

INSTRUCTION No. 146 of 28.12.2006

Having regard to the possibility of granting a supplementary protection for medicaments and plant protection products provided for in Art. 31 of the Patent Law No. 64/1991 as republished;

Whereas since 01.01.2007 the Council Regulation (EEC) no. 1768/92 of 18 June 1992 concerning the creation of a supplementary protection certificate for medicaments and the Regulation (EC) no. 1610/96 of the European Parliament and of the Council of 23 July 1996 concerning the creation of a supplementary protection certificate for plant protection products are directly applicable in Romania;

Based on Art. 6, paragraph (3) of the Government Decision no. 573/07.09.1998 concerning the organization and functioning of the State Office for Inventions and Trademarks, published in the Official Gazette no.345 of 11 September 1998,

the Director General of the State Office for Inventions and Trademarks issues the following:

INSTRUCTIONS CONCERNING THE SUPPLEMENTARY PROTECTION CERTIFICATE FOR MEDICAMENTS AND THE SUPPLEMENTARY PROTECTION CERTIFICATE FOR PLANT PROTECTION PRODUCTS¹

Definitions

Art.1

In these Instructions the following terms are defined as follows:

- a) *Regulations* - the Council Regulation (EEC) no. 1768/92 of 18 June 1992 concerning the creation of a supplementary protection certificate for medicinal products and the Regulation (EC) no. 1610/96 of the European Parliament and of the Council of 23 July 1996 concerning the creation of a supplementary

¹Named according to the [Government Decision no.1559/23.09.2004 concerning the procedure to homologate plant protection products with a view to placing them on the market and using them on the territory of Romania, representing the transposing of the Council Directive 91/414/EEC published in the Official Gazette 955/19.10.2004](#)

- protection certificate for plant protection products;
- b) *certificate* - the supplementary protection certificate obtained on the basis of the Regulations;
 - c) *product* - the product defined according to Art. 1(b) of the Regulation no. 1768/92 and Art. 1(b) paragraph 8 of the Regulation no.1610/96, respectively;
 - d) *Patent Law* - Law no. 64/1991, republished ²;
 - e) *OSIM* - the State Office for Inventions and Trademarks;
 - f) *BOPI* - the Official Industrial Property Bulletin, Supplementary Protection Certificates Section;
 - g) *Register* - the National Register of the Supplementary Protection Certificates;
 - h) *European patent valid in Romania* - the patent granted based on the European Patent Convention in force in Romania, according to Law no. 611/2002 relating to the issuance of the European patent, published in the Official Gazette No 844 of 22 November 2002, or according to Law no. 32/1997 concerning the approval of the GO No. 32/1996 for the ratification of the Patent Cooperation Agreement between the Government of Romania and the European Patent Organization on the cooperation in the field of patents, signed in Bucharest on 9 September 1994, published in the Official Gazette No. 43 of 14 March 1997;
 - i) *transitional protection certificate* - the certificate granted based on the Law no. 93/1998 on the transitional protection of the patent for invention, published in the Official Gazette No 186 of 20 May 1998;
 - j) *industrial property attorney* - person defined according to Government Ordinance no. 66/2000 relating to organizing and practising the profession of industrial property attorney, published in the Official Gazette No. 758 of 17 October 2002, amended and completed by the Law No.331 of 17.07.2006 published in the Official Gazette No. 646 of 26 July 2006;

Certificate Application

Art. 2

- (1) The certificate application drawn up in Romanian shall be filed with OSIM.
- (2) The application shall be filed within the time limits provided for by Art. 7 of the

²Law no. 64/1991 as republished according to Art. III of the Law no. 203/2002 published in the Official Gazette No.340 - Part I, of 22 May 2002

Regulations:

- directly at the OSIM Registry;
- by mail.

(3) Where the basic patent defined in paragraph (9) is a European patent, the time limit of 6 months provided for in Art. 7(2) of the Regulations shall be calculated from the date when the translation into Romanian of the European patent specification is filed with OSIM.

