# DRAFT QUESTIONNAIRE ON THE GRANT AND PUBLICATION OF SUPPLEMENTARY PROTECTION CERTIFICATES AND EXTENSIONS OF THE PATENT TERM

## CONTACT DETAILS

Name   
*Please indicate the name of the person who completed the questionnaire in the format "First Name LAST NAME”*

Title   
*Please indicate the title of the person who completed the questionnaire*

Country/Organization   
*Please indicate the country name or name of your Organization and the corresponding ST.3 code*

E-mail address   
*Please indicate the e-mail address of the person who completed the questionnaire*

Facsimile   
*Please indicate the facsimile of the person who completed the questionnaire*

Telephone   
*Please indicate the telephone number of the person who completed the questionnaire*

This questionnaire relates to mechanisms that enable owners of patents under certain conditions to obtain, during a limited period, continued protection for certain products that are subject to pre-market regulatory approval, namely supplementary protection certificates (SPCs) and patent term extensions (PTEs).

### Question 1

Does your Office/Organization provide SPCs or PTEs?

* Yes
* No

### Question 2

If you have answered “NO” to Question 1, will your Office/Organization start providing SPCs or PTEs in the future?

* Yes. Please use the field below for comments to indicate when.
* No.

Comments:

### Question 3

Please specify for which products an SPC or PTE can be obtained (or are planned to be introduced):

* medicinal products
* plant protection products
* all products subject to regulatory approval for marketing
* other:

Please describe the requirements for granting SPCs or PTEs.

*Examples:*

* *the product has been protected by a patent,*
* *the product has been subject to a regulatory review procedure before its commercial marketing or use,*
* *an SPC or PTE has never been granted on the product.*

If available, please provide a link to guidelines on filing applications for SPCs or PTEs.

### Question 4

Please specify the legal basis for granting SPCs or PTEs. For example, relevant provisions of the national law (article or rule number), regional regulation, decrees, ordinances etc.

If legal grounds are different for the objects indicated in Question 3, please list all of them, indicating corresponding products.

### Question 5

Please give the name of the SPC or PTE granted by your Office/Organization in English and the original language.

*Example: DE – Supplementary Protection Certificate (in German: “Ergänzendes Schutzzertifikat”).*

If names are different for the products indicated in Question 3, please list all of them, indicating corresponding products.

### Question 6

If your Office/Organization assigns (or intends to assign) a specific application and/or grant/registration number to SPCs or PTEs, please give examples and details of:

* the numbering system for applications:
* the numbering system for registration or grant (if different from the above):

Comments:

### Question 7

Does your Office/Organization or other relevant national authority publish, or intend to publish, one or more of the following events for an SPC or PTE? Please mark the corresponding cell in the table below with an “X”.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| EVENT | MEDICINAL PRODUCTS | PLANT PROTECTION PRODUCTS | ALL PRODUCTS SUBJECT TO REGULATORY APPROVAL FOR MARKETING | OTHER |
| Request (application) for an SPC or PTE filed |  |  |  |  |
| SPC or PTE granted |  |  |  |  |
| SPC or PTE not granted |  |  |  |  |
| SPC or PTE opposed by third parties |  |  |  |  |
| SPC or PTE came into force |  |  |  |  |
| SPC or PTE ceased because of a lapse or expiry |  |  |  |  |
| Extension of SPC term requested |  |  |  |  |
| Extension of SPC term granted |  |  |  |  |
| Extension of SPC term not granted |  |  |  |  |

Comments:

### Question 8

If you have marked at least one cell in the table in Question 7, please respond to the following questions 8.1 to 8.4. If the answers vary for different products or events, please use the “Comments” section below to explain the difference or copy questions 8.1 to 8.4 and answer them for each of the products or events.

* 1. In what form is the corresponding event published?
  + as part of an Official Gazette
  + through public online databases (please indicate the name and the URL of the database)
  + by opening the document for public inspection
  + by delivering a copy of the publication on request
  + other (please specify):
  1. What are the minimum elements that this publication must contain?
  + application number
  + filing date
  + name and address of the applicant
  + number of the relevant patent
  + title of the invention
  + name of the product
  + authorization details
  + date of the said authorization
  + other elements (please specify):
  1. What is the planned timetable for publishing this information?

* 1. Please attach an example(s) of published events and/or of corresponding announcements.

Attachments

Comments:

### Question 9

Does your Office/Organization or other relevant national authority publish (or intend to publish) the announcement of state changes for an SPC or PTE as defined in WIPO Standard ST.27?

Please mark the corresponding cell in the table below with an “X”.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| STATE | MEDICINAL PRODUCTS | PLANT PROTECTION PRODUCTS | ALL PRODUCTS SUBJECT TO REGULATORY APPROVAL FOR MARKETING | OTHER |
| Changed to “Active” |  |  |  |  |
| Changed to “Not active” |  |  |  |  |
| Changed to “Terminated” |  |  |  |  |

### Question 10

If you have marked at least one cell in the above table, please respond to the following questions 10.1 to 10.4.

If the answers vary for different products or states, please use the “Comments” section below to explain the difference or copy questions 10.1 to 10.4 and answer them for each of the products or states.

* 1. In what form is the announcement related to the state change published?
  + as part of an Official Gazette
  + through public online databases (please indicate the name and the URL of the database)
  + by opening the document for public inspection
  + by delivering a copy of the publication on request
  + other (please specify):
  1. What are the minimum elements that this publication must contain?
  + registration number allotted to the SPC or PTE, which has come into force
  + date of SPC or PTE registration, which has come into force
  + name and address of the SPC or PTE holder
  + number of the relevant patent
  + title of the invention
  + name of the product
  + authorization details
  + date of said authorization
  + duration of the SPC or PTE
  + other elements, e.g. patent classification (please specify):

* 1. What is the planned timetable for publishing this information?

* 1. Please attach a specimen(s) of corresponding announcements.

Attachments

Comments:

[End of Annex and of document]