99005024001000

Erlaubnis zum Großhandel mit Arzneimitteln Erteilung

Modul	Sachverhalt
Leistungsschlüssel	99005024001000
Leistungsbezeichnung I	Erlaubnis zum Großhandel mit Arzneimitteln Erteilung
Leistungsbezeichnung II	Permission for wholesale trade in medicinal products Issuance
Typisierung	2/3 - Bund: Regelung (2 oder 3), Land/Kommune: Vollzug
Quellredaktion	Bremen
Freigabestatus Katalog	unbestimmter Freigabestatus
Freigabestatus Bibliothek	unbestimmter Freigabestatus
Begriffe im Kontext	
Leistungstyp	
Leistungsgruppierung	
Verrichtungskennung	
SDG-Informationsbereich	
Lagen Portalverbund	Erlaubnisse und Genehmigungen (2010400)

Modul	Sachverhalt
Einheitlicher Ansprechpartner	
Fachlich freigegeben am	29.02.2024
Fachlich freigegen durch	
Handlungsgrundlage	https://www.gesetze-im-internet.de/amg_1976/__52a.html
Teaser	If you wish to operate a wholesale business in human pharmaceuticals, you must obtain permission from the competent authority before commencing operations.
Volltext	If you wish to operate a wholesale business with medicinal products for human use, you need the permission of the competent authority before starting the activity. The term "medicinal products" includes not only preparations that are available in pharmacies or administered by doctors, such as tablets, capsules, ointments, creams, cough syrups, drops, vaccines and infusion solutions, but also products that are not recognized as medicinal products at first glance. The German Medicines Act also applies, for example, to medical gases, biotechnologically and genetically engineered active ingredients, blood and blood products, radioactive medicines, tissue and tissue preparations such as bones, vessels and corneas. You can only be granted a wholesale permit if you meet certain personnel and material requirements. In addition, you must notify a responsible person and attach the documents specified in § 52a AMG to the application. Permission is generally granted on a site-by-site basis. In the case of several production sites that are located in the area of responsibility of different supervisory authorities, a separate approval procedure must be carried out for each production site by the respective authority responsible for the production site.

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	If you have applied for a corresponding permit, your company or facility will be inspected by the competent authority at regular intervals and on special occasions, for example in the event of a change to the permit or concerns about drug safety. The inspection of your company or facility is subject to a fee according to § 64 AMG.
Erforderliche Unterlagen	• Floor plans of the rooms Submission of floor plans of the rooms in which medicines are stored and distributed. As a rule, the floor plans should be presented on a scale of 1:100 and should include the name of the operating rooms as well as their m^2. Furthermore, essential furnishings as well as the individual storage areas (quarantine storage, locked storage) should be drawn in.
Voraussetzungen	The requirements result from § 52a AMG. With the application, the applicant must: • specify the particular premises as well as the activities and the medicinal products for which the authorization is to be granted, • submit evidence that it has suitable and sufficient premises, equipment and facilities to ensure proper storage and distribution and, where provided, proper decanting, packaging and labeling of medicinal products, • designate a responsible person who possesses the expertise required to perform the activity; and • include a statement in which he or she undertakes in writing to comply with the regulations applicable to the proper operation of a wholesale business.
Kosten	Please note that there is a fee for issuance of the permit pursuant to Section 501.13 of the current Bremen Health Care Cost Ordinance.
Verfahrensablauf	You can submit the application for a wholesale authorization according to § 52a AMG in writing or electronically. Once you have submitted the application and all documents are complete, the competent authority will

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	check whether you meet all the requirements. If you meet all requirements, the legally required acceptance inspection by the competent authority will follow. You will then receive the permit you applied for. You may not start work until you have received the permit.
Bearbeitungsdauer	If the documents are complete, your application will be processed promptly.
Frist	You may not start wholesaling before the permit has been granted. The competent authority must make a decision on the application for a permit within a period of three months.
weiterführende Informationen	
Hinweise	Exempt from the licensing requirement are finished medicinal products released for circulation outside pharmacies, which may be dispensed in itinerant trade (cf. Section 52a (1) of the German Medicines Act). Responsible for applications for permission to wholesale veterinary medicinal products in the state of Bremen is the department 42 of the senatorial authority for health, women and consumer protection.According to § 52 a Abs. 7 AMG, no permission is required for wholesale activities that are carried out within the framework of normal pharmacy operations. These include: • The supply of pharmaceuticals to physicians (consultation hour supplies) or hospitals (hospital supplies according to § 14 ApoG) within Germany, • returns to pharmaceutical wholesalers, returns to wholesalers as part of regular stock clearing by the pharmacy, • the purchase of medicinal products within the framework of purchasing syndicates or the passing on of medicinal products to other pharmacies, provided that no profit is to be made in the process, and • the passing on of medicinal products within a

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	branch network.
Rechtsbehelf	
Kurztext	
Ansprechpunkt	
Zuständige Stelle	
Formulare	
Ursprungsportal	Serviceportal der Freien Hansestadt Bremen, Service portal of the Free Hanseatic City of Bremen