99005024001000

Authorisation for wholesale trade in medicinal products Issue

Modul	Sachverhalt
Leistungsschlüssel	99005024001000
Leistungsbezeichnung I	Authorisation for wholesale trade in medicinal products Issue
Leistungsbezeichnung II	Authorisation for wholesale trade in medicinal products Issue
Typisierung	2/3 - Bund: Regelung (2 oder 3), Land/Kommune: Vollzug
Quellredaktion	Baden-Württemberg
Freigabestatus Katalog	unbestimmter Freigabestatus
Freigabestatus Bibliothek	unbestimmter Freigabestatus
Begriffe im Kontext	
Leistungstyp	
Leistungsgruppierung	
Verrichtungskennung	
SDG-Informationsbereich	
Lagen Portalverbund	

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Einheitlicher Ansprechpartner	
Fachlich freigegeben am	
Fachlich freigegen durch	
Handlungsgrundlage	Arzneimittelgesetz (AMG): • § 52a Großhandel mit Arzneimitteln Verordnung über den Großhandel und die Arzneimittelvermittlung (AM-HandelsV) Leitlinien der Europäischen Kommission vom 05.11.2013 für die gute Vertriebspraxis von Humanarzneimittteln Delegierte Verordnung (EU) 2016/161 der Kommission vom 02. Oktober 2015 zur Ergänzung der Richtlinie 2001/83/EG des Europäischen Paralaments und des Ratesdurch die Festlegung genauer Bestimmungen über die Sicherheitsmerkmale auf der Verpackung von Humanarzneimitteln
Teaser	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.
Volltext	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. 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. 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

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	Products Act with the application. 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. If you have applied for a corresponding license, your company or facility will be inspected by the competent authority at regular intervals and on special occasions, for example if the license 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/she 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

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	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 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, • submit 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

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	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 submit the application for a wholesale authorization in accordance with the German Medicinal Products Act in writing or electronically. Once you have submitted the application and all documents are complete, the competent authority will check whether you meet all requirements. If you meet all the requirements, you will receive the requested permit. You may only start your activity once you have received the permit.
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	
Ansprechpunkt	
Zuständige Stelle	
Formulare	
Ursprungsportal	