted contrary to the provisions of Article 36 of Regulation (EC) No 1901/2006. In this event, Article 15 of Law 1733/1987 shall be implemented mutatis mutandis.

The revocation shall be published in the Industrial Property Bulletin.
(Article 52 para 8 Regulation (EC) 1901/2006)

Article 13
Duties

A duty shall be payable to the OBI upon application for the extension of the duration of a certificate.
(Article 52 para 3 (c) Regulation (EC) 1901/2006)

The amount of the duty shall be determined by a decision of the OBI Board of Directors.

PART FIVE

FINAL PROVISIONS

Article 11
Effective date

This decision shall enter in effect upon its publication with the Government's Gazette.

This decision is to be published in the Government's Gazette.