99005105000000

WHO Certificate (CPP) for the export of medicinal products for human use

Modul	Sachverhalt
Leistungsschlüssel	99005105000000
Leistungsbezeichnung I	WHO Certificate (CPP) for the export of medicinal products for human use
Leistungsbezeichnung II	Application for a WHO certificate (CPP) for the export of pharmaceuticals
Typisierung	2a - Bundesauftragsverwaltung: Regelung, Land: Vollzug
Quellredaktion	Hamburg
Freigabestatus Katalog	unbestimmter Freigabestatus
Freigabestatus Bibliothek	unbestimmter Freigabestatus
Begriffe im Kontext	Certificate for export of medicines , Export Certificate WHO , WHO certificate for export
Leistungstyp	

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Leistungsgruppierung	
Verrichtungskennung	
SDG-Informationsbereich	
Lagen Portalverbund	
Einheitlicher Ansprechpartner	Nein
Fachlich freigegeben am	04.12.2023
Fachlich freigegen durch	
Handlungsgrundlage	[§ 73a AMG Medicines Act](https://www.gesetze-im-internet.de/amg_1976/__73a.html) [§ 77 AMG Medicines Act](https://www.gesetze-im-internet.de/amg_1976/__77.html)
Teaser	To export a medicinal product approved in Germany to a country outside the EU, you need a certificate issued in accordance with the recommendations of the World Health Organization (WHO).
Volltext	Germany participates in the "Certification System of the World Health Organization (WHO) for the Quality of Pharmaceutical Products in International Trade". Certificates under this system attest to the marketability of the medicinal product in the country of origin and serve to facilitate the movement of medicinal products. In principle, the certificates are issued by the competent authority of the federal state in which the holder of the drug's authorization is based and authorized (exporting country) in accordance with Section 73a Paragraph 2 AMG. For drugs manufactured outside Germany, only authorization-related information can be certified. In this case, the GMP information is certified in the country of manufacture (GMP - Good Manufacturing Practice). The WHO certificate with GMP information certifies that the drug complies with the "WHO's Basic Rules for the

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	Manufacture of Drugs and the Assurance of Their Quality". If it is a matter of confirming information related to the authorisation and the authorisation holder is based outside Germany, the higher federal authorities are responsible for issuing the WHO certificates. A WHO certificate can be used by the competent authorities of importing third countries in the following regulatory situations: • in the context of authorisation applications • in the context of applications for renewal, extension, amendment or review of an authorisation • when importing medicinal products approved in the exporting country WHO certificates can be applied for by the marketing authorisation holder or the pharmaceutical company or the competent authority of the country of destination. Furthermore, a certificate can also be issued to other applicants if there is a legitimate interest in this. A power of attorney from the marketing authorisation holder is required in these cases. To do so, you must submit all the documents required for the decision on issuing the WHO certificate. Before a WHO certificate is issued, the certifying authority checks the information for accuracy and timeliness.
Erforderliche Unterlagen	• A completed WHO Certificate for Pharmaceutical Products (CPP) • Declaration that no changes have been made outside the fields provided in the submitted form (only in the case of a paper-based application) • Where applicable, the product or product information approved by the competent national regulatory authority • If applicable, the summary of the authorization basis • If applicable, the declaration of consent of the marketing authorisation holder (power of attorney)

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Voraussetzungen	• You must be the marketing authorisation holder or pharmaceutical company, the competent authority of the country of destination or an applicant with a legitimate interest (for example, manufacturer or co-distributor). • If you are not the marketing authorisation holder of the medicinal product, a power of attorney from the marketing authorisation holder is required.
Kosten	There is an administration fee, which varies depending on the responsible authority.
Verfahrensablauf	• Depending on the responsible authority, you have the option of submitting the application via the online form or in writing. • If you submit the application using the online form, you submit the data from the online application, the WHO certificate automatically generated from it and the required attachments to the automatically determined competent authority online. • If you instead apply for the certificate in writing, send the completed WHO draft with the required documents by post or, if necessary, by email to the responsible authority. • The application and documents are checked for accuracy and completeness. If the legal requirements are met and all information is correct and up to date, the WHO certificate is issued. • A different office in Hamburg is responsible for additional certifications (apostilles). Please apply for these separately there. • You will receive the requested certificate and the fee notice by post. Payment is made retrospectively (transfer after receipt of the fee notice)
Bearbeitungsdauer	Processing time is two to four weeks.
Frist	No
weiterführende Informationen	https://www.zlg.de/arzneimittel/service/dokumente https://www.zlg.de/arzneimittel/service/dokumente
Hinweise	• The applicant must submit all documents and information relevant to the decision on the issuance of the WHO certificate.

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	• In cases where an authorised person applies for a WHO certificate, the consent of the marketing authorisation holder is required. A corresponding written authorisation must be submitted. • In the case of a paper-based application, a separate certificate must be applied for for each medicinal product, i.e. for each authorisation number and for each importing country. • The requirements of the WHO template must be followed. Irrelevant passages in the text must not be omitted, i.e. empty fields in sections on which no statement can or should be made are left blank. Additions for the sake of transparency (e.g. trade name in the recipient country) can be included in an appendix if necessary. • For applications that are not submitted via the online application tool, a declaration must be submitted that no changes have been made outside of the designated fields of the submitted form. • In the case of online application, it is possible for you to directly apply for WHO certificates for “several” importing countries for “one” medicinal product approval number. • Attachments to the certificate must be enclosed in a neutral form (without company logo; does not apply to samples, e.g. the instructions for use) and at least in German. Another official WHO language (English, French, Spanish) can be considered. The required forms can be found on the ZLG website (see further information). • The certifying authority must ensure that the information is correct and up-to-date. • The official language is German according to Section 23 of the Administrative Procedure Act. The foreign language part (according to the official WHO translation) of the synoptically structured certificate is neither signed, sealed nor stamped by the authority (see also Section 3.10 of the WHO guidelines). The issuance of a synoptically structured certificate in a language for which the WHO does not offer an official translation is possible upon presentation of a translation by a state-recognized translator, whose signature must be notarized. • The "General Information" and "Explanations" are part of every certificate and must always be included.

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	Please also note the explanations for the individual numbers in the appendix to the WHO certificate as well as the WHO guidelines. • The declaration of the authorisation status for one or more pharmaceutical products is not the subject of this application procedure. • Batch certificates for pharmaceutical products are not the subject of this application process. Such a certificate is applied for by the manufacturer and is only issued by the federal authority carrying out the batch testing, the Paul Ehrlich Institute (PEI), if state batch testing is required and carried out for the product. Information about batch testing can be found on the PEI website: [https://www.pei.de/](https://www.pei.de/DE/home/home-node.html)
Rechtsbehelf	An appeal against this decision may be filed with the administrative court (depending on the registered office of the authorisation holder or applicant) within one month of notification.
Kurztext	• Applying for a WHO certificate (CPP) • Application for the issuance of a certificate in accordance with the certificate system of the World Health Organization (WHO) for authorisation purposes in a third country. • The jurisdiction depends on the registered office of the marketing authorization holder / pharmaceutical company
Ansprechpunkt	
Zuständige Stelle	Justice and Consumer Protection Authority
Formulare	
Ursprungsportal	Hamburg Service, Hamburg Service (Currently this link is only available in german)