99005024001000, 99005024001000

Application for authorisation for the wholesale distribution of medicinal products

Modul	Sachverhalt
Leistungsschlüssel	99005024001000, 99005024001000
Leistungsbezeichnung I	Application for authorisation for the wholesale distribution of medicinal products
Leistungsbezeichnung II	
Typisierung	2/3 - Bund: Regelung (2 oder 3), Land/Kommune: Vollzug
Quellredaktion	Hessen
Freigabestatus Katalog	unbestimmter Freigabestatus
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

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	Zulassungen im Hinblick auf die Gründung und Führung eines Unternehmens
Lagen Portalverbund	Erlaubnisse und Genehmigungen (2010400)
Einheitlicher Ansprechpartner	Ja
Fachlich freigegeben am	15.12.2022
Fachlich freigegen durch	Hessian Ministry of Social Affairs and Integration
Handlungsgrundlage	https://www.gesetze-im-internet.de/amg_1976/__4.html https://www.gesetze-im-internet.de/amg_1976/__4.html
Teaser	Do you want to operate a wholesale business with medicines? Then you need a permit.
Volltext	If you want to operate a wholesale business in medicines, you need a permit from the competent authority. Applicants are natural persons, legal persons, associations without legal capacity and companies under civil law.
Erforderliche Unterlagen	- excerpt from the commercial register or trade register application,- completed and signed personal declaration in which the applicant undertakes to comply with the regulations applicable to the proper operation of a wholesaler, as well as an assurance of the completeness and accuracy of the information and a declaration that the applicant is aware that incorrect or incomplete information may lead to the withdrawal of the licence, - Completed and signed personal declaration by the responsible person in accordance with § 52a paragraph 2 number 3 AMG that he or she agrees to the designation,- Professional career with information on education and previous professional activity (curriculum vitae, degree certificate, employment references) of the responsible person in accordance with § 52a paragraph 2 number 3 of the AMG,- floor plans of the establishment or premises (scale 1 : 100 or 1 : 50), showing the size, location and functional designations (e.g. warehouse, administration) of the individual premises. In the case

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	of several storage sites or non-contiguous premises, a list of these storage facilities or premises shall be attached to the application:- proof of availability of the rooms (rental agreement, land register excerpt, etc.),- table of contents of the quality assurance (QA) manual,- Completed and signed self-disclosure of criminal and investigative proceedings by the management and the responsible person,- if necessary. Contract documents and GHE/GDPZ of the warehouse(s) on a contract basis,- Excerpt from the central trade register according to § 150 Abs. 5 Gewerbeordnung (GewO) of the applicant and the management or according to § 150 GewO for the responsible person,- Certificate of good conduct of the applicant, the responsible person according to § 52a paragraph 2 number 3 AMG and the management, which must not be older than three months (document type O; please indicate "wholesale license AM (+ name of the company)" as the reason for payment). In the case of a legal entity, certificates of good conduct for the members of the management or the board of directors.
Voraussetzungen	Permission must be granted upon application if you meet all requirements pursuant to Section 52a (2) of the German Medicines Act (AMG). Prerequisites include: - designation of at least one establishment in Hesse,- suitable and sufficient premises, installations and facilities,- designation of a responsible person with the necessary expertise,- declaration pursuant to § 52a paragraph 2 no. 4 of the German Medicines Act (AMG),- reliability of both the applicant and the responsible person.
Kosten	Gebühr: 2.500€ New application Gebühr: 150€ Authorisation to wholesale medicinal products
Verfahrensablauf	- You submit your application to the competent authority via the online form and upload the required documents,- The permit or confirmation is issued

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	when the competent authority determines that the legal requirements have been met.In the case of a new application, an appointment must be made for the acceptance inspection of the wholesale trade before the start of the activity.
Bearbeitungsdauer	3 Monat(e) Upon receipt of the written request.
Frist	3 Monat(e) The application must be received three months before the desired start of the activity.
weiterführende Informationen	
Hinweise	In order for the authority to be able to fulfil its monitoring obligation, there is a duty to notify (§ 67 Arzneimittelgesetz - AMG) for "companies and facilities that develop, manufacture, clinically test or subject medicinal products to a residue test, test, store, package, place on the market or otherwise trade with them". https://hlfgp.hessen.de/arzneimittel-apotheken/arzneimittelvertrieb https://hlfgp.hessen.de/arzneimittel-apotheken/arzneimittelvertrieb
Rechtsbehelf	Administrative court action
Kurztext	- Apply for permission to wholesale medicinal products- Anyone wishing to operate a wholesale trade in medicinal products requires authorisation from the competent authority. Applicants are natural persons, legal persons, associations without legal capacity and companies under civil law.- Responsible: Regierungspräsidium Darmstadt
Ansprechpunkt	Please contact the Hessian State Office for Health and Care.
Zuständige Stelle	Hessian State Office for Health and Care.
Formulare	Forms/online services available: YesWritten form required: NoInformal application possible: NoPersonal appearance required: No

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Ursprungsportal	Application for authorisation for the wholesale distribution of medicinal products, Antrag auf Erteilung einer Erlaubnis für den Großhandel mit Arzneimitteln