

1. Applicant's/representative's reference number

2. Basic patent number

3. The application in relation to the SPC

- a. ☐ The application is made when lodging the SPC application
- b. ☐ The application regards an SPC application pending, number:
- c. ☐ The application regards a granted SPC: expiring:

4. Applicant

Name/Company name	
Address	Phone number (daytime)
Postcode/City/Country	Cell phone number

5. Representative

Name	
Address	Phone number (daytime)
Postcode/City/Country	Cell phone number

6. The authorized product's trivial/generic name

7. The authorized product's trade name

8. Certification

- a. ☐ The medicinal product has *not* been designated as an orphan drug pursuant to Regulation (EC) No 141/2000
- b. ☐ The applicant has not applied for an extension of the period of marketing protection for the medicinal product concerned
- c. ☐ A one-year extension of the period of marketing protection for the medicinal product concerned has not been granted

9. Choice of language

I choose to receive PRV's office actions and decisions in: ☐ Swedish ☐ English

10. Fees (SEK)

☐ Application fee 6 000 SEK

11. Method of payment

☐ Electronic payment via www.prv.se

☐ Deposit account, number

12. Applicant's/representative's signature

Place and date

Signature

Clarification of signature (with company name, if applicable)

13-15. Appendices

13. ☐ A copy of the Supplementary Protection Certificate already granted (see item 3c)

14. ☐ Marketing authorization/s to place the product on the market in all EU Member States, updated with statement/s indicating compliance with an agreed and completed paediatric investigation plan.

15. ☐ Power of attorney

1. Applicant's/representative's reference number

State your reference number.

2. Basic patent number

State the application or publication number of the basic patent.

3. The application, in relation to the SPC

State how the application relates to the supplementary protection certificate that is subject to extension. A prerequisite for the extension of the SPC duration is that the product is protected by a SPC under Regulation (EEC) No 469/2009 or by a patent which qualifies for the granting of a SPC.

Tick the applicable box:

- a. An application for extended SPC term can be made at the same time as lodging an SPC application.
- b. An application for extended SPC term can be made when an SPC application is pending before the PRV or before the appellate court.
- c. An application for extended SPC term can be made even if the SPC has already been granted, but shall be lodged not later than two years before the expiry of the certificate.

4. Applicant

State the applicant's name and contact information. Note that only the proprietor of the basic patent, or his successor in title, can be entitled to the SPC. Hence, the extended term is only granted to the proprietor of the patent/SPC.

5. Representative

If you have appointed a representative, state his/her name and contact information. If the representative was appointed in the basic patent, or the SPC, you are not required to file a new power of attorney to apply for the extended SPC term.

6. The authorized product's trivial/generic name

State the trivial/generic name of the authorized product. The product is the active ingredient or combination of active ingredients of a medicinal product. The product's trivial name shall be in Swedish or English and will be published in the Swedish Patent Gazette.

7. The authorized product's trade name

You may state the authorized medicinal product's trade name. The information is not compulsory and will not be published.

8. Certification

a. The medicinal product is not an orphan drug

By ticking the box, the applicant certifies that the medicinal product has not been designated as an orphan drug (see Article 36.4 of Regulation (EU) No 1901/2006).

b. Applicant has not applied for extension of marketing protection period

c. Applicant has not been granted an extension of marketing protection period

By ticking these boxes, the applicant certifies that no application has been filed, or granted, to obtain a one-year extension of the period of marketing protection for the medicinal product concerned (see Article 36.5 of Regulation (EU) No 1901/2006).

9. Choice of language

You should choose in which language you wish to receive PRV's office actions and decisions.

10. Application fee

The application fee is 6 000 SEK. The application will not be examined unless the fee is paid.

The annual fee for a SPC is 20 000 SEK per annual fee year. Annual fees are not due until the SPC is granted.

11. Method of payment

Pay using our e-service "Electronic payment" at www.prv.se after your application has been registered. You can also make payments using our Bank Giro account or your deposit account.

Unfortunately, we can't send you an invoice.

When making payments, please state the application number, SPC number or basic patent number.

12. Signature by applicant/representative

The application must be signed and dated by the applicant/representative. Clarify the signature and state the company name, if applicable.

13. A copy of the Supplementary Protection Certificate already granted (see item 3c)

If the application for extended SPC term regards an already granted SPC (see item 3c), a copy of the SPC decision shall be submitted.

14. Marketing authorization/s to place the product on the market in all EU Member States

The application for extended SPC term shall contain evidence to prove that the applicant has authorization to market the product in all EU Member States (see Article 36.3 of Regulation (EU) No 1901/2006). The authorization/s must be updated with a statement that studies and tests have been completed in compliance with an agreed paediatric investigation plan.

15. Power of attorney

If the representative was appointed in the SPC, you are not required to file a new power of attorney to use the same representation in your application for the extended term.

Do you wish to contact the PRV?

Do you have any questions? Call or send an e-mail to the PRV's Customer Service. Phone: +46 8 782 28 00, e-mail: kundsupport@prv.se.

Customer Service is open Monday-Friday 08.00-16.00

Some restrictions may apply on day before holiday.

For more information, please visit our website, www.prv.se.

Send your application to PRV, P.O. Box 5055, SE-102 42 Stockholm, Sweden