

99005110169000, 99005110169000

# Notification of a pharmaceutical brokerage

Heruntergeladen am 18.06.2025

<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                                                                                                                                                                                                                                                                                                                                                           |
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| Einheitlicher Ansprechpartner | Nein                                                                                                                                                                                                                                                                                                                                                                  |
| Fachlich freigegeben am       | 15.12.2022                                                                                                                                                                                                                                                                                                                                                            |
| Fachlich freigegeben durch    | Hessian Ministry for Social Affairs and Integration                                                                                                                                                                                                                                                                                                                   |
| Handlungsgrundlage            | <a href="https://www.gesetze-im-internet.de/amg_1976/__67.html">https://www.gesetze-im-internet.de/amg_1976/__67.html</a><br><a href="https://www.gesetze-im-internet.de/amg_1976/__67.html">https://www.gesetze-im-internet.de/amg_1976/__67.html</a>                                                                                                                |
| 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<br>- 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,                                                                                                                                                                                                                                        |
| Bearbeitungsdauer             | 2 - 4 Woche(n)                                                                                                                                                                                                                                                                                                                                                        |
| Frist                         | The notification must be made before the start of the activity                                                                                                                                                                                                                                                                                                        |
| weiterführende Informationen  |                                                                                                                                                                                                                                                                                                                                                                       |
| 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                                                                                                                                                                                                       |

| Modul             | Sachverhalt                                                                                                                                                                                                                                                                                                                      |
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|                   | 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                                                                                                                                                                                                                                                                                     |
| 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                                                                                                                                                                                                                                                                                             |
| Ursprungsportal   | Notification of a pharmaceutical brokerage, Anzeige einer Arzneimittelvermittlung                                                                                                                                                                                                                                                |