

SUPPLEMENTARY PROTECTION CERTIFICATES AND PATENT TERM EXTENSIONS

Response ID:74; zejm Data

1. Country code page

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

ES

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) el producto está protegido por una patente de base en vigor; b) el producto ha obtenido una autorización de comercialización vigente; c) el producto no ha sido objeto ya de un certificado; d) la autorización mencionada en la letra b) es la primera autorización de comercialización del producto

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.

Reglamento (CE) nº 469/2009 del Parlamento Europeo y del Consejo de 6 de mayo de 2009 relativo al certificado complementario de protección para los medicamentos; Reglamento (CE) nº 1610/96 del Parlamento Europeo y del Consejo de 23 de julio de 1996 por el que se crea un certificado complementario de protección para los productos fitosanitarios; Ley 24/2015, de 24 de julio, de Patentes (Art. 45-47) y Real Decreto, de 1 de abril de 2017, por el que se aprueba el Reglamento para la ejecución de la Ley 24/2015 (Art. 54-57) para ambas modalidades de CCP.

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.

Supplementary Protection Certificate for medicinal products (en español: "Certificado Complementario de Protección para medicamentos"); Supplementary Protection Certificate for plant protection products (en español: "Certificado Complementario de Protección para productos fitosanitarios").

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:: C aaaaannnnn (solicitudes en formato papel); C aaaa3nnnn (solicitudes en formato electrónico)

Comments: Ejemplos: C 201700001 (solicitudes en formato papel); C 201730001 (solicitudes en formato electrónico)

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	X	X		
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): <http://consultas2.oepm.es/ceo/>

by opening the document for public inspection

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

other elements (please specify):: Representante; Fecha límite de validez del CCP; Fecha de la concesión del CCP

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

Ya se publica automáticamente dentro de un plazo de 4 días desde la resolución de la incidencia correspondiente mediante un sistema informático.

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

[Ejemplos_de_publicación_de_incidencias.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"				
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.