

99005024001000

# Permission to wholesale medicinal products granted

Heruntergeladen am 27.06.2025

<https://fimportal.de/xzufi-services/S1000020010000012149/S100002>

Modul	Sachverhalt
Leistungsschlüssel	99005024001000
Leistungsbezeichnung I	Permission to wholesale medicinal products granted
Leistungsbezeichnung II	Apply for a license to wholesale medicines
Typisierung	2/3 - Bund: Regelung (2 oder 3), Land/Kommune: Vollzug
Quellredaktion	Hamburg
Freigabestatus Katalog	unbestimmter Freigabestatus
Freigabestatus Bibliothek	unbestimmter Freigabestatus
Begriffe im Kontext	<div lang="en-x-mtfrom-de">drug</div> , <div lang="en-x-mtfrom-de">Wholesale license for pharmaceuticals</div> , <div lang="en-x-mtfrom-de">Wholesale permit</div> , <div lang="en-x-mtfrom-de">AMG</div> , <div lang="en-x-mtfrom-de">pharmaceutical wholesale</div> , <div lang="en-x-mtfrom-de">Permission medicines</div> , <div lang="en-x-mtfrom-de">test sera</div> , <div lang="en-x-mtfrom-de">test antigens</div>
Leistungstyp	

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Leistungsgruppierung	
Verrichtungskennung	
SDG-Informationsbereich	
Lagen Portalverbund	
Einheitlicher Ansprechpartner	Nein
Fachlich freigegeben am	23.05.2024
Fachlich freigegeben durch	
Handlungsgrundlage	§ 52a Medicines Act (AMG)
Teaser	You need a permit to trade in pharmaceuticals wholesale.
Volltext	<p>If you want to operate a wholesale pharmaceutical business, you can apply for a permit from the relevant authority. If you operate multiple establishments, you will need a separate permit for each establishment. You do not need a permit if you want to distribute finished medicinal products that are approved for sale outside of pharmacies. As the holder of the permit, your pharmaceutical wholesale business will be inspected regularly and on special occasions by the responsible authority. Special occasions include safety concerns regarding a medicinal product or a change to the permit.</p>
Erforderliche Unterlagen	<p>If you have your headquarters in Hamburg: Business registration if you are not yet listed in the commercial register          If your headquarters are outside Hamburg: Certified copy of the commercial register extract (if applicable also of the general partner), which is not older than 3 months          Business registration if the business premises in Hamburg are not registered in the commercial register          Floor plan of the rooms in which medicines are stored and distributed, in duplicate on a scale of 1: 100 with the designation of the operating rooms and indication of the square meters and essential furnishings as well as the storage areas (quarantine storage, restricted storage)</p>

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Declaration in which you or the managing director or the board of directors undertake to observe and comply with the regulations applicable to the proper operation of the wholesale business. Police clearance certificate of the applicant or managing person or the board of directors of document type 0 for submission to an authority according to Section 30 Paragraph 5 BZRGU, which is not older than 3 months and a declaration that there are currently no criminal proceedings (please state company name, file number and purpose when applying). Proof of the qualifications of the responsible person (professional career, certificates) in certified copy Police clearance certificate of the responsible person (certificate type 0 for submission to an authority according to Section 30 Paragraph 5 BZRG, not older than 3 months) and a declaration from the responsible person that there are currently no criminal proceedings against him or her. (Please state company name, reference number and purpose when applying.) Personal declaration by the responsible person that he or she will immediately inform the competent authority if there are any changes to his or her function as responsible person (change in area of responsibility, leaving the wholesale business). organization chart List of suppliers List of customers and drug purchasers, with the exception of domestic pharmacies) Table of contents of your quality assurance system (for example, list of procedural instructions)

**Voraussetzungen**

They meet certain personnel and material requirements. They indicate a responsible person.

**Kosten**

There are fees for visiting your business or facility.

**Verfahrensablauf**

You apply for the wholesale trade licence for the specific establishment as well as the activities and the medicinal products for which the licence is to be granted, in writing or electronically. You submit the application with all the necessary documents to the responsible authority. With the application you have specify the specific establishment and the activities and medicinal products for which the authorisation is to be granted, provide evidence that you have suitable and sufficient premises, facilities and equipment to ensure

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proper storage and distribution and, where applicable, proper decanting, packaging and labelling of medicinal products, to appoint a responsible person who has the necessary expertise to carry out the activity, and enclose a declaration in which you undertake in writing to comply with the regulations applicable to the proper operation of a wholesale business The responsible authority will check your documents and, if necessary, request additional documents from you. The responsible authority will examine your application. The responsible authority inspects and checks your company. You will receive a notification.

## Bearbeitungsdauer

If your documents are complete, the responsible authority will decide on your application within 3 months.

## Frist

You need a permit before you can start wholesale distribution of medicinal products. The competent authority must generally make a decision on the application for a permit within three months.

## weiterführende Informationen

## Hinweise

You do not need a permit for wholesale activities that are carried out as part of normal pharmacy operations. This applies, among other things, to: the supply of medicinal products to doctors (outpatient supplies) or hospitals (clinical supplies according to Section 14 ApoG) within Germany, Returns to pharmaceutical wholesalers, returns to wholesalers as part of regular stock clearance at the pharmacy, the purchase of medicinal products within the framework of purchasing groups or passing them on to other pharmacies, provided that no profit is to be made in doing so and the distribution of medicines within a branch network. The Medicines Act also applies to medical gases, active substances produced using biotechnology and genetic engineering, blood and blood products, radioactive medicines, tissues and tissue preparations such as bones, vessels and corneas. You must enclose the wholesale trade permit with your registration with the commercial register. If your company is not yet registered in the commercial register, you can obtain a clearance certificate from the

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	relevant authority. On this basis, which is binding on the registry court, your company can be registered in the commercial register.
Rechtsbehelf	Administrative lawsuit
Kurztext	Operating a wholesale business in pharmaceuticals requires a licence No authorisation requirement for the distribution of finished medicinal products that are approved for sale outside of pharmacies Permission is granted on a per-site basis Apply for permission for each business premises separately
Ansprechpunkt	
Zuständige Stelle	Justice and Consumer Protection Authority
Formulare	
Ursprungsportal	Hamburg Service, Hamburg Service (Currently this link is only available in german)