

99005024001000, 99005024001000

Authorization for wholesale trade in medicinal products Issue

Heruntergeladen am 27.06.2025

<https://fimportal.de/xzufi-services/106180134/L100010>

Modul	Sachverhalt
Leistungsschlüssel	99005024001000, 99005024001000
Leistungsbezeichnung I	Authorization for wholesale trade in medicinal products Issue
Leistungsbezeichnung II	
Typisierung	2/3 - Bund: Regelung (2 oder 3), Land/Kommune: Vollzug
Quellredaktion	Saarland
Freigabestatus Katalog	fachlich freigegeben (gold)
Freigabestatus Bibliothek	fachlich freigegeben (silber)
Begriffe im Kontext	
Leistungstyp	Leistungsobjekt mit Verrichtung
Leistungsgruppierung	Arzneimittel (005)
Verrichtungskennung	Erteilung (001)
SDG-Informationsbereich	Erlangung von Lizenzen, Genehmigungen oder Zulassungen im Hinblick auf die Gründung und Führung eines Unternehmens

Modul	Sachverhalt
Lagen Portalverbund	Erlaubnisse und Genehmigungen (2010400)
Einheitlicher Ansprechpartner	Nein
Fachlich freigegeben am	18.01.2024
Fachlich freigegeben durch	Ministry of Labor, Health and Social Affairs NRW
Handlungsgrundlage	https://www.gesetze-im-internet.de/amg_1976/_52a.html https://www.gesetze-im-internet.de/amg_1976/_52a.html
Teaser	If you wish to operate a wholesale business with medicinal products, you require a permit from the competent authority. You can find out more here.
Volltext	<p>If you would like to operate a wholesale business with medicinal products, you will need a license from the competent authority before starting your activity.</p> <p>The term "medicinal products" includes not only the corresponding preparations that are available in pharmacies or prescribed by a doctor, such as tablets, capsules, ointments, creams, (cough) juices, drops, vaccines and infusion solutions, but also products that are not recognized as medicinal products at first glance.</p> <p>You can only be granted a wholesale license if you meet certain personal and material requirements. In addition, you must notify a responsible person and enclose the documents specified in the Medicinal Products Act with the application.</p> <p>The permit is generally only valid for a single establishment. If there are several business premises located within the jurisdiction of different supervisory authorities, a separate application must be submitted for each business premises, which will be processed by the supervisory authority in whose local jurisdiction the respective business premises are located.</p> <p>If you have applied for a corresponding permit, your company or facility will be inspected by the competent</p>

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authority at regular intervals and on special occasions, for example if the permit needs to be amended or if there are concerns about drug safety.

Erforderliche Unterlagen

- As a rule: Extract from the entry of the company in the commercial register (not older than 3 months).
- According to the GmbH Act, the wholesale license must be enclosed with the application to the commercial register if the object of the company requires approval. In the event that the company has not yet been entered in the commercial register, the competent authority can issue a certificate of non-objection. On this basis, to which the registration court is bound, the entry in the commercial register can be made.
- Submission of floor plans of the rooms in which medicinal products are stored and distributed.
- As a rule, the floor plans should be submitted on a scale of 1:100 and include the name of the business premises and the number of square meters. Furthermore, essential furnishings and the individual storage areas (quarantine storage, restricted storage) should be shown.
- Declaration by the applicant (managing director/board member) in which he undertakes to observe/comply with the regulations applicable to the proper operation of the wholesale business.
- Police clearance certificate of the applicant (managing director/board member) of document type 0 for submission to an authority (not older than 3 months) as well as a declaration by the applicant (managing director/board member) that there are currently no criminal proceedings against him/her (please state company name, file number and purpose when applying).
- Proof of the responsible person's qualifications (professional background, certificates) on the basis of certified copies
- Police clearance certificate of the person responsible (document type 0 for submission to an authority, not older than 3 months) and a declaration by the person

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responsible that there are currently no criminal proceedings against them. (Please state the company name, file number and purpose when applying).

- Personal declaration by the responsible person that they will inform the competent authority immediately if there are any changes to their function as a responsible person (changed area of responsibility, departure from the wholesale company).
- Organizational chart
- List of suppliers
- List of customers/purchasers of medicinal products (except pharmacies in Germany)
- List of contents of your quality assurance system (e.g. list of procedural instructions)

Procedural instructions in accordance with the Ordinance on Wholesale Distribution and Brokerage of Medicinal Products apply.

Voraussetzungen

The requirements are set out in the Medicinal Products Act:

With the application, the applicant must

- name the specific business premises as well as the activities and medicinal products for which the authorization is to be granted,
- provide evidence that he/she has suitable and sufficient premises, facilities and equipment to ensure proper storage and distribution and, where provided for, 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

Is based on the respective administrative fee schedule of the federal state or on the fee statutes of the authorities responsible under federal state law.

Verfahrensablauf

You can apply for a wholesale authorization in accordance with the German Medicinal Products Act in

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	<p>writing or electronically.</p> <p>Once you have submitted the application and all documents are complete, the competent authority will check whether you meet all requirements.</p> <p>If you meet all the requirements, you will receive the requested permit.</p> <p>You may only start your activity once you have received the permit.</p>
Bearbeitungsdauer	
Frist	The competent authority must generally make a decision on the application for a permit within three months of receiving the complete documentation.
weiterführende Informationen	
Hinweise	
Rechtsbehelf	
Kurztext	<ul style="list-style-type: none"> • Permit for the wholesale of medicinal products Issuance • The operation of a wholesale trade in medicinal products is subject to authorization • Applicant must fulfill certain personnel and factual requirements • Applicant must indicate a responsible person • Permission is granted on a site-specific basis • Responsible: Depends on the respective federal state
Ansprechpunkt	
Zuständige Stelle	<p>The MASFG is responsible for the wholesale of medicinal products for human use.</p> <p>Technical responsibility for the wholesale of veterinary medicinal products lies with the State Office for Consumer Protection.</p>
Formulare	Further information on the wholesale trade in medicinal products can be found in the following leaflet.

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Ursprungsportal	Erlaubnis zum Großhandel mit Arzneimitteln Erteilung, Authorization for wholesale trade in medicinal products Issue