99005105012002, 99005105012002

Apply for a WHO certificate for the export of medicinal products for human use if the marketing authorization holder is based in Germany

Modul	Sachverhalt
Leistungsschlüssel	99005105012002, 99005105012002
Leistungsbezeichnung I	Apply for a WHO certificate for the export of medicinal products for human use if the marketing authorization holder is based in Germany
Leistungsbezeichnung II	Apply for a WHO certificate for the export of medicinal products for human use if the marketing authorization holder is based in Germany
Typisierung	3 - Bundesaufsichtsverwaltung: Regelung
Quellredaktion	Sachsen-Anhalt
Freigabestatus Katalog	unbestimmter Freigabestatus
Freigabestatus Bibliothek	unbestimmter Freigabestatus
Begriffe im Kontext	

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Leistungstyp	Leistungsobjekt mit Verrichtung
Leistungsgruppierung	Arzneimittel (005)
Verrichtungskennung	Ausstellung (012)
SDG-Informationsbereich	
Lagen Portalverbund	Import und Export (2070200)
Einheitlicher Ansprechpartner	Nein
Fachlich freigegeben am	
Fachlich freigegen durch	
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	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 the German Medicinal Products Act. For medicinal products manufactured outside Germany, 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's basic rules for the manufacture of medicinal products and the assurance

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	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 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. The WHO certificate is issued synoptically and bilingually in the following official languages: German and one of the following second languages: English, French or Spanish. The authority will only authenticate the German part of the WHO certificate. Depending on the competent authority, you can apply for one or more additional services (legalization with apostille or legalization/sealing with thread) for the certificate when applying for the certificate.
Erforderliche Unterlagen	The application can be submitted online or in writing: • In the case of an application via online service, the form will advise you of necessary supporting documents according to the information you have provided and offer an option to upload them. • In the case of a paper-based application: the WHO Certificate for Pharmaceutical Products (CPP) prepared in terms of content Declaration that no changes have

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	been made outside the fields provided in the deposited form • Optional documents for both application options: the instructions for use/technical information approved by the competent national supervisory authority Product information in English complete composition of the pharmaceutical form Summary of the basis for authorization Evidence of inspection relating to the manufacture of the dosage form type (GMP certificate) Notarized translations as part of further evidence • Application by proxy: If an authorized representative applies for the certificate, declaration of consent of the marketing authorization holder (power of attorney)
Voraussetzungen	• You must be an institution involved in the manufacturing process, for example the manufacturer of the dosage form. • You must submit all documents and information relevant to the decision on issuing the WHO certificate. • Attachments belonging to the certificate must be enclosed in 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 homepage of the Central Office of the Federal States for Health Protection with regard to Medicinal Products and Medical Devices (ZLG). • For applications that are not submitted via the online application tool: You submit a declaration that no changes have been made outside of the fields provided on the deposited form. You comply with the WHO template. Non-relevant passages in the text may not be omitted, i.e. empty fields in sections where no statement can or should be made remain blank. Additions for the sake of transparency (such as the trade name in the recipient country) can be included in an annex. The "General notes" and "Explanatory notes" are part of each certificate and must always be attached. Please also note the explanations of the individual sections in the annex to the WHO certificate and the WHO guidelines.
Kosten	• The administrative fee varies depending on the competent authority.

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	• Additional costs are incurred depending on the type of additional services applied for.
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 via the online form, you submit the data from the online application, the automatically generated WHO certificate and the required attachments online to the automatically determined competent authority. • In the case of a paper-based application, send the completed WHO draft with the required documents by post or e-mail 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 this has been applied for, the requested over-certification/sealing with thread is carried out. • You will receive the requested certificate and the fee notice by post or, in the case of authentication with My Business Account (MUK), in the digital inbox of your MUK account. • Payment is made retrospectively (after receipt of the fee notice).
Bearbeitungsdauer	As soon as the required documents are complete and correct, the certificate is usually issued within 2 to 4 weeks of the application being submitted. Additional services applied for are not included in the above information on processing time.
Frist	none
weiterführende Informationen	https://www.auswaertiges-amt.de/de/service/fragenkatalog-node/12-apostille-ausl/606196 https://www.zlg.de/arzneimittel/service/dokumente https://www.auswaertiges-amt.de/de/service/fragenkatalog-node/12-apostille-ausl/606196 https://www.zlg.de/arzneimittel/service/dokumente
Hinweise	The following information is available: • In the case of online applications, it is possible to

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	apply directly for WHO certificates for several importing countries for one medicinal product. • In the case of a paper-based application, a separate certificate must be applied for per medicinal product, i.e. per authorization number, and per importing country. • The official language is German in accordance with the Administrative Procedure Act. The foreign language part (according to the official WHO translation) of the synoptic certificate is neither signed nor sealed/stamped by the authority. The issuance of a synoptic certificate in a language for which the WHO does not provide an official translation is possible upon submission of a translation by a state-recognized translator whose signature must be notarized. • The declaration of authorization status for a pharmaceutical product or several pharmaceutical products is not subject to this application procedure. • Batch certificates for pharmaceutical products are not the subject of this application procedure. Such a certificate is applied for by the manufacturer and only issued by the higher federal authority conducting the batch test, the Paul Ehrlich Institute (PEI), if state batch tests are prescribed and carried out for the product. Information on batch testing can be found on the PEI website. https://www.gesetze-im-internet.de/vwvfg/__23.html https://www.pei.de/DE/home/home-node.html https://www.gesetze-im-internet.de/vwvfg/__23.html https://www.pei.de/DE/home/home-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	• WHO certificate (CPP) for the export of medicinal products for human use with marketing authorization in the exporting country • Application for the issue of a certificate according to the certificate system of the World Health Organization (WHO). • It may be necessary for the export of a medicinal product or for authorization purposes in a third country.

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	• Application procedure online or in writing • Responsibility: State Administrative Office (depends on the registered office of the marketing authorization holder or manufacturer/exporter)
Ansprechpunkt	State Administration Office
Zuständige Stelle	
Formulare	
Ursprungsportal	Apply for a WHO certificate for the export of medicinal products for human use if the marketing authorization holder is based in Germany, WHO-Zertifikat für die Ausfuhr von Arzneimitteln zur Anwendung bei Menschen beantragen, wenn der Zulassungsinhaber seinen Sitz in Deutschland hat