(4) The certificate application shall contain:

a) the form for requesting the grant of a certificate, wherein there shall be mentioned:

- the applicant's identification data;
- the industrial property attorney's identification data, where appropriate;
- the number of the basic patent and the title of the invention;
- the number and date of the first authorization to place the product as a medicament or as a plant protection product, respectively, on the market in Romania;
- in case this is not the first authorization to place the product on the market in the EEA, the number and date of the latter;
- the product (active substance or a combination of active substances) identified by the authorization, for which the grant of a certificate is requested;
- the Regulation based on which the certificate is requested.

(b) a copy of the authorization to place the product on the market in Romania, valid on the date of filing the certificate application, indicating:

- the product name;
- the authorization number and date;
- a summary of the product characteristics;
- the authorization validity term;

(c) if the first authorization to place the product on the market in Romania is not the first authorization to place product on the market in the EEA, the latter shall contain:

- the identity of the product authorized thereby;
- the legal provision based on which the authorization was granted;
- a copy of the notice of publishing the authorization in an appropriate official publication (in the absence of such a publication there will be

presented a document proving the granting of the authorization, the date of the authorization, the Member State where it was granted and the identity of the product authorized thereby).

- (5) The application shall contain all the indications allowing the identification of the product protected by the basic patent, for example, the indication of the claim relating to the product.
- (6) The certificate application shall be accompanied by the proof of payment of the corresponding fee.
- (7) The certificate may be applied for only by the holder of the basic patent or the successor in title thereof.
- (8) If the certificate applicant is not the holder of the basic patent, he shall prove that he is the successor in title of the holder.
- (9) Within the meaning of Art.1, paragraph (c) of the Regulations No.1768/1992 and Art. 1 paragraph (9) of the Regulations No. 1610/1996, the basic patent may be:
 - a patent in force granted in Romania according to the Patent Law;
 - a European patent valid in Romania;If a transitional protection was recognized according to Law no. 93/1998, throughout the present Instructions, the basic patent shall also include a transitional protection certificate in force.
- (10) The authorization to place the product on the market in Romania is:
 - an authorization valid in Romania for medicaments for human use, issued by the National Agency for Medicament, according to Law no.95/2006 concerning the Health Reform, Title XVII, chapter III, section 1, Art. 700, published in the Official Gazette No. 372 of 28.04.2006;
 - an authorization valid in Romania for medicaments for veterinary use, issued by the National Sanitary Veterinary and Food Safety Authority, according to the

Order of Minister of Agriculture, Forestry and Environment no.1111/2003 for the approval of the Sanitary-Veterinary Norm concerning the code relating to veterinary medicinal products, published in the Official Gazette 278 of 30.03.2004;

- an authorization for medicaments of human or veterinary use issued by the European Agency for the Evaluation of Medicinal Products (EMA);

- a homologation certificate for the plant protection products, issued by the Interdepartmental Commission for Homologation of Plant Protection Products, based on the Government Decision no. 1559/23.09.2004 concerning the procedure to homologate plant protection products with a view to placing them on the market and using them on the territory of Romania, published in the Official Gazette No.955 of 19 October 2004, including the subsequent amendments and completions.

- (11) For further processing, OSIM is entitled to require the certified translation in Romanian of any document of the certificate application.

Filing the Application

Art.3

- (1) OSIM shall consider the application as filed and shall enter the certificate application in the Register, if at least the following requirements are met:

- an indication of requesting a certificate and the product for which the certificate is requested;

- the applicant's identification data;

- the number of the basic patent and the title of the invention;

- the number and date of the first authorization to place the product on the market in Romania, or, if this is not the first authorization to place the product on the market in the EEA, the number, date and country where said authorization was obtained;

- (2) If the requirements referred to in paragraph (1) are not met, the applicant shall be invited to remedy the deficiencies within 1 month.

