

99005112169000, 99005112169000

# Notification of other activities involving medicinal products, active substances, other substances and tissues intended for the manufacture of medicinal products

Heruntergeladen am 21.06.2025

<https://fimportal.de/xzufi-services/399192214/L100001>

| Modul                     | Sachverhalt                                                                                                                                                       |
|---------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Leistungsschlüssel        | 99005112169000, 99005112169000                                                                                                                                    |
| Leistungsbezeichnung I    | Notification of other activities involving medicinal products, active substances, other substances and tissues intended for the manufacture of medicinal products |
| Leistungsbezeichnung II   |                                                                                                                                                                   |
| Typisierung               | 3 - Bundesaufsichtsverwaltung: Regelung                                                                                                                           |
| Quellredaktion            | Hessen                                                                                                                                                            |
| Freigabestatus Katalog    | unbestimmter Freigabestatus                                                                                                                                       |
| Freigabestatus Bibliothek | unbestimmter Freigabestatus                                                                                                                                       |
| Begriffe im Kontext       |                                                                                                                                                                   |

| Modul                         | Sachverhalt                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
|-------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 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           |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
| Einheitlicher Ansprechpartner | Ja                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| Fachlich freigegeben am       | 05.02.2024                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
| Fachlich freigegeben durch    | Hessian Ministry of Labor, Integration, Youth and Social Affairs and Hessian Ministry for Family Affairs, Senior Citizens, Sport, Health and Care                                                                                                                                                                                                                                                                                                                                                                                                                           |
| 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 any other activity in connection with medicinal products, active substances, other substances and tissues intended for the manufacture of medicinal products?                                                                                                                                                                                                                                                                                                                                                                                         |
| Volltext                      | <p>If you</p> <ul style="list-style-type: none"> <li>• a retail business with over-the-counter medicines,</li> <li>• the storage of medicinal products and their documents,</li> <li>• the brokerage of medicinal products,</li> <li>• the license-free manufacture of medicinal products for doctors, dentists and other persons authorized to practice medicine on humans, or</li> <li>• the license-free manufacture of medicinal products for hospitals or rescue service organizations</li> </ul> <p>you must notify the Hessian State Office for Health and Care.</p> |

| Modul                           | Sachverhalt                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
|---------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|                                 | <p>The Hessian State Office for Health and Care is also your point of contact for changes to the notified activities.</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
| <b>Erforderliche Unterlagen</b> | <p>Notification of retail trade in over-the-counter medicines:</p> <ul style="list-style-type: none"> <li>• see form on the page on the distribution of medicinal products</li> </ul> <p>Notification of a warehouse or document storage facility:</p> <ul style="list-style-type: none"> <li>• Name and address of the company</li> <li>• Precise description of the activities (for whom is what stored?)</li> </ul> <p>Notification of a pharmaceutical brokerage:</p> <ul style="list-style-type: none"> <li>• See form on the page on the distribution of medicinal products</li> </ul> <p>Notification of licence-free manufacture of medicinal products for doctors, dentists and other persons authorized to practice medicine on humans and notification of licence-free manufacture of medicinal products for hospitals and emergency services:</p> <ul style="list-style-type: none"> <li>• see form on the page on the obligation to notify</li> </ul> <p>Notification of a medicinal product collection:</p> <ul style="list-style-type: none"> <li>• see information sheet on the page on the distribution of medicinal products</li> </ul> <p><a href="https://hlfgp.hessen.de/arzneimittel-apotheken/arzneimittelvertrieb">https://hlfgp.hessen.de/arzneimittel-apotheken/arzneimittelvertrieb</a><br/> <a href="https://hlfgp.hessen.de/arzneimittel-apotheken/anzeigepflicht">https://hlfgp.hessen.de/arzneimittel-apotheken/anzeigepflicht</a><br/> <a href="https://hlfgp.hessen.de/arzneimittel-apotheken/arzneimittelvertrieb">https://hlfgp.hessen.de/arzneimittel-apotheken/arzneimittelvertrieb</a><br/> <a href="https://hlfgp.hessen.de/arzneimittel-apotheken/anzeigepflicht">https://hlfgp.hessen.de/arzneimittel-apotheken/anzeigepflicht</a></p> |
| <b>Voraussetzungen</b>          | <p>The respective requirements must be met for the advertisement.</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |

## Modul

## Sachverhalt

Prerequisites include

Notification of a retail trade in over-the-counter medicines:

- Appointment of a responsible person with the required expertise
- Name and address of the retailer

Notification of a warehouse or document storage facility:

- Name and address of the company
- Precise description of the activities (for whom is what stored?)

