

Strada Ion Ghica nr.5, Sector 3, Bucure_ti - Cod 70018 - ROMÂNIA *Telefon:* 315.19.65; 315.19.64; 314.59.64; 314.59.65; 314.59.66;

e-mail: office@osim.ro

Fax: 312.38.19

Nr. Dvs. _____/____

Nr. OSIM _____/____

Referring to the Circular <u>C.SCIT 2539</u> 06

Through which our office was invited to check and to make comments regarding the accuracy of the information given in the attached Survey .

We have analyzed the survey on the grant and publication of supplementary protection certificates for medicinal and phytopharmaceutical products and we have information referring to Romania which we consider necessary to be introduced in WIPO Handbook on Industrial Property Information and Documentation on CD-ROM.

Please find appended the pagea containing the proposed information regarding SPCs for Romania.

Sincerely yours,

Originally signed by Gabor Varga DIRECTOR GENERAL

Annex 3 pages

Annex

Question 1:

- (a) in the field of medicinal products
 - <u>No :</u> RO
- (b) in the field of phytopharmaceutical products No: RO

Question 2: Will your Office start granting SPCs in the future

(a) in the field of medicinal products

- <u>Yes:</u> RO
- (b) <u>No</u>: RO

Remarks:

RO : A new draft legislation is prepared for being considered in the future by the Romanian Parliament

<u>Question 3:</u> Please specify the legal basis for granting SPCs (national law, regional regulation, etc.).

(a) in the field of medicinal products

RO: National legislation regarding SPCs for medicinal and phytopharmaceutical products harmonized with Council Regulations (EEC) 1768/92 and 1610/96

(b) in the field of phytopharmaceutical products

RO: National legislation regarding SPCs for medicinal and phytopharmaceutical products harmonized with Council Regulations (EEC) 1768/92 and 1610/96 <u>Question 6:</u> Does your Office publish or intend to publish the receipt of an application for an SPC? (If "Yes", lease attach specimen of a front page of an SPC and/or of announcements regarding SPCs made in an Official Gazette.)

(a) in the field of medicinal products

<u>Yes:</u> RO

Remarks:

RO: Intends to publish the receipts of SPC applications when the system will be operational

(b) in the field of phytopharmaceutical products

<u>Yes:</u> RO

Remarks:

RO: Intends to publish the receipts of SPC applications when the system will be operational in the Bulletin

<u>Question 7:</u> If your reply to question 6 is "Yes", please state the minimum elements that a publication must contain

(a) in the field of medicinal products

Remarks:

RO: The Office intends to publish : (i) number assigned to the receipt of the application, (ii) date of receipt, (iii) the name and address of the applicant, (iv) the number of the basic patent, (v) title of the invention, (vi) number of any marketing authorization, including the product identified in the authorization, (vii) date of the authorization.

(b) in the field of phytopharmaceutical products

Remarks:

RO: The Office intends to publish : (I) number assigned to the receipt of the application, (ii) date of receipt, (iii) the name and address of the applicant, (iv) the number of the basic patent, (v) title of the invention, (vi) number of any marketing authorization, including the product identified in the authorization, (vii) date of the authorization.

Question 8:Does your Office publish or intend to publish the fact that an S.C. has
been granted? (If "Yes", please attach specimen of a front page of an S.C.
and/or of announcements regarding the grant of SPCs made in an Official
Gazette.)

(a) in the field of medicinal products

<u>Yes:</u> RO

Remarks:

RO: Intends to publish the grant of SPCs when the system will be operational in the Bulletin

(b) in the field of phytopharmaceutical products

<u>Yes:</u> RO

Remarks:

RO: Intends to publish the grant of SPCs when the system will be operational in the Bulletin

Question 9: If your replay to question 8 is "Yes", please state the minimum elements that a publication must contain

(a) in the field of medicinal products

Remarks:

RO: The Office intends to publish : (I) the registration number assigned to the granted S.C., (ii) date of registration of the granted S.C., (iii) name and address of the holder of the S.C., (iv) the number of the basic patent, (v) title of the invention, (vi) number and date of any marketing authorization, including the product identified in the authorization, (vii) date of the authorization, (viii) duration of the S.C..

(b) in the field of phytopharmaceutial products

Remarks:

RO: The Office intends to publish : (I) the registration number assigned to the granted S.C., (ii) date of registration of the granted S.C., (iii) name and address of the holder of the S.C., (iv) the number of the basic patent, (v) title of the invention, (vi) number and date of any marketing authorization, including the product identified in the authorization, (vii) date of the authorization, (viii) duration of the S.C..

<u>Question 10:</u> In what form does your Office make or intend to make the publication referred to in questions 6 and 8?

(a) in the field of medicinal products

- (I) As regards applications for SPCs (a) As part of an Official Gazette? <u>Yes:</u> RO
- (ii) As regards granted SPCs?
 (a) As part of an Official Gazette? Yes: RO

(b) in the field of phytopharmaceutical products

- (I) As regards applications for SPCs
 - (a) As part of an Official Gazette? <u>Yes:</u> RO
- (ii) As regards granted SPCs?
 - (a) As part of an Official Gazette? <u>Yes:</u> RO

<u>Question 11 :</u> If your Office enters or intends to enter data from the documents relating to SCPs in online database (internal or commercial), please give the name(s) of the database(s) and specify the bibliographic data elements:

- (a) in the field of medicinal products
 - (I) Name of the database

RO : Data will be included in an internal database

(b) in the field of phytopharmaceutical products

(I) Name of the database

RO : Data will be included in an internal database