

SUPPLEMENTARY PROTECTION CERTIFICATES AND PATENT TERM EXTENSIONS

Response ID:80; tcgi Data

1. Country code page

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

CZ

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.

The product has been protected by a patent. The product has been subject to a regulatory review procedure before its commercial marketing and use. An SPC has never been granted on the product. Link: <https://www.upv.cz/en/ip-rights/supplementary-protection-certificates.html>

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.

EU legislation - Regulations

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.

CZ - Supplementary Protection Certificate (in Czech: "Dodatkové ochranné osvědčení"). Abbreviations: "SPC" and/or "DOO"

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/CZYYYY/number series

the numbering system for registration or grant (if different from the above):: Patent number/SPC number series

Comments: Examples: Application (INID Code 21): SPC/CZ2018/605 Granted (INID Code 11): 1641823/404

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				
SPC or PTE ceased because of a lapse or expiry				
Extension of SPC term requested	X			
Extension of SPC term granted	X			
Extension of SPC term not granted	X			

Comments:

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): web of the IPO CZ / Patents / SPCs ; <https://upv.cz/en/client-services/online-databases.html>

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?

This information is already published.

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

Comments: https://isdv.upv.cz/doc/vestnik/2018/vestnik_UPV_201846.pdf Example 1, Request for SPC: (22) 10.10.2018 (21) SPC/CZ2018/606 (71) Novartis AG, 4056 Basel, CH (68) 2902039 (54) Antagonistické protilátky proti IL-17 (92) EU/1/14/980, 23.11.2015 (93) EU/1/14/980, 23.11.2015, EU (95) Cosentyx - secukinumab, léčivý přípravek, Example 2, SPC granted: (73) ELI LILLY AND COMPANY, Indianapolis, IN 46285, US (68) 1641823 (11) 1641823/404 (54) Fúzní proteiny GLP-1 analogu (92) EU/1/14/956, 25.11.2014 (93) EU/1/14/956, 25.11.2014, EU (95) Trulicity-dulaglutidum, léčivý přípravek (94) 10.06.2029

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"	X	X		
Changed to "Not active"	X	X		
Changed to "Terminated"	X	X		

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

through public online databases (please indicate the name and the URL of the database):

<https://isdv.upv.cz/webapp/lresdb.pta.frm>

other (please specify):: bulk data

15. 10b. 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 SPC or PTE authorization

duration of the SPC or PTE

other elements, e.g. patent classification (please specify):: pediatric extension

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

Q2 2020

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