

99005024001000

Authorization for wholesale trade in medicinal products Issue

Heruntergeladen am 09.06.2025

<https://fimportal.de/services/99005024001000>

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

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	Führung eines Unternehmens
Lagen Portalverbund	Erlaubnisse und Genehmigungen (2010400)
Einheitlicher Ansprechpartner	Ja
Fachlich freigegeben am	14.04.2025
Fachlich freigegeben durch	Federal Ministry of Health (BMG)
Handlungsgrundlage	https://www.gesetze-im-internet.de/amg_1976/_52a.html https://www.gesetze-im-internet.de/amg_1976/_4.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 wish to operate a wholesale business with medicinal products for human use, you generally require a license from the competent authority before starting your business.</p> <p>Human medicinal products are medicinal products within the meaning of the Medicinal Products Act that are intended for use in humans.</p> <p>Wholesale trade in medicinal products is defined as any professional or commercial trade that</p> <ul style="list-style-type: none"> • procures, • stores, • dispenses or • exports them. <p>The supply of medicinal products to consumers other than doctors, dentists, veterinarians or hospitals is not considered wholesale.</p> <p>You can only be granted a wholesale license if you meet certain personal and factual requirements. In particular, you must appoint a responsible person who</p>

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has the necessary expertise to carry out the activity.

The permit is only valid for the respective business premises and for the activities and medicinal products for which the permit is issued. If you wish to operate several business premises, you can obtain information from the competent authority as to whether a separate application is required for each business premises.

If you have applied for a wholesale authorization, your business premises are subject to monitoring by the competent authority.

Erforderliche Unterlagen

When applying for a wholesale authorization, you must:

- name the specific establishment and the activities and medicinal products for which the authorization is to be granted
- provide evidence that you have suitable and sufficient premises, facilities and equipment for
 - proper storage
 - proper distribution
 - where provided, proper decanting, packaging and labeling of medicinal products
- name a responsible person who has the necessary expertise
- enclose a declaration in which you undertake to comply with the regulations applicable to the proper operation of a wholesale business.

Voraussetzungen

- You would like to operate a wholesale business with medicinal products.
- Your establishment or company is already registered in the SPOR database of the European Medicines Agency (EMA). SPOR stands for Substance, Product, Organization, Referentials.

Kosten

Verfahrensablauf

Bearbeitungsdauer

3 Monat(e)

Frist

You may only start work once you have received permission.

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weiterführende Informationen	
Hinweise	<p>You do not require a license to wholesale medicinal products for</p> <ul style="list-style-type: none"> • the distribution of finished medicinal products released outside pharmacies which <ul style="list-style-type: none"> • are medicinal waters and their salts in their natural mixing ratio or their imitations and • may be dispensed in the itinerant trade • Activities that are carried out as a pharmacy as part of normal pharmacy operations.
Rechtsbehelf	
Kurztext	<ul style="list-style-type: none"> • The operation of a wholesale trade in medicinal products requires a license <ul style="list-style-type: none"> • Applicants must fulfill certain personal and factual requirements • Applicants must appoint a responsible person • Permission is granted on a site and medicinal product basis
Ansprechpunkt	
Zuständige Stelle	
Formulare	
Ursprungsportal	