

Application for grant of an Extension to a Supplementary Protection Certificate

(See the notes on the back of this form. You can also get an explanatory booklet from the Office to help you fill in this form)

Concept House
Cardiff Road
Newport
South Wales
NP10 8QQ

1. Your reference

2. Granted certificate number or certificate application number

(If you are filing for an extension at the same time as making an application for a certificate the Office will fill in this part.

If you already have a granted certificate you should enter its number and expiry date)

(Article 8(1a)(1b))

Expiry date of granted certificate

(day/month/year)

3. Full name, address and postcode of the or of each applicant *(underline all surnames)*

ADP number *(if you know it)*

4. Name of your agent *(if you have one)*

“Address for service” in the European Economic Area or Channel Islands to which all correspondence should be sent

(including the postcode) (see note (e))

ADP number *(if you know it)*

5. What is the product that you want to protect ?

(Identify the active ingredient(s) or active substance(s). If possible use chemical or generic names. If a certificate has been granted use the definition on the granted certificate)

6. Number, title and expiry date of the basic patent (GB or EP(UK)).

Number

Title

Expiry date

(day/month/year)

7. Number and date of the authorization containing the statement of compliance with an agreed completed paediatric investigation plan as referred to in Article 36(1) of Regulation (EC) No 1901/2006. Include the state if necessary.

State and Number

Date

(day/month/year)

Form SP4

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8. Indicate whether the product has been authorized in all member states by
- (a) an authorization issued by the EMEA in accordance with Directive 2001/83/EC
 - or
 - (b) by national authorizations granted by each member state
- (Article 8(1)(d)(ii) of the EC Regulation)*
- (Answer by writing (a) or (b) as appropriate)*

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9. State which of the following documents you are filing, *(Answer by writing (a) - (d) as appropriate)*
- (a) Copy of the statement or a copy of the authorization containing the statement indicating compliance with an agreed completed paediatric investigation plan referred to in 7
(Article 8(1)(d)(i) of the EC Regulation)
 - (b) Copy of the authorization(s) or notice(s) publishing the authorization(s) referred to in 8
(Article 8(1)(d)(ii) of the EC Regulation)
 - (c) Copy of the granted certificate referred to in 2 (if applicable)
(Article 8(1b) of the EC Regulation)
 - (d) Other *(please specify)*

10. I/We request the grant of an extension of a certificate on the basis of this application.	Signature	Date
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11. Name, e-mail address, telephone, fax and / or mobile number, if any, of a contact point for the applicant.

Reminder

Documents relating to an application for a certificate will normally be open to public inspection. If you want us to keep copies of any documents such as marketing authorizations (or parts of them) confidential, you must ask for this on filing or sending the document. You must give reasons for your request.

Notes

- a) If you need help to fill in this form or you have any questions, please contact the Office on 08459 500505.
- b) Write your answers in capital letters using black ink or you may type them.
- c) If there is not enough space for all the relevant details on any part of this form, please continue on a separate sheet of paper and write "see continuation sheet" in the relevant part(s). Any continuation sheet should be attached to this form.
- d) Although you may have an address for service in the Channel Islands, any agent you appoint to act for you must reside in or have a place of business in the European Economic Area or Isle of Man.
- e) Once you have filled in the form remember to sign and date it.
- f) For details of the fee and ways to pay please contact the Office.