99005008005000

Modul	Sachverhalt
Leistungsschlüssel	99005008005000
Leistungsbezeichnung I	
Leistungsbezeichnung II	Medicinal products; application for an import permit and an import certificate for medicinal products for human use and active substances subject to 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	

Modul	Sachverhalt
Einheitlicher 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/__72.html http://bundesrecht.juris.de/amg_1976/__72.html http://www.gesetze-im-internet.de/amg_1976/__72a.html http://www.gesetze-im-internet.de/amg_1976/__72a.html http://bundesrecht.juris.de/amg_1976/__73.html http://bundesrecht.juris.de/amg_1976/__73.html https://www.gesetze-bayern.de/Content/Document/BayZustVAMUeB/true https://www.gesetze-bayern.de/Content/Document/BayZustVAMUeB/true
Teaser	You require an import permit and an additional certificate if you wish to import certain medicinal products from countries that are not member states of the European Union or other contracting states of the Agreement on the European Economic Area.
Volltext	An import permit in accordance with Section 72 of the German Medicines Act (AMG) is required by anyone who • medicinal products within the meaning of § 2 para. 1 or para. 2 no. 1 AMG, • active substances which are of human, animal or microbial origin or which are produced by genetic engineering, or • other substances of human origin intended for the manufacture of medicinal products from countries that are not member states of the European Union or other states party to the Agreement on the European Economic Area into the

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	area of application of this Act on a commercial or professional basis. The same shall apply to persons and institutions who wish to import medicinal products of human origin for direct administration to humans on a professional or commercial basis. The import permit must be applied for informally before commencing the activity. The governments of Upper Bavaria and Upper Franconia are responsible for issuing the import permit. The government of Upper Bavaria is responsible for the administrative districts of Lower Bavaria, Upper Bavaria and Swabia and the government of Upper Franconia for the administrative districts of Middle Franconia, Upper Franconia, Lower Franconia and Upper Palatinate. For the import of medicinal products within the meaning of Section 2 para. 1 and para. 2 no. 1, 1a, 2 and 4 AMG as well as certain active substances subject to authorization, a certificate in accordance with Section 72 a para. 1 sentence 1 no. 1 AMG or a certificate in accordance with Section 72 a para. 1 sentence 1 no. 2 AMG is also required. **** **A certificate in accordance with § 72 a para. 1 sentence 1 no. 1 AMG is sufficient,** • if the competent authority of the country of manufacture has confirmed in this certificate that the medicinal products or active substances are manufactured in accordance with recognized rules for the manufacture and assurance of their quality (in particular of the European Communities, the World Health Organization or the Pharmaceutical Inspection Convention) and • such certificates are mutually recognized (i.e. between the Federal Republic of Germany and the respective country of manufacture). **If certificates are not mutually recognized, a certificate according to § 72 a para. 1 sentence 1 no. 2

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	AMG is required.** Such a certificate can only be issued if the competent authority or a competent authority of a member state of the European Union or another state party to the Agreement on the European Economic Area has regularly verified in the country of manufacture that the above-mentioned basic rules are observed in the manufacture of the medicinal products or active substances. The costs of such an inspection of the production site abroad for the manufacture of medicinal products or active substances shall be borne by the applicant. The governments of Upper Bavaria and Upper Franconia are responsible for issuing the certificate in accordance with § 72 a para. 1 sentence 1 no. 2 AMG. The government of Upper Bavaria is responsible for the administrative districts of Lower Bavaria, Upper Bavaria and Swabia and the government of Upper Franconia for the administrative districts of Middle Franconia, Upper Franconia, Lower Franconia and Upper Palatinate. **Attention! The following applies to private individuals:** Medicinal products that are not authorized or registered in Germany are subject to a prohibition of movement according to § 73 AMG. This means that these medicines may not be brought into Germany by private individuals. It is irrelevant whether there is a corresponding medicinal product or even a medicinal product with the same name available in Germany.
Erforderliche Unterlagen	
Voraussetzungen	The requirements for issuing the import permit in accordance with Section 72 AMG and the certificate in accordance with Section 72 a para. 1 sentence 1 no. 2 AMG can be found in the information sheets under "Forms".
Kosten	The following fees are set on the basis of the factual and time-consuming administrative work involved and

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	the importance of the matter for the applicant: • Import authorization under pharmaceutical law: € 200 to € 20,000 (according to the list of costs - tariff no. 7.IX.8/tariff item 6.1) • Certificate according to § 72 a or b AMG: 500 to 50,000 € (according to the list of costs - tariff no. 7.IX.8/tariff item 6.2) • Certificate in accordance with Section 72 a No. 1e AMG in conjunction with Annex II Directive (EU) No. 2015/566: €100 (according to the list of costs - tariff no. 7.IX.8/tariff item 6.3) This also includes expenses for necessary on-site inspections by our pharmaceutical officials (according to the list of costs - tariff no. 7.IX.8/tariff item 6.9).
Verfahrensablauf	
Bearbeitungsdauer	
Frist	Deadlines do not have to be observed.
weiterführende Informationen	https://formularserver.bayern.de/intelliform/forms/stmi+regierungen/rof/b5/53.2/rof_53.2-065/index https://formularserver.bayern.de/intelliform/forms/stmi+regierungen/rof/b5/53.2/rof_53.2-065/index https://formularserver.bayern.de/intelliform/forms/stmi+regierungen/rof/b5/53.2/rof_53.2-067/index https://formularserver.bayern.de/intelliform/forms/stmi+regierungen/rof/b5/53.2/rof_53.2-067/index
Hinweise	
Rechtsbehelf	Administrative court action
Kurztext	
Ansprechpunkt	
Zuständige Stelle	
Formulare	
Ursprungsportal	BayernPortal, BayernPortal