

Send the request by mail, e-mail or fax to:
Läkemedelsverket / Medical Product Agency
Kanslienheten/ Registrations office
Box 26
S-751 03 Uppsala
Sweden
Fax. +46 (18) 54 85 66
Tel. + 46 (18) 17 46 00
registrator@mpa.se

Medical Products Agency Request for certificate of a pharmaceutical product¹

Information	
No. of Certificates requested:	Importing (requesting) country:
Asp. number:	1. Name, dosage form and strength of the medicinal product:
2A.1 Marketing Authorisation number ²	2A.2 Marketing Authorisation Holder (name and address):
2A.3 Status of the Marketing Authorisation Holder ³ a b c d (key in the appropriate category as defined in note 3)	
2A.3.1 For categories b, c and d the name and address (street address and postal address as stated in the Manufacturing Authorisation) of the manufacturing site producing the dosage form are: ⁴	
2A.5 If any additional information is requested to the ordinary certificate, the Medical Products Agency encloses a Summary of Product Characteristics (SPC). See further in note 5. SPC enclosed to the certificate? Yes No	
2A.6 Applicant for certificate if different from Marketing Authorisation Holder (name and address): ⁶	

Requesting company		
Contact person:		Address:
Phone number:	Fax number:	

Signature
I hereby verify that the above mentioned information is correct.

Explanatory notes

1. This certificate, which is in the form recommended by WHO, establishes the status of the medicinal product and of the applicant for the certificate in Sweden. It is for a single product only since manufacturing arrangements and approved information for different dosage forms and different strengths can vary.
2. Indicate, when applicable, if the Marketing Authorisation is provisional.
3. Specify whether the person responsible for placing the product on the market:
 - (a) manufactures the dosage form;
 - (b) packages and/or labels a dosage form manufactured by an independent company; or
 - (c) is not involved in manufacturing, packaging or labelling but is responsible for the quality and release of the product.
 - (d) is involved in none of the above.

4. This information can be provided only with the consent of the Marketing Authorisation Holder. Non-completion of this section indicates that the party concerned has not agreed to inclusion of this information.

It should be noted that information concerning the site of production is part of the Marketing Authorisation. If the production site is changed, the Marketing Authorisation must be updated or it will cease to be valid.

5. No additional information (e.g. indication, pack size, shelf life etc.) is provided on the certificate, but the Medical Products Agency can enclose the latest approved Summary of Product Characteristics (SPC) in which such information is to be found. The box marked "Yes" should be marked in this case.

It should be noted that, if the Medical Products Agency has approved only the Swedish SPC, it is the applicant's responsibility to translate the latest approved SPC into English by using an Authorised Translator. (i.e. that the applicant assumes the whole responsibility for the accuracy of the translation of the text from Swedish into English.) The translation should be enclosed to the request of the certificate.

6. In this circumstance, permission for issuing the certificate is required from the Marketing Authorisation Holder. This permission must be provided to the authority by the applicant.