SUPPLEMENTARY PROTECTION CERTIFICATES AND PATENT TERM EXTENSIONS

Response ID:83; iucu Data

1. Country code page

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

HR

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) 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. For now, we have avalaible only guidelines in croatian: https://www.dziv.hr/hr/prirucnik-za-ispitivanje-patenata/dio-g/

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.

National law: Patent Act and the Act on amending the Patent Act (OG No. 173/2003, 87/2005, 76/2007, 30/2009, 128/2010, 49/2011, 76/2013, 46/2018): Articles 1.a and 87.a to 87.l; 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; 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.

in English - Supplementary Protection Certificate; in Croatian - Svjedodžba o dodatnoj zaštiti

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:: S20130001A
the numbering system for registration or grant (if different from the above):: S20130001
Comments: Application and grant numbers start with S, followed by four digits for year and four digits for the ordinal number of the filing in the year. Grant number does not have letter A in the end.

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

Comments: Data on when SPC came into force it will be visible in our online database at the end of 2019 as a first date in period of validity

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): it will be possible at the end of 2019 at https://www.dziv.hr/en/e-services/on-line-database-search/
by opening the document for public inspection
by delivering a copy of the publication on request

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?

biweekly (Official Gazette)

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

SPC_example1.pdf
Comments:

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"				

14. 10a. 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): it will be possible at the end of 2019 at https://www.dziv.hr/en/e-services/on-line-database-search/
by opening the document for public inspection
by delivering a copy of the publication on request

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

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

biweekly (Official Gazette)

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

SPC_example2.pdf