99005105012002, 99005105012002

WHO certificate (CPP) for the export of medicinal products for human use Issued to domestic marketing authorization holders

Modul	Sachverhalt
Leistungsschlüssel	99005105012002, 99005105012002
Leistungsbezeichnung I	WHO certificate (CPP) for the export of medicinal products for human use Issued to domestic marketing authorization holders
Leistungsbezeichnung II	
Typisierung	3 - Bundesaufsichtsverwaltung: Regelung
Quellredaktion	Thüringen
Freigabestatus Katalog	unbestimmter Freigabestatus
Freigabestatus Bibliothek	unbestimmter Freigabestatus
Begriffe im Kontext	
Leistungstyp	Leistungsobjekt mit Verrichtung
Leistungsgruppierung	Arzneimittel (005)

Modul	Sachverhalt
Verrichtungskennung	Ausstellung (012)
SDG-Informationsbereich	
Lagen Portalverbund	Import und Export (2070200), Verbraucherschutz (2140100)
Einheitlicher Ansprechpartner	Nein
Fachlich freigegeben am	04.12.2023
Fachlich freigegen durch	Thuringian Ministry of Labor, Social Affairs, Health, Women and Family
Handlungsgrundlage	https://www.gesetze-im-internet.de/amg_1976/__73a.html https://www.gesetze-im-internet.de/amg_1976/__73a.html
Teaser	Do you need a WHO certificate for the export of pharmaceutical products? You can apply for this from the competent authority.
Volltext	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 requirements of the World Health Organization (WHO). Germany participates in the "World Health Organization (WHO) Certificate System on the Quality of Pharmaceutical Products in International Trade". Certificates according to 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. 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). For medicinal products manufactured outside Germany, only authorization-related information can be certified. In this case, the GMP (Good Manufacturing Practice) information is certified in the country of manufacture.

Modul	Sachverhalt
	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". A WHO certificate can be used by the competent authorities of importing third countries in the following regulatory situations: • in the context of marketing authorization applications • in the context of applications for renewal, extension, variation or review of a marketing authorization • for the import of medicinal products authorized in the exporting country
Erforderliche Unterlagen	• Fully completed certificate template • Instructions for use or technical information on the product as an attachment (if required)
Voraussetzungen	• Marketing authorization holder, manufacturer and exporter according to the German Medicines Act based in Thuringia • Competent authority in the country of destination • Application using the WHO certificate templates
Kosten	Gebühr: 125€ https://landesrecht.thueringen.de/bsth/document/jlr-SozMinVwKostOTHrahmen
Verfahrensablauf	• At the Thuringian State Office for Consumer Protection (TLV), you have the option of submitting the application via the online form or in writing. • If you submit the application via the online form, the data will be used automatically to create the WHO certificate and the attachments. • In the case of a paper-based application, send the completed WHO draft certificate with the required documents to the TLV by post and, if necessary, also by email. • 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 you apply for over-certification, your application will be forwarded to the competent authority.

Modul	Sachverhalt
	• You will receive the requested certificate and the fee notice by post. • Payment is made afterwards (bank transfer after receipt of the fee notice).
Bearbeitungsdauer	6 - 12 Woche(n)
Frist	
weiterführende Informationen	https://www.bfarm.de/SharedDocs/Downloads/DE/Arzneimittel/Zulassung/ZulRelThemen/whoZertifikate/WHOZertifikatpharmazeutischeProdukteCPPDeEn.html https://www.bfarm.de/SharedDocs/Downloads/DE/Arzneimittel/Zulassung/ZulRelThemen/whoZertifikate/WHOZertifikatpharmazeutischeProdukteCPPDeEn.html
Hinweise	
Rechtsbehelf	Contradiction
Kurztext	• WHO certificate (CPP) for the export of medicinal products for human use Issued to domestic marketing authorization holders
Ansprechpunkt	Please contact the Thuringian State Office for Consumer Protection (TLV) - Pharmacy Department.
Zuständige Stelle	
Formulare	
Ursprungsportal	WHO certificate (CPP) for the export of medicinal products for human use Issued to domestic marketing authorization holders, WHO-Zertifikat (CPP) für die Ausfuhr von Arzneimitteln zur Anwendung bei Menschen Ausstellung bei inländischen Zulassungsinhabern