Notification of a pharmaceutical brokerage:

- Specific description of the activity
- Name and address of the companies you wish to work for

Notification of licence-free manufacture of medicinal products for doctors, dentists and other persons authorized to practise medicine on humans and notification of licence-free manufacture of medicinal products for hospitals and rescue service organizations:

- Personal details, name and address of the practice or rescue organization or hospital
- Details of the exact activities
- Designation of the responsible person with the required expertise

Notification of a collection of medicinal products:

- see information sheet on the homepage:  
<https://hlfgp.hessen.de/arzneimittel-apotheken/arzneimittelvertrieb>  
<https://hlfgp.hessen.de/arzneimittel-apotheken/arzneimittelvertrieb>

## Kosten

Verwaltungsgebühr: 33€ - 275€

| Modul                        | Sachverhalt                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
|------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|                              | <a href="https://www.rv.hessenrecht.hessen.de/bshe/document/jlr-SozMinVwKostOHE2012V6Anlage/part/G">https://www.rv.hessenrecht.hessen.de/bshe/document/jlr-SozMinVwKostOHE2012V6Anlage/part/G</a>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
| Verfahrensablauf             | <ul style="list-style-type: none"> <li>• Please complete the relevant form, preferably on your PC, sign it and send it as a scan attached to an e-mail to the following address: <a href="mailto:Anzeige67@hlfgp.hessen.de">Anzeige67@hlfgp.hessen.de</a>.</li> <li>• Further information is available at the following link: <a href="https://hlfgp.hessen.de/arzneimittel-apotheken/anzeigespflicht">https://hlfgp.hessen.de/arzneimittel-apotheken/anzeigespflicht</a><br/><a href="https://hlfgp.hessen.de/arzneimittel-apotheken/anzeigespflicht">https://hlfgp.hessen.de/arzneimittel-apotheken/anzeigespflicht</a></li> </ul>                                                                                                                                                                                   |
| Bearbeitungsdauer            | 2 - 4 Woche(n)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
| Frist                        | Notification must be made before the start of the activity                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
| weiterführende Informationen | <p>The Hessian State Office for Health and Care monitors the movement of medicinal products for human use at all pharmaceutical companies as well as wholesalers and retailers in Hesse.</p> <p><a href="https://hlfgp.hessen.de/arzneimittel-apotheken/anzeigespflicht">https://hlfgp.hessen.de/arzneimittel-apotheken/anzeigespflicht</a><br/> <a href="https://hlfgp.hessen.de/arzneimittel-apotheken/arzneimittelvertrieb">https://hlfgp.hessen.de/arzneimittel-apotheken/arzneimittelvertrieb</a><br/> <a href="https://hlfgp.hessen.de/arzneimittel-apotheken/anzeigespflicht">https://hlfgp.hessen.de/arzneimittel-apotheken/anzeigespflicht</a><br/> <a href="https://hlfgp.hessen.de/arzneimittel-apotheken/arzneimittelvertrieb">https://hlfgp.hessen.de/arzneimittel-apotheken/arzneimittelvertrieb</a></p> |
| Hinweise                     |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
| Rechtsbehelf                 | Administrative court action                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
| Kurztext                     | <ul style="list-style-type: none"> <li>• Notification of other activities involving medicinal products, active substances, other substances and tissues intended for the manufacture of medicinal products</li> <li>• Other activities in connection with medicinal products, active substances, other substances and tissues intended for the manufacture of medicinal products must be notified</li> <li>• Responsible: Hessian State Office for Health and Care</li> </ul>                                                                                                                                                                                                                                                                                                                                          |
| Ansprechpunkt                |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |

| Modul             | Sachverhalt                                                                                                                                                                                                                                                                                       |
|-------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Zuständige Stelle | The Hessian State Office for Health and Care is responsible.                                                                                                                                                                                                                                      |
| Formulare         | Forms/online services available: Yes Written form required: No Informal application possible: Partially Personal appearance necessary: No                                                                                                                                                         |
| Ursprungsportal   | Notification of other activities involving medicinal products, active substances, other substances and tissues intended for the manufacture of medicinal products, Anzeige sonstiger Tätigkeiten mit Arzneimitteln, Wirkstoffen, anderen zur Arzneimittelherstellung bestimmten Stoffe und Gewebe |