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Apply for a certificate for a pharmaceutical product (CPP) in accordance with the World Health Organization (WHO) certification system for the export of medicinal products for human use

Heruntergeladen am 08.06.2025

<https://fimportal.de/xzufi-services/9747887/L100001>

Modul	Sachverhalt
Leistungsschlüssel	99005105012000, 99005105012000
Leistungsbezeichnung I	Apply for a certificate for a pharmaceutical product (CPP) in accordance with the World Health Organization (WHO) certification system for the export of medicinal products for human use
Leistungsbezeichnung II	
Typisierung	1 - Bund: Regelung und Vollzug, 3 - Bundesaufsichtsverwaltung: Regelung
Quellredaktion	Hessen
Freigabestatus Katalog	unbestimmter Freigabestatus

Modul	Sachverhalt
Freigabestatus Bibliothek	unbestimmter Freigabestatus
Begriffe im Kontext	
Leistungstyp	Leistungsobjekt mit Verrichtung
Leistungsgruppierung	Arzneimittel (005)
Verrichtungskennung	Ausstellung (012)
SDG-Informationsbereich	
Lagen Portalverbund	
Einheitlicher Ansprechpartner	Nein
Fachlich freigegeben am	29.09.2022
Fachlich freigegeben durch	Hessian Ministry for Social Affairs and Integration (HMSI)
Handlungsgrundlage	https://www.gesetze-im-internet.de/amg_1976/_73a.html https://www.gesetze-im-internet.de/amg_1976/_73a.html
Teaser	To export a medicinal product for human use approved in Germany to a country outside the EU, you need the WHO certificate, which is issued in accordance with the specifications of the World Health Organization (WHO).
Volltext	<p>Germany participates in the "World Health Organization (WHO) certification system for the quality of pharmaceutical products in international trade". Certificates under this system certify the marketability of the medicinal product for human use in the country of origin and serve to facilitate the movement of medicinal products.</p> <p>In principle, the certificates are issued by the competent authority of the federal state in which the medicinal product is manufactured and authorized (exporting country) in accordance with Section 73a (2) AMG. For medicinal products manufactured outside Germany, only authorization-related information can</p>

Modul

Sachverhalt

be certified. In this case, the GMP (Good Manufacturing Practice) information is certified in the country of manufacture. The WHO certificate with GMP information certifies that the medicinal product complies with the "WHO principles for the manufacture of medicinal products and the assurance of their quality".

If it concerns the confirmation of marketing authorization-related information and the marketing authorization holder is based outside Germany, the higher federal authorities are responsible for issuing 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 applications for marketing authorization
- in the context of applications for renewal, extension, modification or review of a marketing authorization
- for the import of medicinal products authorized in the exporting country

WHO certificates can be applied for by the marketing authorization holder (pharmaceutical company), by the manufacturer, by the exporter of the medicinal product authorized in Germany or by the competent authority of the country of destination. You must submit all documents required for the decision to issue the WHO certificate.

Before a WHO certificate is issued, the certifying authority checks the information for accuracy and completeness.

Erforderliche Unterlagen

- The content of the prepared WHO Certificate for Pharmaceutical Products (CPP)
 - Declaration that no change has been made outside the fields provided in the form on file (only in the case of a paper-based application)
 - If applicable, the package leaflet/information leaflet

Modul
Sachverhalt

approved by the competent national supervisory authority

- Complete composition of the pharmaceutical form, if applicable
- Summary of the basis for authorization, if applicable
- If an authorized representative is applying for the certificate, declaration of consent of the marketing authorization holder (power of attorney)

Voraussetzungen

- You must be the marketing authorization holder, manufacturer or a person or authority of the country of destination authorized by the marketing authorization holder.
- If you are not the marketing authorization holder, the permission of the marketing authorization holder/authorized representative is required.

Kosten

- The administrative fee varies depending on the competent authority.
- Additional costs are incurred depending on the type of additional certification requested.

Verfahrensablauf

- Depending on the competent 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 automatically generated WHO certificate and the required attachments to the automatically determined competent authority online.
- In the case of a paper-based application, send the completed WHO draft with the required documents by post and, if necessary, also by email to the competent authority.
- The application and documents will be checked for accuracy and completeness. If the legal requirements are met and all information is correct and up-to-date, the WHO certificate will be issued.
- If the service is offered by the competent authority and you have also applied for over-certification, the requested over-certification will be carried out.
- You will receive the requested certificate and the fee notice by post.
- Payment is made afterwards (bank transfer after receipt of the fee notice)

Modul	Sachverhalt
Bearbeitungsdauer	As soon as the required documents are complete and correct, the certificate is usually issued within 2 to 4 weeks of the application. after the application is submitted. If special additional certifications have been applied for, the processing time is not included.
Frist	
weiterführende Informationen	
Hinweise	https://www.auswaertiges-amt.de/de/service/fragenkatalog-node/12-apostille-ausl/606196 https://www.bfarm.de/DE/Arzneimittel/Zulassung/Zulassungsrelevante-Themen/Ausstellung-von-WHO-Zertifikaten/_artikel.html https://www.pei.de/DE/regulation/zulassung-human/who-zertifikate/who-zertifikate-node.html https://www.auswaertiges-amt.de/de/service/fragenkatalog-node/12-apostille-ausl/606196 https://www.bfarm.de/DE/Arzneimittel/Zulassung/Zulassungsrelevante-Themen/Ausstellung-von-WHO-Zertifikaten/_artikel.html https://www.pei.de/DE/regulation/zulassung-human/who-zertifikate/who-zertifikate-node.html
Rechtsbehelf	An appeal against this decision may be lodged with the competent administrative court (depending on the registered office of the authorization holder or applicant) within one month of notification.
Kurztext	<ul style="list-style-type: none"> • Export of medicinal products Certification <ul style="list-style-type: none"> • Application for the issue of a certificate in accordance with the World Health Organization (WHO) certificate system. <ul style="list-style-type: none"> • It may be necessary for the export of a medicinal product or for authorization purposes in a third country. <ul style="list-style-type: none"> • Online or written application procedure • In the case of state authorities, responsibility depends on the registered office of the marketing authorization holder (pharmaceutical company) or the manufacturer or exporter. In the case of federal authorities, the responsibility depends on the type of medicinal product that justifies the responsibility of the

Modul	Sachverhalt
	respective higher federal authority.
Ansprechpunkt	Please contact the Hessian State Office for Health and Care (HLfGP). https://hlfgp.hessen.de/ https://hlfgp.hessen.de/
Zuständige Stelle	Hessian State Office for Health and Care
Formulare	Forms available: Yes Written form required: No Informal application possible: No Personal appearance necessary: No Online services available: Yes https://www.zlg.de/arzneimittel/service/dokumente https://www.zlg.de/arzneimittel/service/dokumente
Ursprungsportal	Apply for a certificate for a pharmaceutical product (CPP) in accordance with the World Health Organization (WHO) certification system for the export of medicinal products for human use, Zertifikat für ein pharmazeutisches Produkt (CPP) entsprechend dem Zertifikatsystem der Weltgesundheitsorganisation (WHO) für die Ausfuhr von Humanarzneimitteln beantragen