99005001005000

Modul	Sachverhalt
Leistungsschlüssel	99005001005000
Leistungsbezeichnung I	
Leistungsbezeichnung II	Medicinal products; application for authorization to manufacture medicinal products for human use and active substances requiring authorization
Typisierung	2/3 - Bund: Regelung (2 oder 3), Land/Kommune: Vollzug
Quellredaktion	Bayern
Freigabestatus Katalog	unbestimmter Freigabestatus
Freigabestatus Bibliothek	unbestimmter Freigabestatus
Begriffe im Kontext	
Leistungstyp	
Leistungsgruppierung	
Verrichtungskennung	
SDG-Informationsbereich	
Lagen Portalverbund	
Einheitlicher	

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Ansprechpartner	
Fachlich freigegeben am	17.04.2025
Fachlich freigegen durch	Bayerisches Staatsministerium für Gesundheit, Pflege und Prävention (Bavarian State Ministry of Health, Care and Prevention)
Handlungsgrundlage	http://bundesrecht.juris.de/amg_1976/ http://bundesrecht.juris.de/amg_1976/ https://www.gesetze-bayern.de/Content/Document/BayZustVAMUeB/true https://www.gesetze-bayern.de/Content/Document/BayZustVAMUeB/true
Teaser	You require a manufacturing authorization if you wish to manufacture medicinal products within the meaning of Section 2 (1) or (2) of the Medicinal Products Act, test sera, test antigens or other specific active substances for the purpose of supplying them to others.
Volltext	Germany participates in the World Health Organization (WHO) certification system for 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 WHO certificate can contain approval-related information and, with regard to manufacturing quality (GMP), certify that the medicinal product complies with the WHO's basic rules for the manufacture of medicinal products and the assurance of their quality. For medicinal products manufactured outside Germany, only marketing authorization-related information can be certified. If only marketing authorization-related information can be certified and the marketing authorization holder is based outside Germany, the higher federal authorities are responsible for issuing the WHO certificates.
Erforderliche Unterlagen	• List of medicinal products to be exported according to the WHO scheme • Country of destination • If applicable, complete composition of the pharmaceutical form • If applicable, the approved instructions for

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	use/specialized information • List of manufacturers, if applicable • If an authorized representative is applying for the certificate, declaration of consent from the marketing authorization holder • The following documents are required:
Voraussetzungen	WHO certificates for export can be applied for by the marketing authorization holder (pharmaceutical company), the manufacturer or the exporter of the medicinal product authorized in Germany.
Kosten	The fee is set out in the schedule of costs, tariff no. 7.IX.8/8. The costs (fee and expenses) are to be borne by the applicant.
Verfahrensablauf	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 from the online application, the automatically generated WHO certificate and the required attachments are submitted online to the automatically determined competent authority. • In the case of a paper-based application, send the completed draft WHO certificate with the required documents by post and, if necessary, also by email to the competent authority.
Bearbeitungsdauer	Depending on the scope of the documents to be checked
Frist	
weiterführende Informationen	https://formularserver.bayern.de/intelliform/forms/stmi+regierungen/rof/b5/53.2/rof_53.2-064/index https://formularserver.bayern.de/intelliform/forms/stmi+regierungen/rof/b5/53.2/rof_53.2-064/index
Hinweise	
Rechtsbehelf	Administrative court action
Kurztext	
Ansprechpunkt	
Zuständige Stelle	

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Formulare	
Ursprungsportal	BayernPortal, BayernPortal