Notes for applicants concerning the issuance of WHO Certificates of pharmaceutical products (CPPs)

Pursuant to Section 73a subsection 2 of the AMG (German Medicines Act), the Paul-Ehrlich-Institut (PEI) issues certificates in accordance with the certification system of the World Health Organization (WHO) upon request for pharmaceutical companies with registered office outside the territory in which the AMG is applicable.

The Paul-Ehrlich-Institut only confirms information that falls within the remit of the Paul-Ehrlich-Institut and that is relevant for the marketing authorisation process in Germany. This means that “not applicable” must be selected in section 3 of the CPP template (Does the certifying authority arrange for periodic inspection of the manufacturing plant in which the of the dosage form is produced?), since the information in question is related to Good Manufacturing Practice (GMP).

For the certification of section 3 the application must be submitted to the competent authority. If the manufacturing site is located within Germany, the certification of section 3 is performed by the competent authority of the respective German federal state (BundesLand).

Please note the following information:

- The applicant must submit all documents relevant for the decision on issuing the WHO certificate.
- In cases where a representative submits the certificate application, consent from the marketing authorisation holder is required. The appropriate power of attorney must be submitted in writing.
- The certifying authority must ensure that the information provided is accurate and up-to-date.
- The content of the certificates is prepared by the applicant. Please use the CPP templates on the Paul-Ehrlich-Institut’s website.
- A separate certificate application must be submitted for each distinguishable product (per marketing authorisation number) and for each importing country.
- The requirements of the WHO template must be complied with. Non-relevant passages in the text must not be omitted, i.e. empty fields in sections where no statement can or must be made should be left blank.
- Annexes belonging to the certificate must be attached in a neutral form (without the company logo; this does not apply to samples, e.g. the package leaflet) and must be in German. Attachments in an additional WHO language (English, French, Spanish) can also be provided.
- Each pre-filled CPP must be packaged in a separate ZIP file together with the appropriate annexes (if required).
- Please send the prepared certificates to: eSubmission@pei.de
- The official language is German pursuant to Section 23 of the Verwaltungsverfahrensgesetz (Administrative Procedure Act). The part of the synoptically structured certificate prepared in a language other than German (corresponding to an official WHO translation) will not be signed or stamped/sealed by the authority (see also section 3.10 of the WHO Guidelines). The issuance of a synoptically structured certificate for which the WHO does not offer an official translation is possible upon submission of a translation by a state certified translator, whose signature must be notarised. The “General

Instructions" and "Explanatory Notes" are an integral part of all certificates and must always be attached.

- Information on the international communication of documents can be found on the web pages of the German Federal Foreign Office (Auswärtiges Amt) under this link.

Please also note the General Instructions and Explanatory Notes on the individual points in the annex to the WHO certificate and the WHO Guidelines.