

Annex to C. SCIT 2505

Country

QUESTIONNAIRE

ON THE GRANT AND PUBLICATION OF "SUPPLEMENTARY PROTECTION CERTIFICATES" FOR MEDICINAL AND PHYTOPHARMACEUTICAL PRODUCTS OR EQUIVALENT INDUSTRIAL PROPERTY RIGHTS (SPCs)

Important Remarks

1. The survey published in 1997 concerned only "Supplementary Protection Certificates" for medicinal products or equivalent industrial property titles of protection, but not the "Supplementary Protection Certificates" for phytopharmaceutical products.
2. This questionnaire aims at updating the 1997 survey and at including the industrial property titles of protection for phytopharmaceutical products.
3. In order to facilitate the updating of the said survey and the inclusion of information on phytopharmaceutical products, appropriate entries have been added. For the purposes of the survey, medicinal products and phytopharmaceutical products are both covered by the abbreviation "SPCs."
4. The survey will be made available through the WIPO Web site and will be kept up to date. For this purpose, you are kindly requested to inform the International Bureau of any change in the applicable legislation in your country.
5. Offices not covered by the previous survey are kindly requested to provide information as available.
6. If your Office participated in the previous survey and there are no changes, please indicate "no change."
7. Please, refer to Part 7.2.1 of the WIPO "Handbook on Industrial Property Information and Documentation" when responding to the following questions:

Question 1: Does your Office grant “supplementary protection certificates” for medicinal products or equivalent industrial property rights (SPCs) that extend the validity of patents covering medicinal, pharmaceutical, agrochemical or cognate products and phytopharmaceutical products?

(a) In the field of medicinal products

No

(b) In the field of phytopharmaceutical products

No

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

(a) In the field of medicinal products

Yes

(b) In the field of phytopharmaceutical products

Yes

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

(a) In the field of medicinal products

(1) Laws

(2) Decrees, ordinances

(3) Other Council Regulations (EEC) No 1768/92 of June 18, 1992 (after the incorporation of Bulgaria to European Patent Convention – July, 2002)

(b) In the field of phytopharmaceutical products

(1) Laws

(2) Decrees, ordinances

(3) Other As at question 3(a)

Question 4: Please specify the name of the SPC granted by your Office.

(a) In the field of medicinal products – Supplementary Protection Certificate, in Bulgarian language: Svidetelstvo za dopalnitelna zakrila

(b) In the field of phytopharmaceutical products As at question 4 (a)

Question 5: Please specify for which fields of technology or which products an SPC can be obtained (for example, medicinal products, phytopharmaceutical products, herbicides, agro-chemicals, all products subject to regulatory approval for marketing, etc.). As defined in Council Regulation (EEC) No 1768/92

Question 6: Does your Office publish or intend to publish the receipt of an application for an SPC?

(If "Yes," please 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

No

(b) In the field of phytopharmaceutical products

No

Question 7: **If your reply to question 6 is “Yes,” please indicate the minimum elements a publication must contain:**

- (a) In the field of medicinal products
 - (i) number allotted to receipt of the application
 - (ii) date of said receipt
 - (iii) name and address of the applicant
 - (iv) number of the basic patent
 - (v) title of the invention
 - (vi) number of any authorization to place the product on the market, including the product identified in that authorization
 - (vii) date of the said authorization
 - (viii) other elements (please specify)

- (b) In the field of phytopharmaceutical products
 - (i) number allotted to receipt of the application
 - (ii) date of said receipt
 - (iii) name and address of the applicant
 - (iv) number of the basic patent
 - (v) title of the invention
 - (vi) number of any authorization to place the product on the market, including the product identified in that authorization
 - (vii) date of the said authorization

(viii) other elements (please specify)

Question 8: Does your Office publish or intend to publish the fact that an SPC has been granted?

(If "Yes," please attach specimen of a front page of an SPC and/or of announcements regarding the grant of SPCs made in an Official Gazette.)

