

99005105012000

Apply for a WHO certificate for the export of medicinal products for human use

Heruntergeladen am 08.06.2025

<https://fimportal.de/xzufi-services/6019355/L100022>

Modul	Sachverhalt
Leistungsschlüssel	99005105012000
Leistungsbezeichnung I	Apply for a WHO certificate for the export of medicinal products for human use
Leistungsbezeichnung II	Apply for a WHO certificate for the export of medicinal products for human use
Typisierung	3 - Bundesaufsichtsverwaltung: Regelung, 1 - Bund: Regelung und Vollzug
Quellredaktion	Baden-Württemberg
Freigabestatus Katalog	unbestimmter Freigabestatus
Freigabestatus Bibliothek	unbestimmter Freigabestatus
Begriffe im Kontext	
Leistungstyp	
Leistungsgruppierung	
Verrichtungskennung	

Modul	Sachverhalt
SDG-Informationsbereich	
Lagen Portalverbund	
Einheitlicher Ansprechpartner	
Fachlich freigegeben am	
Fachlich freigegeben durch	
Handlungsgrundlage	
Teaser	<p>If you wish to export medicinal products to non-EU third countries, you will need a certificate. This certificate must comply with the certificate system of the World Health Organisation (so-called WHO certificates).</p>
Volltext	<p>If you wish to export medicinal products to non-EU third countries, you will need a certificate. This certificate must comply with the certificate system of the World Health Organisation (so-called WHO certificates).</p> <p>A WHO certificate can be applied for in the following cases:</p> <ul style="list-style-type: none"> • WHO certificate for pharmaceutical products: This declaration certifies the authorisation status and GMP conformity of the manufacture, insofar as this can be confirmed by the certifying authority. • Declaration of authorisation status for pharmaceutical products: This declaration certifies that marketing authorisations exist for one or more products in the exporting country. • Batch certificates for pharmaceutical products: This certificate is normally issued by the manufacturer and only exceptionally - if government batch testing is carried out - by the federal authority carrying out the batch testing. These certificates are therefore not the subject of these procedural instructions.
Erforderliche Unterlagen	<p>You need the pre-completed WHO certificate template (product-related / authorisation status). Please submit this as a Word document (file format "docx").</p>

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Voraussetzungen	<p>WHO certificates can be issued at the request of the pharmaceutical company or at the request of the competent authority of the export destination country.</p> <p>The marketing authorisation holder for the medicinal product to be exported must be based in Baden-Württemberg</p>
Kosten	Fees are charged for the issue of WHO certificates in accordance with the state fee schedule. Depending on the scope or effort involved, these range from 25 to 500 euros.
Verfahrensablauf	You can apply for the certificates from the office responsible for the pharmaceutical company that wishes to export the medicinal product. For Baden-Württemberg, this is the Baden-Württemberg Drug Monitoring Centre at the Tübingen Regional Council. The WHO certificate forms must be completed and submitted in advance by the applicant. The link to the forms can be found under "Notes".
Bearbeitungsdauer	The processing time depends, among other things, on \\- the number of medicinal products for which a WHO certificate is requested \\- the scope of the individual applications
Frist	not applicable
weiterführende Informationen	
Hinweise	[The WHOcertificateforms can be foundhere : Service/download page of the Drug Monitoring Centre Baden-Württemberg](https://rp.baden-wuerttemberg.de/rpt/abt2/ref26/leitstellearztnei/seiten/service/)
Rechtsbehelf	not applicable
Kurztext	
Ansprechpunkt	
Zuständige Stelle	
Formulare	

Modul

Sachverhalt

Ursprungsportal