99005023008000, 99005023008000

# Notify a competent person in accordance with the Medicinal Products Act

Heruntergeladen am 06.07.2025
https://fimportal.de/xzufi-services/554830204/L100040

| Modul | Sachverhalt |
|---|---|
| **Leistungsschlüssel** | 99005023008000, 99005023008000 |
| **Leistungsbezeichnung I** | Notify a competent person in accordance with the Medicinal Products Act |
| **Leistungsbezeichnung II** | |
| **Typisierung** | 2a - Bundesauftragsverwaltung: Regelung, Land: Vollzug |
| **Quellredaktion** | Niedersachsen |
| **Freigabestatus Katalog** | unbestimmter Freigabestatus |
| **Freigabestatus Bibliothek** | unbestimmter Freigabestatus |
| **Begriffe im Kontext** | |
| **Leistungstyp** | Leistungsobjekt mit Verrichtung |
| **Leistungsgruppierung** | Arzneimittel (005) |
| **Verrichtungskennung** | Bestätigung (008) |
| **SDG-Informationsbereich** | Erlangung von Lizenzen, Genehmigungen oder |

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| | Zulassungen im Hinblick auf die Gründung und Führung eines Unternehmens, Vorschriften für und Anforderungen an Erzeugnisse |
| **Lagen Portalverbund** | Anmeldepflichten (2010100), Mitarbeiterbezogene Meldepflichten (2030400) |
| **Einheitlicher Ansprechpartner** | Nein |
| **Fachlich freigegeben am** | 05.07.2024 |
| **Fachlich freigegen durch** | Lower Saxony Ministry for Social Affairs, Labor, Health and Equality |
| **Handlungsgrundlage** | https://www.gesetze-im-internet.de/amg_1976/__14.html<br>https://www.gesetze-im-internet.de/amg_1976/__15.html<br>https://www.gesetze-im-internet.de/amg_1976/__19.html<br>https://www.gesetze-im-internet.de/amg_1976/__20.html<br>https://www.gesetze-im-internet.de/amg_1976/__14.html<br>https://www.gesetze-im-internet.de/amg_1976/__15.html<br>https://www.gesetze-im-internet.de/amg_1976/__19.html<br>https://www.gesetze-im-internet.de/amg_1976/__20.html |
| **Teaser** | Any pharmaceutical entrepreneur who manufactures medicinal products within the meaning of Section 2 para. 1 or para. 2 no. 1 AMG or places them on the market in accordance with Section 4 para. 17 AMG must notify the competent authority of a qualified person. |
| **Volltext** | The requirements for various responsible persons are described in the Medicinal Products Act. It stipulates that you must notify the competent authority of a competent person with appropriate qualifications and reliability for the decision on manufacturing authorization. Any changes must also be reported immediately. |

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| **Erforderliche Unterlagen** | Employment references (copy)<br><br>Proof of training (copy)<br><br>Curriculum vitae<br><br>Certificate of good conduct for submission to the authorities.<br><br>Declaration of commitment<br><br>Apart from the declaration of commitment, the other documents are not mandatory. This depends on existing documents and plausibility in the individual case. |
| **Voraussetzungen** | Qualified persons must have the necessary expertise and reliability.<br><br>They must have a university degree in pharmacy, chemistry, biology, human or veterinary medicine |
| **Kosten** | |
| **Verfahrensablauf** | You can notify a competent person in writing, by e-mail or online.<br><br>You notify the competent person by means of a written application or using the online service.<br><br>The notification is then received by the authority.<br><br>The authority checks the notification formally and for completeness.<br><br>If the check reveals missing documents, the person who made the report will be contacted and asked to provide the missing documents.<br><br>Once the missing documents have been submitted or the formal check has been passed, the competent authority will make a decision.<br><br>The application can be confirmed or rejected, |

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| | The decision will be communicated to the person making the application.<br><br>A statement of fees will then be drawn up and also sent to the applicant with a request for payment. |
| **Bearbeitungsdauer** | |
| **Frist** | |
| **weiterführende Informationen** | A fine may be imposed in the event of a violation. |
| **Hinweise** | |
| **Rechtsbehelf** | The notice of costs contains information on legal remedies. |
| **Kurztext** | Notification of the qualified person in accordance with Section 14 of the Medicinal Products Act, Section 14 when applying for a license (initial notification) Section 20 AMG when changing a qualified person<br><br>The German Medicinal Products Act describes the requirements for various responsible persons.<br><br>In order to obtain a manufacturing authorization as a pharmaceutical entrepreneur, the competent authority must be notified of a qualified person with the appropriate qualifications and reliability.<br><br>For the corresponding notification of responsibility, please use the online service or submit the document in writing. Notification to the trade supervisory authorities is also possible by e-mail. |
| **Ansprechpunkt** | In Lower Saxony, drug monitoring is ensured by the central state trade supervisory offices in Braunschweig, Hanover, Lüneburg and Oldenburg. |
| **Zuständige Stelle** | |
| **Formulare** | |
| **Ursprungsportal** | Eine sachkundige Person nach dem Arzneimittelgesetz anzeigen, Notify a competent person in accordance with the Medicinal Products Act |