

99005072261000

# Display Retail sale of over-the-counter medicines Acceptance

Heruntergeladen am 08.07.2025

<https://fimportal.de/services/99005072261000>

| Modul                     | Sachverhalt  |
|---------------------------|--|
| Leistungsschlüssel        | 99005072261000   |
| Leistungsbezeichnung I    | Display Retail sale of over-the-counter medicines<br>Acceptance                            |
| Leistungsbezeichnung II   | Show retail sale of over-the-counter medicines   |
| Typisierung               | 3 - Bundesaufsichtsverwaltung: Regelung  |
| Quellredaktion            | Baustein Leistungen  |
| Freigabestatus Katalog    | unbestimmter Freigabestatus  |
| Freigabestatus Bibliothek | fachlich freigegeben (silber)  |
| Begriffe im Kontext       |  |
| Leistungstyp              | Leistungsobjekt mit Verrichtung  |
| Leistungsgruppierung      | Drugs (individuell, 005)   |
| Verrichtungskennung       | Entgegennahme (261)  |
| SDG-Informationsbereich   | Erlangung von Lizenzen, Genehmigungen oder<br>Zulassungen im Hinblick auf die Gründung und |

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|                               | Führung eines Unternehmens  |
| Lagen Portalverbund           | Erlaubnisse und Genehmigungen (2010400)   |
| Einheitlicher Ansprechpartner |   |
| Fachlich freigegeben am       | 28.08.2024  |
| Fachlich freigegeben durch    | Ministry of Labor, Health and Social Affairs NRW  |
| Handlungsgrundlage            | <a href="https://www.gesetze-im-internet.de/amg_1976/_44.html">https://www.gesetze-im-internet.de/amg_1976/_44.html</a><br><a href="https://www.gesetze-im-internet.de/amg_1976/_50.html">https://www.gesetze-im-internet.de/amg_1976/_50.html</a><br><a href="https://www.gesetze-im-internet.de/amg_1976/_52.html">https://www.gesetze-im-internet.de/amg_1976/_52.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><br><a href="https://www.gesetze-im-internet.de/amg_1976/_51.html">https://www.gesetze-im-internet.de/amg_1976/_51.html</a>   |
| Teaser                        | <p>If you want to sell over-the-counter medicines in retail outlets outside of pharmacies, you must report this. You can find out more here.</p>  |
| Volltext                      | <p>You may sell certain non-prescription and non-pharmacy-only medicines outside of pharmacies. These are known as over-the-counter medicines. The ordinance on pharmacy-only and over-the-counter medicines specifies which medicines these are.</p> <p>The retail sale of over-the-counter medicines is subject to notification. Companies and establishments must notify the competent authority before commencing this activity. This also applies to persons who carry out these activities independently and on a professional basis. The activity must also be notified to the competent authority prior to commencement if medicinal products are dispensed in a traveling trade.</p> <p>This notification in accordance with the Medicinal Products Act must be submitted in addition to the business registration in accordance with the Trade, Commerce and Industry Regulation Act.</p> |

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Retail sales of over-the-counter medicinal products may only be carried out if the entrepreneur has the necessary expertise, either by a person legally appointed to represent the entrepreneur or by a person entrusted with the management of the company or with the sale.

Specialist knowledge is not required in the case of medicinal products that may be dispensed in the traveling trade, are intended for the prevention of pregnancy or sexually transmitted diseases, or disinfectants or oxygen intended exclusively for external use.

In the case of companies with several branches, there must be a person with the necessary expertise for each branch. If over-the-counter medicines are offered for self-service, a person with specialist knowledge must be available during opening hours.

Proof of expertise must be provided by passing an examination at the competent Chamber of Industry and Commerce. Certain professional qualifications (e.g. pharmaceutical commercial clerk, pharmaceutical technical assistant) are also recognized as proof of expertise.

## Erforderliche Unterlagen

- Identity document
- Proof of expertise, e.g. through:
  - IHK examination of expertise
  - Completed degree in pharmacy
  - License to practice as a pharmacist
  - University degree in chemistry, biology, human medicine, veterinary medicine in conjunction with further evidence such as theoretical and practical instruction in certain basic subjects (Section 15 of the German Medicines Act)
  - Completed training as a druggist
  - Final examination as a pharmacy assistant or pharmaceutical-commercial employee
  - Completed training as a pharmaceutical-technical assistant
  - Proof that you have carried out one of the following activities before 1978 after passing the commercial

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|                              | <p>assistant examination: if applicable, an additional practical activity of at least three years in a commercial enterprise with over-the-counter medicines or a five-year commercial activity, two years of which in a managerial position, with over-the-counter medicines</p>   |
| Voraussetzungen              | <ul style="list-style-type: none"> <li>• Knowledge and skills in the following areas: Filling, packing, labeling and storage placing on the market of medicinal products.</li> </ul> <p>Regulations that apply to over-the-counter medicines:</p> <ul style="list-style-type: none"> <li>• If you do not have the required expertise yourself, one of the following persons must have it:</li> <li>• a person legally appointed to represent the company</li> <li>• a person appointed by you to manage the company or</li> <li>• a person appointed by you to handle sales</li> </ul> <p>If there are several branches, there must be a person in each branch who has the required expertise. If over-the-counter medicines are offered on a self-service basis, a person with the necessary expertise must be available during opening hours.</p> |
| Kosten                       | The fees are based on the respective state law  |
| Verfahrensablauf             | <ul style="list-style-type: none"> <li>• You report the retail sale of over-the-counter medicines</li> <li>• The competent authority checks your notification</li> <li>• Once your notification has been approved, you can start retailing</li> </ul>   |
| Bearbeitungsdauer            | Once you have notified us that you have started work, you may begin retailing.  |
| Frist                        | The notification must be made before commencing work.   |
| weiterführende Informationen |   |
| Hinweise                     | If you wish to operate a mail-order business for over-the-counter medicines, you must also register in  |

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the mail-order register, as every mail-order supplier of medicines in the European Union is obliged to use the common European mail-order logo on its website. It shows consumers that a mail order company is authorized to sell medicinal products for human use by mail order via the Internet in accordance with its respective national law. At first glance, the consumer can recognize the Member State in which the mail order company is established.

The logo must be clearly visible on the website. The click leads to the mail order register.

## Rechtsbehelf

### Kurztext

- Notification Retail sale of over-the-counter medicines Receipt
- Retail sale of over-the-counter medicines is subject to notification
- Retail trade may only be carried out if the entrepreneur has the necessary expertise, either by a person legally appointed to represent the company or by a person entrusted with the management of the company or the sale.
- Exceptions apply to medicinal products which may be dispensed in the itinerant trade, are intended for the prevention of pregnancy or sexually transmitted diseases, and for disinfectants or oxygen intended exclusively for external use
- Responsible: Depends on the respective state law

### Ansprechpunkt

### Zuständige Stelle

### Formulare

### Ursprungsportal