SUPPLEMENTARY PROTECTION CERTIFICATES AND PATENT TERM EXTENSIONS

Response ID:72; pspu Data

1. Country code page

1. Please enter the two-letter country code corresponding to your Office or Organization.

SE

2. Questions page

2. 1. Does your Office/Organization provide SPCs or PTEs?

Yes

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

Comments:

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

medicinal products
plant protection products

4. 3a. 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.

A certificate shall be granted a medicinal product if, the application is submitted and at the date of that application a)the product is protected by a basic patent in force; b)a valid authorisation to place the product on the market as a medicinal product has been granted in accordance with Directive 2001/83/EC or Directive 2001/82/EC, as appropriate; c) the product has not already been the subject of a certificate; d) the authorisation referred to in point (b) is the first authorisation to place the product on the market as a medicinal product. A certificate shall be granted a plant protection product if, the application is submitted and at the date of that application a)the product is protected by a basic patent in force; b) a valid authorization to place the product on the market as a plant protection product has been granted in accordance with Article 4 of Directive 91 /414/EEC or an equivalent provision of national law; c) the product has not already been the subject of a certificate; (d) the authorization referred to in (b) is the first authorization to place the product on the market as a plant protection product.

5. 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.

Article 9 and 10 Regulation (EC) No 469/2009 of the European Parliament and of the Council of 6 May 2009 concerning the supplementary protection certificate for medicinal products. Article 9 and article 10 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.

6. 5. Please give the name(s) of the SPCs or PTEs granted by your Office/Organization in both 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 the protections, indicating corresponding products.

SE - Supplementary Protection Certificate (in Swedish: "Tilläggsskydd", (SPC))

7. 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:: SPC: YY900NN-C, SPC-F: YY9M0NN-C
Comments: YY = year N = sequence numbering 0,...,9 M = sequence numbering 1,...,9 C = check sum 0,...,9 SPC-F means "extension of SPC"

8. 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?

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

Comments: See example: https://was.prv.se/spd/spc?lang=en&hits=true&spcnummer=+0190035-6&spcsystem=EP&hitsstart=0&tab=4&number=01900356&start=0

9. 8a. 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): Swedish Patent Database: https://was.prv.se/spd/search?tab=4&lang=en, Detaild information: https://was.prv.se/spd/spc?lang=en&hits=true&spcnummer=+0190035-6&spcsystem=EP&hitsstart=0&tab=4&number=01900356&start=0
by opening the document for public inspection
by delivering a copy of the publication on request
other (please specify):: The information that an SPC has entered into force is not published in the Official Gazette, but it may be seen through the the other forms of publication mentioned above.

10. 8b. 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 SPC or PTE authorization

11. 8c. What is the planned timetable for publishing this information?

When it is notified in the Swedish Patent Gazette, weekly.

12. 8d. Please attach an example(s) of published events and/or of corresponding announcements.

Comments: https://was.prv.se/spd/spc?lang=en&hits=true&spcnummer=+0190035-6&spcsystem=EP&hitsstart=0&tab=4&number=01900356&start=0

13. 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?

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

14. 10a. In what form is the announcement related to the state change published?

15. 10b. What are the minimum elements that this publication must contain?

16. 10c. What is the planned timetable for publishing this information?

17. 10d. Please attach a specimen(s) of corresponding announcements.