- (3) If the deficiencies are remedied within the granted period of time, the date of receiving the rectification shall be deemed to be the date of filing.
Otherwise, the application shall be deemed not having been filed.
- (4) If the documents provided for in Art. 2 paragraph (4) have not been filed or the fees have not been paid according to the provisions of Art.6 paragraph (1), OSIM shall invite the applicant by a written notification to submit, within a time limit of 1 month, the documents missing on the date of filing the application and to pay the corresponding fees.
- (5) If the applicant does not comply with OSIM invitation within the granted period of time, the application shall be considered as being withdrawn.

Examination of Application for Grant of the Certificate

Art. 4

- (1) OSIM shall examine if the conditions in respect of the application form are satisfied, namely if:
 - a) the form according to the Annexe was correspondingly filled in;
 - b) the application was submitted within the time limits stipulated in Art. 7 of the Regulations, the provisions of Art. 2, paragraph (3) of these Instructions being also taken into account;
 - (c) where the time limit provided for in Art. 7 of the Regulations has expired, OSIM shall examine if the application was submitted within a 6-month interval from Romania's accession to the EU, for medicaments and plant protection products, respectively, for which the first authorization to place the product on the market as a medicament or plant protection product, in Romania, was obtained after 01.01.2000.
 - (d) the application contains the information provided for in Art.2 paragraph (4) of the present Instructions;
 - (e) the application is attended by a copy of the valid authorization to place the product on the market in Romania;
 - (f) the application contains, where necessary, information relating to the first authorization to place the product on the market, in EEA, and a copy of the authorization publication in an appropriate official publication;

- (g) the basic patent is in force on the date of filing the application;
 - (h) the certificate applicant is the same person as the basic patent holder, namely, if there exists a document proving the succession, for the situation in which the application has been submitted by a successor in title;
- (2) If deficiencies have been ascertained in meeting the requirements of paragraph (1), OSIM shall inform the applicant accordingly and shall invite him to remedy said deficiencies within 60 days from the date of the notification. If the applicant fails to comply with said invitation within the granted period of time, the application shall be rejected.
- (3) After the date of filing the application, OSIM shall not allow the change of the basic patent or the product for which the certificate is requested.
- (4) OSIM shall publish the application in BOPI as soon as the requirements stipulated under paragraph (1) are met and shall mention at least the following:
- the certificate application number and date;
 - the identification data of the person applying for the certificate;
 - the number of the basic patent;
 - the title of the invention;
 - the name of the product for which the certificate is requested;
 - the number, date and authority issuing the first authorization to place the product on the market in Romania;
 - where appropriate, the number, date and country of the first authorization to place the product on the market in the EEA.
- (5) OSIM shall perform the substantive examination with regard to the fulfilment, on the date of filing the application, of the conditions provided for in Art. 3 letters a, b and c of the Regulations, namely, if:
- the product is protected by the basic patent;
 - the authorization to place the product on the market in Romania is valid;
 - the product has not already been the subject of a certificate in Romania.
- (6) OSIM, through the Examination Board, shall make the decision to grant the certificate or to reject the certificate application.
- (7) The certificate shall be granted to the basic patent holder or to the successor

in title thereof.

- (8) The decisions of the Examination Board shall be communicated to the applicant within one month from the date of making the decision.
- (9) OSIM shall publish the mention of the decision to grant the certificate in BOPI and shall make the copy of the valid authorization to place the product on the market in Romania available to the public, at the OSIM premises.
- The mention of the decision to grant the certificate or to reject the application, shall be published within one month from the date of expiry of the time limit stipulated under Art. 9 paragraph (2), or, as the case may be, within one month from the communication of a decision of the Board of Appeal.
- (10) The mention of the decision to grant the certificate shall contain the following information:
- the identification data of the certificate holder;
 - the identification data of the industrial property attorney, if appropriate;
 - the number of the basic patent and the title of the invention;
 - the name of the product for which the authorization was issued;
 - the number, date and authority issuing the first authorization to place the product on the market in Romania;
 - the number, date and Member State where the first authorization to place the product on the market in the EEA was obtained;
 - the date on which the protection by certificate starts and the duration of the certificate.

