SUPPLEMENTARY PROTECTION CERTIFICATES AND PATENT TERM EXTENSIONS

Response ID:77; tcna Data

1. Country code page

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

ca

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

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 CSP may be granted on application to Health Canada if: The applicant is the patentee and is recorded as an owner of the patent in the Patent Office or is the manufacturer who is authorized to file on their behalf; the patent is issued and in force at the time of filing and issuance; the patent contains a claim for: the medicinal ingredient (in the case of a drug containing only one medicinal ingredient) or combination of all the medicinal ingredients (in the case of a drug containing more than one medicinal ingredient) in a drug, including in product-by-process form or a use of the medicinal ingredient (in the case of a drug containing only one medicinal ingredient) or combination of all the medicinal ingredients (in the case of a drug containing more than one medicinal ingredient) in a drug; the above drug is approved by Health Canada via a Notice of Compliance (NOC); the NOC: issued on or after September 21, 2017, is the first approval issued with respect to the single medicinal ingredient or combination, as the case may be, or a prescribed variation thereof, issued from a submission filed within twelve months of the filing of the first application for marketing approval of the medicinal ingredient or combination in the European Union or any member country thereof, U.S., Australia, Switzerland and Japan (the transitional provision has now expired); the CSP application is filed with Health Canada within 120 days of the later of the date of grant of the NOC and patent grant date (if the patent is granted after the NOC grant date); the prescribed fee is paid; no prior CSP has issued for the medicinal ingredient or combination of medicinal ingredients or a prescribed variation thereof; there is no conflict with a competing application, or the conflict has been resolved; the application sets out the patent number, the medicinal ingredient or combination of medicinal ingredients and the number of the authorization for sale in relation to which the certificate is sought, and; the application also contains the applicant's name and contact information in Canada, including their complete address; the filing date of the application for the patent (must be on or after October 1, 1989), the date on which the patent was granted and the date of which the term of the patent will expire, and a description of the method of payment used to pay the prescribed fee. Health Canada Guidance Document - Certificate of Supplementary Protection Regulations https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/applications-submissions/guidance-documents/register-certificates.html = Comments: The CIPO Patent Office does not provide SPCs or PTEs. That responsibility

lies with Health Canada and Health Canada will continue to carry this responsibility in the future. In the survey, "Office/Organization" refers to Health Canada.

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.

Sections 104 to 134 of the Patent Act and the Certificate of Supplementary Protection 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.

Original in English: "Certificate of Supplementary Protection", Original in French: "Certificat de protection supplémentaire"

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:: the first Certificate of Supplementary Protection application was numbered "900001", and subsequent applications are numbered in chronologically increasing order

Comments:

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

Comments: Lapse (no), expiry (yes)

9. 8a. In what form is the corresponding event published?

through public online databases (please indicate the name and the URL of the database): Register of Certificates of Supplementary Protection and Applications. URL: https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/applications-submissions/guidance-documents/register-certificates.html Registre des certificats de protection supplémentaire et des demandes. URL : https://www.canada.ca/fr/sante-canada/services/medicaments-produits-sante/medicaments/demandes-presentations/lignes-directrices/registre-certificats.html

10. 8b. What are the minimum elements that this publication must contain?

number of the relevant patent
other elements (please specify):: patent expiry date, medicinal ingredient(s), human or veterinary use, number of the authorization for sale, certificate of supplementary protection (CSP) number, the day on which the CSP term begins and on which its term ends

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

The Register of Certificates of Supplementary Protection and Applications and the Registre des certificats de protection supplémentaire et des demandes are already published and are updated as needed

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

reg-cert-sup-eng.pdf
reg-cert-sup-fra.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			
Changed to “Not active”	X			
Changed to “Terminated”	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): gister of Certificates of Supplementary Protection and Applications URL: https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/applications-submissions/guidance-documents/register-certificates.html Registre des certificats de protection supplémentaire et des demandes URL : https://www.canada.ca/fr/sante-canada/services/medicaments-produits-sante/medicaments/demandes-presentations/lignes-directrices/registre-certificats.html

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

other elements, e.g. patent classification (please specify):: patent expiry date, medicinal ingredient(s), human or veterinary use, number of the authorization for sale, certificate of supplementary protection (CSP) number, the day on which the CSP term begins and on which its term ends

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

The Register of Certificates of Supplementary Protection and Applications and the Registre des certificats de protection

supplémentaire et des demandes are already published and are updated as needed

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

reg-cert-sup-eng.pdf
reg-cert-sup-fra.pdf