DANISH PATENT AND TRADEMARK OFFICE

Application for paediatric extension of a Supplementary Protection Certificate for a Medicinal Product

Danish Patent
and Trademark Office

Helgeshøj Allé 81
2630 Taastrup

Tel. : +45 43 50 80 00
Fax : +45 43 50 80 01
E-mail : pvs@dkpto.dk
Web : www.dkpto.dk
CVR No : 17 03 94 15

Ministry of Industry, Business
and Financial Affairs

Please consult the Guide for filling in the Application for paediatric extension of a Supplementary Protection Certificate.

1. Your reference:

2. Applicant details (full name and address):
(Applicant(s)=proprietor(s) of the basic patent)

☐ Additional applicants on reverse page

CVR number: P number: E-mail:
Tel. (residence): Tel. (work): Mobile:

3. Representative (name, address and CVR number, if any):

Tel.: Fax:

4. The application

a) The application is filed together with an application for a Supplementary Protection Certificate for a medicinal Product

☐ Yes ☐ No

b) The application refers to extension of application for Supplementary Protection Certficate No CA , filed with the Danish Patent and Trademark Office on

c) The application refers to extension of Supplementary Protection Certificate registration No CR expiring on

5. a) The product you want to protect (can be continued on reverse page if necessary):

b) Tradename:

6. Basic patent:

a) Number:

b) Title of the invention (can be continued on reverse page if necessary):

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

8. ☐ The product you want to protect (box 5) is not classified as a medicinal product for rare diseases.

9. ☐ No request has been filed for a one-year prolongation of the period covered by the marketing authorization for the product applied for, on the basis of the paediatric indication.

12. ☐ The application has previously been filed by fax on:

14. Date and signature:

10. Fees:

☐ Application fee

11. Enclosed documents:

☐ Copy of the granted Supplymentary Protection Certificate

☐ Copy of the statement indicating compliance with an agreed completed paediatric investigation plan

☐ Documentation showing marketing authorizations issued for all EU member states

☐ Power of Attorney

13.

☐ Processing in English of the application etc. is requested

Application continued:

Applicant details (full name and address):

CVR number:	P number:	E-mail:
Tel. (residence):	Tel. (work):	Mobile:

Applicant details (full name and address):

CVR number:	P number:	E-mail:
Tel. (residence):	Tel. (work):	Mobile:

5. a) The product you want to protect (continued):

6. b) Title of the invention (continued):

Guide for filling in the "Application for paediatric extension of a Supplementary Protection Certificate for a Medicinal Product"

The numbering below corresponds to the numbers on the application form.

1. This box is for your own reference.

2. Only the proprietor (or proprietors if more than one) of the basic patent/certificate can apply for a pediatric extension of the certificate. If the basic patent/certificate has more than one proprietor, please state all of them in this box. In the event that one of the proprietors of the basic patent/certificate is entitled to receive correspondence on behalf of all proprietors, please indicate this by underlining the name in question. You may also appoint a representative (please see 3).
For practical reasons, please check whether the register information of the basic patent/certificate is (still) correct.

3. If someone else is representing you during the processing of the application, you must provide the name and address of this representative. Power of Attorney must be enclosed; a form can be obtained from the DKPTO.

4. You may file an application for extension of the term of the supplementary protection certificate together with an application for grant of a supplementary protection certificate or during processing of this. Application for extension may also be filed for a granted certificate, but the application must at the latest be filed two years before expiration of the certificate.

5. a) In this box you shall state the product for which your supplementary certificate has been granted or if the supplementary protection certificate has not yet been granted, the medicinal product you want to protect.

b) In this box you may state the name under which the medicinal product is sold, i.e. trade name.

6. In this box you shall state the Danish patent (or the European patent valid in Denmark) on which the supplementary protection certificate application is based. As mentioned in 2, the applicant must be the proprietor of the basic patent/certificate. The basic patent must be the same as in the supplementary protection certificate application. The selection of a basic patent is final; it cannot be replaced after filing of the application.

In b) you shall state the title of the invention of the basic patent. You will find the title in the basic patent or in the patent register.

7. In this box you shall certify (by ticking the box) that a valid marketing authorization for all EC Member States is enclosed. The authorization/s must be updated with a statement that studies and tests have been completed in compliance with an agreed paediatric investigation plan.

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

9. In this box you shall certify (by ticking the box) that a one-year prolongation of the period (term) covered by the marketing authorization for the product applied for, on the basis of the paediatric indication, has not been applied for and approved.

10. The application fee shall be paid when filing the application. Refund of fees is not possible. This also applies if you withdraw the application or, for other reasons, the application is not granted. The fee appears from our price list.

11. Please see 3 and 4.

Copy of granted certificate:
If the application refers to extension of a granted certificate, a copy must be enclosed.

Statement of compliance with an agreed completed paedi-atric investigation plan: You must file a copy of the relevant authorization containing the statement indicating compliance with an agreed completed paediatric investigation plan. It must appear from the statement that substantial amount of investigations or all investigations in the agreed completed paediatric investigation plan have been completed before commencement of Regulation (EEC) No. 1901/2006, cf. article 45 (3). The statement will be part of the marketing authorization with wording like: "Development of this medicinal product apply to all steps in the agreed completed paediatric investigation plan (reference number). For the purposes of appliance of article 45 (3), in regulation No. 1901/2006 a substantial amount (or all) investigations in the agreed completed paediatric investigation plan (reference number) completed after the commencement of this Regulation".

Documentation showing marketing authorizations issued for

all EU member states:
You must file documentation showing the marketing authorization for the product you want to protect including information about the result of the paediatric studies in all EU member states.
Power of Attorney:
Under certain circumstances the DKPTO may request Power of Attorney enclosed to the application.

12. If you previously sent the application by fax, please tick the box.

13. Please tick this box if you wish the processing of the application and the correspondence to be in English.
If English is not selected, the processing will be in Danish.

14. The application must be signed by the applicant (or applicants if more than one). In the event that the applicant is an enterprise, the signature must be accompanied by the enterprise’s stamp.
If a representative has been appointed, the representative is entitled to sign on behalf of the applicant.

Please contact us if you have any further questions on telephone 43 50 83 01.