Conditions for the Certificate Entry into Force Art. 5

- (1) The certificate shall take effect at the end of the lawful term of the basic patent , for a period of time settled according to Art.13 of the Regulations, the expiry and invalidity grounds provided for in Art. 14 and Art.15 of the Regulations, respectively, being also taken into account.
- (2) If the certificate has lapsed, according to the provisions of Art.14 b), c) and d) of the Regulations, OSIM shall publish in BOPI a mention to this effect.

Fees

Art. 6

- (1) The fees for filing, examining the application and issuing the certificate are provided in Annexe 1, paragraph 24 of the Government Ordinance no. 41/1998, concerning the fees to be paid in the industrial property field, amended and completed by the Law no. 381/2005 published in the Official Gazette No. 6 of 4 January 2006.
- (2) If payment of the fees referred to in paragraph (1) is not made, the application shall be deemed to be withdrawn.
- (3) Depending on the calculated duration of the granted supplementary protection certificate, the holder shall pay the annual fees for the certificate maintenance in force, provided for in the Annexe 1, paragraph 25 of the Government Ordinance no. 41/1998 concerning the fees to be paid in the industrial property protection field, amended and completed by the Law no. 381/2005.
- (4) The fee for the maintenance in force shall be due on the first day of the year of protection concerned. If the final protection period is less than 12 months, it shall be considered a full fee year.
- (5) In respect of the certificate applications for which a decision was not made by OSIM prior to the expiry of the basic patent, the annual fee for the first years of protection shall be paid on the date of publishing the mention of the decision to grant the certificate.

National Register for Supplementary Protection Certificates

Art. 7

- (1) OSIM is the depository of the National Register of Supplementary Protection Applications and Certificates. The Register shall be established and kept by

OSIM.

- (2) The registration number of the certificate applications shall be entered in the Register in the increasing order, according to the date of filing thereof with OSIM and shall observe the form provided by WIPO standards (ST10 and ST13).
- (3) The registration number shall appear on every document sent to OSIM and on every notification sent by OSIM.
- (4) The certificate shall have the same number as the certificate application.
- (5) The Register shall contain the following information:
 - the certificate applicant's or holder's identification data;
 - the basic patent holder's identification data;
 - the industrial property attorney's identification data;
 - the number and title of the basic patent;
 - the product's name;
 - the number and date of the first authorization to place the product on the market in Romania;
 - the number and date of the first authorization to place the product on the market in the EEA and the issuing authority;
 - the certificate application publication date;
 - the decision made as a result of the certificate application examination and the date of publication thereof;
 - the date when the certificate protection begins and ends;
 - the lodged appeals and revocation applications, as well as the decisions made by the Board of Appeal.
 - the Regulations under which the certificate was granted.
- (6) Mentions are also made in the Register relating to the granted certificates concerning the changes in the certificate legal status, such as the transfer of rights, lapse of holder's rights, certificate cancellation, reinstatement to previous position, renunciation, withdrawal, termination, suspension, pledging etc.

- (7) Information concerning the transfer of rights, disputes, executory measures, entered or to be entered in the National Register for the basic patent, shall also be entered in the Register.
- (8) The Register represents the *prima facie* evidence for any information entered therein.
- (9) The data contained in the Register may be consulted by any interested person. By request, a certified copy of excerpts from the Register may be obtained, subject to the payment of legal fees.

Certificate Issuance

Art. 8

- (1) OSIM shall issue the certificate concomitantly with the publication of the decision to grant.
- (2) The issued certificate shall contain the following indications:
 - the Regulation under which the certificate has been issued;
 - the number of the certificate;
 - the holder of the certificate;
 - the name of the product for which the authorization has been issued;
 - the number and title of the basic patent;
 - the date of entry into force of the certificate protection and the certificate duration.

