



BROCHURE SUPPLEMENTARY PROTEC- TION CERTIFICATES (SPC)

In this brochure:

Supplementary Protection Certificates (SPC)

Extension of the term of patents

Applying for a certificate

Additional extension for medicinal products for pediatric use

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Supplementary Protection Certificates (SPC)

Extension of the term of patents

Supplementary protection certificates can be granted for a product, meaning the active ingredient or combination of active ingredients of medicinal products or plant protection products, protected by a patent. A requirement for obtaining a supplementary protection certificate is that an authorization to place the product on the market as a medicinal product or plant protection product has been granted. Supplementary protection certificates extend the term of patents by a maximum of 5 years. Supplementary protection certificates are granted on the basis of a European Regulation. The certificate is restricted to the product for which the authorization was granted. Under one patent several certificates for different products may be granted. For one product several certificates may be granted to different owners of different patents.

Applying for a certificate

Supplementary protection certificates have to be applied for within 6 months after the date of granting the authorization or the grant of the patent in case the authorization was granted earlier on. The application for a supplementary protection certificate has to be filed with the Dutch Patent Office, which examines whether the application meets the requirements of the Regulation. These requirements are that on the date of the application the product is protected by a valid basic patent, a valid authorization to place the product on the market in accordance with Directive 2001/83/EC or Directive 2001/82/EC (medicinal products) or Directive 91/414/EEC (plant protection products), the product has not already been the subject of a certificate and the authorization mentioned above is the first authorization to place the product on the market as a medicinal product or plant protection product. The duration of the certificate is based on the date of granting the first authorization to place the product on the market as a medicinal product or plant protection product in the European Economic Area (EEA). The certificate is valid from the end of the legal term of the basic

patent, and has a duration that equals the period which elapsed between the date of applying for the basic patent and the date of the first authorization in the EEA, with a maximum duration of 5 years.

Additional extension for medicinal products for pediatric use

For medicinal products for which the use in the pediatric population has been studied, the term of a supplementary protection certificate can be extended by 6 months. Extension of a supplementary protection certificate has to be applied for with the Dutch Patent Office. Extension can be filed for simultaneously with the certificate or after filing the application for the certificate, but has to be filed ultimately 6 months (2 years as from 2012) before expiration of the certificate.