General instructions

Please refer to the guidelines for full instructions on how to complete this form and information on the implementation of the scheme.

The forms should always be submitted as hard copy, with responses printed in type rather than hand-written.

Additional sheets should be appended, as necessary, to accommodate remarks and explanations.

Explanatory notes

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[1] This Certificate, which is in the format recommended by WHO, establishes the status of the medicinal product and of the applicant for the Certificate in the exporting country at the time of issue. It is for a single product at a given point in time since manufacturing arrangements and approved information for different dosage forms and different strengths can vary.

[2] Whenever possible, International Non-proprietary Names (INNs) or national non-proprietary names are used.

[3] The formula (complete composition) of the dosage form should be stated on the certificate or be appended.

[4] Provision of the details of quantitative composition is attached on request of the Marketing Authorisation Holder / Export License Holder.

[5] When applicable, append details of any restriction applied to the sale, distribution or administration of the product that is specified in the Marketing Authorisation /Export License.

[6] Not applicable.

[7] The Marketing Authorisation No. or Export License No. granted by the Danish Medicines Agency (if neither, use CPP-2). Indicate, when applicable, if the Marketing Authorisation has been granted under exceptional circumstances or if the product has not yet been approved.

[8] The company responsible for placing the product on the market:

(a) manufactures the pharmaceutical form;
(b) packages and/or labels a pharmaceutical form manufactured by an independent company;
(c) releases only; or
(d) is involved in none of the above.

[9] This information can only be provided with the consent of the Marketing Authorisation Holder or, in the case of non-registered products, the applicant. Non-completion of this section (2.3.1) 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/export license. If the production site is changed, the authorisation/license has to be updated or it is no longer valid.

[10] This refers to the document published by EMA that summarises the technical basis on which the product has been authorised.

[11] This refers to the product information which forms a part of the Marketing Authorisation such as the Summary of Product Characteristics (SPC).

[12] In this circumstance, permission for issuing the certificate is required from the Marketing Authorisation Holder / Export License Holder. This permission has to be provided to the DMA by the applicant.

[13] (Relevant for CPP-2 only). The reason why the product does not have a Marketing Authorisation / Export License, e.g.:

(a) the product has been developed exclusively for the treatment of conditions – particularly tropical diseases – not endemic in the country of export;
(b) the product has been reformulated with a view to improving its stability under tropical conditions;
(c) the product has been reformulated to exclude excipients not approved for use in pharmaceutical products in the country of import;
(d) the product has been reformulated to meet a different maximum dosage limit for an active ingredient;
(e) any other reason, as specified.

[14] "Not applicable" means the manufacture is taking place in a country other than Denmark and inspection is conducted under the aegis of the country of manufacture.

[15] The requirements for good practices in the manufacture and quality control of medicinal products referred to in the Certificate are those included in the thirty-second report of the Expert Committee on Specifications for Pharmaceutical Preparations (WHO Technical Report Series No 823, 1992, Annex 1). Recommendations specifically applicable to biological products have been formulated by the WHO Expert Committee on Biological Standardization (WHO Technical Report Series, No 822, 1992, Annex 1).

[16] This section is to be completed when the Marketing Authorisation Holder / Export License Holder or applicant conforms to status (b), (c) or (d) as described in note 8 above. It is of particular importance when foreign contractors are involved in the manufacture of the product. In these circumstances the applicant should supply the Certifying Authority with information to identify the contracting parties responsible for each stage of manufacture of the pharmaceutical form, and the extent and nature of any controls exercised over each of these parties.