

99005110169000, 99005110169000

Notification of a pharmaceutical brokerage

Heruntergeladen am 09.07.2025

<https://fimportal.de/xzufi-services/383937834/L100001>

Modul	Sachverhalt
Leistungsschlüssel	99005110169000, 99005110169000
Leistungsbezeichnung I	Notification of a pharmaceutical brokerage
Leistungsbezeichnung II	
Typisierung	3 - Bundesaufsichtsverwaltung: Regelung
Quellredaktion	Hessen
Freigabestatus Katalog	unbestimmter Freigabestatus
Freigabestatus Bibliothek	unbestimmter Freigabestatus
Begriffe im Kontext	
Leistungstyp	Leistungsobjekt mit Verrichtung
Leistungsgruppierung	Arzneimittel (005)
Verrichtungskennung	Anzeige (169)
SDG-Informationsbereich	Erlangung von Lizenzen, Genehmigungen oder Zulassungen im Hinblick auf die Gründung und Führung eines Unternehmens
Lagen Portalverbund	

Modul	Sachverhalt
Einheitlicher Ansprechpartner	Nein
Fachlich freigegeben am	15.12.2022
Fachlich freigegeben durch	Hessian Ministry for Social Affairs and Integration
Handlungsgrundlage	https://www.gesetze-im-internet.de/amg_1976/__67.html https://www.gesetze-im-internet.de/amg_1976/__67.html
Teaser	Do you want to report a brokerage of medicinal products?
Volltext	If you wish to act as an intermediary for medicinal products in accordance with Section 52c AMG, you must notify us in advance.
Erforderliche Unterlagen	- Business registration (for self-employment)
Voraussetzungen	- If you work as a self-employed intermediary, you must have registered a business - You may only act as a medicinal product broker pursuant to Section 52c (1) if you have your registered office in the area of application of this Act, in another member state of the European Union or in another state party to the Agreement on the European Economic Area.
Kosten	Gebühr: 25€ - 250€
Verfahrensablauf	- You submit your notification to the competent authority using the online form and upload the required document if necessary, - the confirmation will be issued if the competent authority determines that the legal requirements have been met.
Bearbeitungsdauer	2 - 4 Woche(n)
Frist	The notification must be made before the start of the activity
weiterführende Informationen	

Modul	Sachverhalt
Hinweise	In addition to a risk-based inspection of companies, monitoring also includes the taking and testing of medicinal product samples. In order for the authorities to fulfill their monitoring obligations, there is a notification obligation (Section 67 of the German Medicinal Products Act (AMG)) for "companies and facilities that develop, manufacture, clinically test or subject to residue testing, test, store, package, place on the market or otherwise trade in medicinal products".
Rechtsbehelf	Administrative court action
Kurztext	- Notification of a pharmaceutical brokerage - The activity of brokering medicinal products must be notified. - Responsible: Darmstadt Regional Council
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: Yes Written form required: No Informal application possible: No Personal appearance necessary: No
Ursprungsportal	Notification of a pharmaceutical brokerage, Anzeige einer Arzneimittelvermittlung