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| (a) | In the field of medicinal products | Yes |
| (b) | In the field of phytopharmaceutical products | Yes |

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

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| (a) | In the field of medicinal products | |
| | (i) registration number allotted to the granted SPC
special registration number will not be allotted | Probably the |
| | (ii) date of registration of the granted SPC | No |
| | (iii) name and address of the holder of the SPC | Yes |
| | (iv) number of the basic patent | Yes |
| | (v) title of the invention | Yes |
| | (vi) number of any authorization to place the product on the market,
including the product identified in that authorization | Yes |
| | (vii) date of the said authorization | Yes |
| | (viii) duration of the SPC | Yes |
| | (ix) other elements, e.g., <u>patent classification</u> , <u>product name</u> (please
specify): | Yes |
| (b) | In the field of phytopharmaceutical products | |
| | (i) registration number allotted to the granted SPC
special registration number will not be allotted | Probably the |

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|--------|--|-----|
| (ii) | date of registration of the granted SPC | No |
| (iii) | name and address of the holder of the SPC | Yes |
| (iv) | number of the basic patent | Yes |
| (v) | title of the invention | Yes |
| (vi) | number of any authorization to place the product on the market, including the product identified in that authorization | Yes |
| (vii) | date of the said authorization | Yes |
| (viii) | duration of the SPC | Yes |
| (ix) | other elements, e.g., <u>patent classification</u> , <u>product name</u> (please specify): | Yes |

Question 10: In which form does your Office make or intend to make the publications referred to in questions 6 and 8?

- (a) In the field of medicinal products
- (i) As regards applications for SPCs
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| (a) | as part of an Official Gazette? | Yes |
| (b) | by publishing the application? | No |
| (c) | by laying the application open to public inspection? | Yes |
| (d) | through online databases (or the Office's Web site)? | Yes |
| (e) | by copy delivery of the application on request? | Yes |

- (ii) As regards granted SPCs
 - (a) as part of an Official Gazette? Yes
 - (b) by publishing the SPC? No
 - (c) by laying the SPC open to public inspection? Yes
 - (d) through online databases (or the Office's Web site)? Yes
 - (e) by copy delivery of the SPC on request? Yes

- (b) In the field of phytopharmaceutical products
 - (i) As regards applications for SPCs
 - (a) as part of an Official Gazette? Yes
 - (b) by publishing the application? No
 - (c) by laying the application open to public inspection? Yes
 - (d) through online databases (or the Office's Web site)? Yes
 - (e) by copy delivery of the application on request? Yes

 - (ii) As regards granted SPCs
 - (a) as part of an Official Gazette? Yes
 - (b) by publishing the SPC? No
 - (c) by laying the SPC open to public inspection? Yes
 - (d) through online databases (or the Office's Web site)? Yes
 - (e) by copy delivery of the SPC on request? Yes

Question 11: If your Office enters or intends to enter data from the documents relating to SPCs in online databases (internal or commercial ones), please indicate the names(s) of the databases(s) and specify the bibliographic data elements:

- (a) In the field of medicinal products
 - (i) name(s) of database(s) Internal database
 - (ii) bibliographic data elements Data elements not selected yet

- (b) In the field of phytopharmaceutical products
 - (i) name(s) of database(s) Internal database
 - (ii) bibliographic data elements Data elements not selected yet

Question 12: If your Office allots or intends to allot specific application and/or registration numbers to SPCs, please give details:

- (a) As regards medicinal products
 - (i) concerning the numbering system for applications for SPCs The specific numbering system will not be applied for.
 - (ii) concerning the numbering system for registrations or grants of SPCs (if different from (a)(i))

- (b) As regards phytopharmaceutical products
 - (i) concerning numbering system for applications for SPCs The specific numbering system will not be applied for.
 - (ii) concerning the numbering system for registrations or grants of SPCs (if different from (b)(i))

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[End of Questionnaire]