99005105012000, 99005105012000

Apply for a WHO certificate (CPP) for the export of medicinal products

Modul	Sachverhalt
Leistungsschlüssel	99005105012000, 99005105012000
Leistungsbezeichnung I	Apply for a WHO certificate (CPP) for the export of medicinal products
Leistungsbezeichnung II	
Typisierung	1 - Bund: Regelung und Vollzug, 3 - Bundesaufsichtsverwaltung: Regelung
Quellredaktion	Rheinland-Pfalz
Freigabestatus Katalog	unbestimmter Freigabestatus
Freigabestatus Bibliothek	unbestimmter Freigabestatus
Begriffe im Kontext	
Leistungstyp	Leistungsobjekt mit Verrichtung
Leistungsgruppierung	Arzneimittel (005)
Verrichtungskennung	Ausstellung (012)
SDG-Informationsbereich	

Modul	Sachverhalt
Lagen Portalverbund	Import und Export (2070200)
Einheitlicher Ansprechpartner	Nein
Fachlich freigegeben am	02.12.2024
Fachlich freigegen durch	Ministry of Science and Health Rhineland-Palatinate
Handlungsgrundlage	https://www.gesetze-im-internet.de/amg_1976/__73a.html https://www.gesetze-im-internet.de/amg_1976/__77.html https://eur-lex.europa.eu/legal-con-tent/DE/TXT/PDF/?uri=CELEX%3A32019R0006&from=DE+ https://www.gesetze-im-internet.de/amg_1976/__73a.html https://www.gesetze-im-internet.de/amg_1976/__77.html https://eur-lex.europa.eu/legal-con-tent/DE/TXT/PDF/?uri=CELEX%3A32019R0006&from=DE+
Teaser	To export a medicinal product approved in Germany to a country outside the EU, you need the certificate issued in accordance with the recommendations of the World Health Organization (WHO).
Volltext	Germany participates in the "World Health Organization (WHO) Certificate System on the Quality of Pharmaceutical Products in International Trade". Certificates under this system certify 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 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 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 medicinal product complies with the "WHO principles for the manufacture of medicinal products and the assurance of their

Modul	Sachverhalt
	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), the manufacturer or the exporter of the medicinal product authorized in Germany. 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 WHO Certificate for Pharmaceutical Products (CPP) prepared in terms of content • Declaration that no changes have been made outside the fields provided in the deposited form (only in the case of a paper-based application) • If applicable, the product / product information 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 from the marketing

Modul	Sachverhalt
	authorization holder
Voraussetzungen	• You must be the marketing authorization holder, manufacturer or another person 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	Gebühr: 106€ Additional costs will be incurred depending on the type of additional notarization 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 are 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 notification of fees (invoice) by post. • Payment is made afterwards (bank transfer after receipt of the fee notice)
Bearbeitungsdauer	2 - 4 Stunde(n)
Frist	There is no legal deadline.
weiterführende Informationen	
Hinweise	https://www.zlg.de/arzneimittel/service/dokumente

Modul	Sachverhalt
	https://www.auswaertiges-amt.de/de/service/fragenkatalog-node/12-apostille-ausl/606196 https://www.bfarm.de/DE/Arzneimittel/Arzneimittelzulassung/ZulassungsrelevanteThemen/WHO-Zertifikate/_node.html https://www.pei.de/DE/regulation/zulassung-human/who-zertifikate/who-zertifikate-node.html https://www.zlg.de/arzneimittel/service/dokumente
Rechtsbehelf	Appeal within one month, see legal remedy in the decision
Kurztext	
Ansprechpunkt	State Office for Social Affairs, Youth and Care
Zuständige Stelle	
Formulare	Forms available: Yes Written form required: No Informal application possible: No Personal appearance necessary: No Online services available: Yes
Ursprungsportal	WHO-Zertifikat (CPP) für die Arzneimittelausfuhr beantragen, Apply for a WHO certificate (CPP) for the export of medicinal products