Appeal, Revocation and Invalidation Procedures

Art. 9

- (1) According to Art. 15 (2) and Art.17 of the Regulations, the Patent Law provisions concerning the appeal, revocation and cancellation of patents shall also apply to the certificates.
- (2) The decisions of the Examination Board may be appealed against before OSIM within a 3-month time limit from their communication.
- (3) Any person may apply for the revocation of the certificate within 6 months from the date of publishing the mention of the decision to grant the certificate, for the grounds

provided for in Art. 15 of the Regulations.

- (4) The appeals against the decisions made by the Examination Board and the applications for revocation shall be settled by a Board of Appeal within the Appeals Department of OSIM.
- (5) The appeal drawn up in Romanian, containing facts and legal grounds related to the statement of the decision appealed against, the documents supporting the claimed reasons, as well as the evidence of the payment of the legal fee shall be filed by the applicant with OSIM.
- (6) The application for the revocation of the certificate shall be lodged with OSIM and shall comprise:
 - (i) the applicant's identification data;
 - (ii) the number of the certificate whose revocation is requested and the holder's identification data;
 - (iii) the grounds on which the application for revocation was made, according to Art. 15(1) of the Regulations and a complete report comprising all the facts, documents and presentations to sustain said grounds;
 - (iv) the identification data of the industrial property attorney, if the applicant is represented by an attorney;
 - (v) where a license is registered in the Register of Certificates, the document proving that the licensee was informed of the filing of the application for revocation.
- (7) Where the appeal or the application for revocation does not comply with the provisions of paragraph (6) i), and where the person having filed the application cannot be established, this shall be rejected.
- (8) If the conditions referred to in paragraph (5) or (6) are not satisfied, OSIM shall invite the person having filed the appeal or the application for revocation to remedy the deficiencies within 1 month, otherwise this shall be rejected.
- (9) OSIM shall send a copy of the application for revocation and of the attached documents to the certificate holder in order to allow him to present his observations within 3 months from communication, and the certificate holder shall be summoned on the date appointed for settling the application for revocation.
- (10) If an application for the revocation of a certificate is filed with OSIM during the validity period of the basic patent, the examination thereof within the Board of Appeal shall be suspended until the patent duration expires.
- (11) In the case referred to in paragraph (10), if the basic patent was declared as null or the holder renounced the patent or lapsed from the rights conferred by the patent, the application for revocation shall be considered as lacking legal ground and shall be rejected.
- (12) When the basic patent undergoes a cancellation procedure, and the duration thereof has expired, an application for the revocation of the certificate may be filed with OSIM during the said procedure, while the examination of the application for revocation shall

be suspended until a final and irrevocable decision is made in respect of the basic patent.

- (13) If a final and irrevocable decision of cancellation of the basic patent was taken, OSIM shall declare the certificate as invalid, according to the provisions of Art. 15 of the Regulations.
- (14) OSIM shall publish the mention of the certificate's invalidity and shall communicate the same to the holder.
- (15) If a decision to maintain the basic patent in part was made, where the product for which the certificate was issued is still protected by the basic patent, OSIM shall allow the parties to present their observations, and shall decide to maintain the certificate or declare the invalidity thereof, as the case may be.
- (16) Any person may ask to the Board of Appeal for the correction of the data provided for in Art. 7 paragraph (5) and entered in the Register, concerning:
 - (a) the omission of data to be entered;
 - (b) an error occurred in entering the data;
 - (c) the certificate duration according to Art.17(2) of the Regulations.

Other Procedures

Art.10

According to Art. 18 of the Regulations, for the procedures concerning the transfer of rights, changes occurred in the legal status, the representation by industrial property attorney or other procedures not provided for in the Regulations, the provisions of the Patent Law shall apply.

Final Provisions

Art.11

The Annexe to these Instructions shall be considered as integrant part thereof. These Instructions shall apply as from the date of Romania's accession to the European Union.

DIRECTOR GENERAL

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