99005105012002

Modul	Sachverhalt
Leistungsschlüssel	99005105012002
Leistungsbezeichnung I	
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	Baustein Leistungen
Freigabestatus Katalog	unbestimmter Freigabestatus
Freigabestatus Bibliothek	fachlich freigegeben (gold)
Begriffe im Kontext	
Leistungstyp	Leistungsobjekt mit Verrichtung
Leistungsgruppierung	Drugs (individuell, 005)
Verrichtungskennung	Ausstellung (012)
SDG-Informationsbereich	nicht SDG-relevant
Lagen Portalverbund	Import und Export (2070200)
Einheitlicher Ansprechpartner	Nein

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Fachlich freigegeben am	11.12.2024
Fachlich freigegen durch	Federal Ministry of Health (BMG)
Handlungsgrundlage	https://www.gesetze-im-internet.de/amg_1976/__73a.html
Teaser	Are you based in Germany and would like to export a medicinal product authorized in Germany for use in humans to a country outside the EU? Then you need a WHO certificate.
Volltext	To export medicinal products from Germany, you must apply for a WHO Certificate for Pharmaceutical Products (CPP). You need the WHO certificate in the importing third country for all regulatory situations relating to the local approval and import of your medicinal product. This may be necessary • 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 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. The certificates are issued by the competent authority of the federal state in which the medicinal product is manufactured and authorized (exporting country). Contents of the certificate The WHO certificate for pharmaceutical products (CCP) certifies that • the domestic authorization of the medicinal product

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	• Your authorization-related information The competent authority can also confirm Good Manufacturing Practice (GMP) if you manufacture in the same federal state in which you are based. This proves that your medicinal product complies with the "WHO's basic rules for the manufacture of medicinal products and the assurance of their quality". If you manufacture abroad or in another federal state, you can obtain the certificate from the competent authority there. Who submits the application? You can apply for the WHO Certificate for Pharmaceutical Products (CPP) if you: • have a marketing authorization • are a pharmaceutical company based in Germany() • are a manufacturing company or • are an exporting company of the medicinal product. If the • competent authority of the country of destination wishes to apply for the certificate, it requires written authorization from you. Additional services As part of the application process, you can request additional services for the certificate if necessary. These can be, for example • Over-authentication by the Federal Office of Justice • Legalization by the diplomatic or consular mission of

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	the importing country in Germany • Sealing with thread You can find out which additional services you require from the competent authority to which you wish to submit the certificate.
Erforderliche Unterlagen	
Voraussetzungen	
Kosten	
Verfahrensablauf	You must apply for the WHO Certificate for Pharmaceutical Products (CCP) in writing using the application form. The form is written in German and in one other language. These are English, French or Spanish. You must apply for a separate certificate for each medicinal product with its own authorization number and for each importing country. You must also observe the requirements of the competent state authority.
Bearbeitungsdauer	
Frist	There are no deadlines.
weiterführende Informationen	https://www.auswaertiges-amt.de/de/service/fragenkatalog-node/12-apostille-ausl/606196
Hinweise	The following information is available: • The declaration of authorization status for a pharmaceutical product is not part of the application procedure. • Batch certificates for pharmaceutical products are not part of the application procedure. Such a certificate is only applied for if state batch tests are prescribed for the product.
Rechtsbehelf	• Objection • Action before the administrative court

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	• within one month of notification
Kurztext	• WHO certificate (CPP) for the export of medicinal products for human use Issued to domestic marketing authorization holders • Application for the issuance of a certificate in accordance with the World Health Organization (WHO) certificate system • WHO certificate (CPP) may be required for the export of a medicinal product or for regulatory purposes in a third country: • 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 certificate (CPP) for the export of medicinal products: • for use in humans • with marketing authorization in Germany • Marketing authorization holder based in Germany • Application procedure in writing using the appropriate form and online in some federal states • Responsible: State authority in which the marketing authorization holder, the manufacturing or the exporting company is based
Ansprechpunkt	
Zuständige Stelle	
Formulare	
Ursprungsportal	