

1. Applicant's/representative's reference number

2. Basic patent number

3. Title of the invention

4. Applicant

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. First authorization to place the product on the Swedish market as a medicinal product

Number and date
This authorization is the first authorization within the EEA <input type="checkbox"/> Yes <input type="checkbox"/> No, (see item 7)

7. First authorization to place the product on the EEA market as a medicinal product

Number, date and country	Legal provision under which the authorization took place
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8. The authorized product's trivial/generic name

9. The authorized medicinal product's trade name

10. Choice of language

I choose to receive PRV's office actions and decisions in: <input type="checkbox"/> Swedish <input type="checkbox"/> English
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11. Fees (SEK)

Application fee 10 000 SEK

12. Method of payment

Electronic payment via www.prv.se

Deposit account, number

13. Signature of applicant/representative

Place and date

Signature

Clarification of signature

14-18. Appendices

- 14. Copy of the marketing authorization in Sweden - identifying the product - and the summary of product characteristics
- 15. Copy of the notice publishing the first marketing authorization, if the first authorization was not for the Swedish market
- 16. Translation
- 17. Information to prove that the basic patent protects the product in question
- 18. Power of attorney

1. Applicant's/representative's reference number

State your reference number.

2. Basic patent number

The product must be protected by a basic patent in force. State the application or publication number of the basic patent.

3. Title of the invention

State the basic patent's title.

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.

5. Representative

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

6. First authorization to place the product on the Swedish market as a medicinal product

State the registration number and date of the first decision to place the product on the Swedish market as a medicinal product. The marketing authorization must be valid at the time of the SPC application.

7. First authorization to place the product on the EEA market as a medicinal product

In accordance with the EEC-agreement, marketing authorizations in an EFTA state (Norway, Iceland and Lichtenstein) are equal to authorizations from an EU state, as these states together form the European Economic Area (EEA). If the Swedish marketing authorization is not the first within the EEA, state the first authorization to place the product on the EEA market as a medicinal product.

8. 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.

9. The authorized medicinal product's trade name

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

10. Choice of language

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

11. Application fee

The application fee is 10 000 SEK. The application will not be examined unless the fee is paid.

The annuity fee for a SPC is 20 000 SEK per year. The annuity fee is not payable until the SPC has been granted.

12. 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 or basic patent number.

13. 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.

14. Copy of the marketing authorization in Sweden - identifying the product - and the summary of product characteristics

The summary of product characteristics is an appendix to the marketing authorization in accordance with Article 11 of Directive 2001/83/EC or Article 14 of Directive 2001/82/EC.

15. Copy of the notice publishing the first marketing authorization, if the first authorization was not for the Swedish market

If the first marketing authorization in Sweden was not the first authorization to place the product on the EEA market, you must state the identity of the product thus authorized and the legal provision under which the authorization procedure took place, and submit a copy of the notice publishing the authorization in the appropriate official publication.

16. Translation

The product's trivial name (item 8) and the marketing authorization for Sweden, including the summary of product characteristics (item 14), shall be submitted in Swedish or English.

17. Information to prove that the basic patent protects the product in question

This information shall give the PRV the possibility to determine that the product is protected by the basic patent.

18. Power of attorney

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

Filing via eOLF

You may also submit your SPC application, and your application for paediatric extension, via eOLF. When filing via eOLF you must state the reference number, 9999999-7. This is a way to circumvent the system which demands a case number in order to submit a SPC application. Many applications are based on validated EP patents for which our current system is unable to handle. In about a week from the date of application you will receive the correct case number. This is a temporary solution in order to enable an electronic filing of a SPC application, and it will change in future electronic filing systems.

Do you wish to contact the PRV?

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