

99005024001000

Heruntergeladen am 27.06.2025

<https://fimportal.de/xzufi-services/55042/L100042>

Modul	Sachverhalt
Leistungsschlüssel	99005024001000
Leistungsbezeichnung I	
Leistungsbezeichnung II	Pharmaceuticals; application for a wholesale license
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 Ansprechpartner	
Fachlich freigegeben am	17.04.2025

Modul	Sachverhalt
Fachlich freigegeben durch	Bayerisches Staatsministerium für Gesundheit, Pflege und Prävention (Bavarian State Ministry of Health, Care and Prevention)
Handlungsgrundlage	https://www.gesetze-im-internet.de/amg_1976/__52a.html https://www.gesetze-im-internet.de/amg_1976/__52a.html http://www.gesetze-im-internet.de/amgrhdlbetr/BJNR023700987.html http://www.gesetze-im-internet.de/amgrhdlbetr/BJNR023700987.html true">https://www.gesetze-bayern.de/Content/Document/BayZustVAMUeB>true true">https://www.gesetze-bayern.de/Content/Document/BayZustVAMUeB>true
Teaser	A wholesale license is required if, for example, companies wish to procure, store, dispense or export medicinal products on a professional or commercial basis (exception: supply to consumers other than doctors, dentists, veterinarians or hospitals).
Volltext	<p>Anyone wishing to engage in wholesale distribution of medicinal products within the meaning of Section 2 para. 1 or para. 2 no. 1 of the German Medicinal Products Act (AMG), test sera or test antigens requires a license. The documents to be submitted are listed in Section 52a para. 2 AMG. The application can be submitted informally.</p> <p>Trading may not commence before the permit has been issued, which is preceded by an inspection. The violation constitutes a criminal offense.</p> <p>Once all documents have been submitted, the inspection has been carried out and the deficiencies have been rectified, the permit, consisting of a decision and a certificate, will be issued within three months.</p>
Erforderliche Unterlagen	<ul style="list-style-type: none"> • Description of the establishment • Site plan of the premises • evidence of suitable and adequate premises, plant and equipment in which the wholesale trade is to take place

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	<ul style="list-style-type: none"> • Certificate of good conduct of the managing director and the responsible person • Written declaration and undertaking to comply with the provisions applicable to the proper operation of a wholesale trade
Voraussetzungen	<p>The requirements are set out in Section 52a AMG:</p> <p>With the application, the applicant must</p> <ul style="list-style-type: none"> • name the specific establishment as well as the activities and the medicinal products for which the authorization is to be granted, • submit evidence that he has suitable and sufficient premises, facilities and equipment to ensure proper storage and distribution and, where provided, proper decanting, packaging and labeling of medicinal products, • appoint a responsible person who has the necessary expertise to carry out the activity, and • to enclose a declaration in which he undertakes in writing to comply with the regulations applicable to the proper operation of a wholesale business.
Kosten	<p>A fee of between €500 and €20,000 is set on the basis of the material and time-consuming administrative work involved and the importance of the matter for the applicant (according to the list of costs - tariff no. 7.IX.8/tariff item 1.1.4). 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 1.2).</p> <p>The costs (fees and expenses) are to be borne by the applicant.</p>
Verfahrensablauf	<p>Informal application to the responsible government (Upper Franconia or Upper Bavaria), which will decide on the application. Other authorities are involved ex officio, if at all.</p>
Bearbeitungsdauer	<p>Legal deadline, if all documents and information are complete, max. 90 days.</p>
Frist	<p>There are no deadlines for the application. It is important to note that wholesale trading may not</p>

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	begin before the permit has been issued (see "Requirements").
weiterführende Informationen	https://formularserver.bayern.de/intelliform/forms/stmi+regierungen/rof/b5/53.2/rof_53.2-062/index https://formularserver.bayern.de/intelliform/forms/stmi+regierungen/rof/b5/53.2/rof_53.2-062/index
Hinweise	Excluded from the licensing requirement are finished medicinal products released for sale outside pharmacies, which may be dispensed in the travel trade (see Section 52a (1) of the German Medicines Act).
Rechtsbehelf	An appeal against the rejection of the application can be lodged with the competent Bavarian Administrative Court.
Kurztext	
Ansprechpunkt	
Zuständige Stelle	
Formulare	
Ursprungsportal	BayernPortal, BayernPortal