

99005010031000

Medicinal products: Demonstrate expertise to sell over-the-counter medicinal products

Heruntergeladen am 08.06.2025

<https://fimportal.de/xzufi-services/6000188/L100009>

Modul	Sachverhalt
Leistungsschlüssel	99005010031000
Leistungsbezeichnung I	Medicinal products: Demonstrate expertise to sell over-the-counter medicinal products
Leistungsbezeichnung II	Medicinal products: Demonstrate expertise to sell over-the-counter medicinal products
Typisierung	2/3 - Bund: Regelung (2 oder 3), Land/Kommune: Vollzug
Quellredaktion	Sachsen
Freigabestatus Katalog	unbestimmter Freigabestatus
Freigabestatus Bibliothek	unbestimmter Freigabestatus
Begriffe im Kontext	
Leistungstyp	
Leistungsgruppierung	
Verrichtungskennung	

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SDG-Informationsbereich	
Lagen Portalverbund	
Einheitlicher Ansprechpartner	
Fachlich freigegeben am	
Fachlich freigegeben durch	
Handlungsgrundlage	<ul style="list-style-type: none"> • § 44 [Arzneimittelgesetz](http://bundesrecht.juris.de/bundesrecht/amg_1976/index.html) (AMG) – Ausnahme von der Apothekenpflicht <ul style="list-style-type: none"> • § 50 AMG – Handel mit freiverkäuflichen Arzneimitteln • § 64 AMG – Überwachung • § 67 AMG – Anzeigepflicht • § 1 bis 5 [Verordnung über den Nachweis der Sachkenntnis im Einzelhandel mit freiverkäuflichen Arzneimitteln](https://www.gesetze-im-internet.de/amsachkv/BJNR007530978.html) (AMSachVK) <ul style="list-style-type: none"> • § 10 AMSachVK – Anerkennung anderer Nachweise • [Sächsisches Kostenverzeichnis](https://revosax.sachsen.de/vorschrift/12126) (SächsKVZ)
Teaser	<p>The sale of regular medicinal products is generally only permitted in pharmacies. However, the sale of so-called over-the-counter medicinal products is also possible outside pharmacies. If over-the-counter medicines are to be sold in a shop, an employee with proven expertise must always be on site. This expertise can be proven by passing an examination at the IHK.</p>
Volltext	<p>The sale of regular medicinal products is generally only permitted in pharmacies. However, the sale of so-called over-the-counter medicinal products is also possible outside pharmacies. If over-the-counter medicines are to be sold in a shop, an employee with proven expertise must always be on site. This expertise can be proven by passing an examination at the IHK.</p> <ul style="list-style-type: none"> • The activity must be reported to the Saxony Regional Directorate (Landesdirektion), Leipzig office, before it is

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taken up.

- As with any other commercial activity, trading in over-the-counter medicinal products requires notification to the Trade Licensing Office.
- The issuance of the certificate of competence is subject to a fee

Over-the-counter medicinal products include:

- Medicinal plants and parts of them, for example violet root
- Mixtures of whole or cut plants or parts of plants, e.g. cough and bronchial tea
- Pressed juices from fresh plants
- Distillates from plants
- Healing earth, bathing-peat, bath preparations, soaps
- Medicinal waters and their salts
- Plasters
- Disinfectants for external use

Erforderliche Unterlagen

- Proof of expertise
- official photo ID for identification at the start of the examination

Voraussetzungen

Expertise test

- Qualified persons must demonstrate knowledge and skills in the proper filling, packaging, labelling and storage of medicinal products and know how to place medicinal products on the market.
- Those who cannot provide such proof must take an examination of expertise before an examination board of a Chamber of Industry and Commerce (IHK).
- Examination applicants register with the Chamber of Industry and Commerce in whose chamber district the place of employment/training or further education is located or the applicant has or last had his or her habitual residence.

****Note:**** With a university degree or vocational

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	<p>training in pharmacy, you may already have this expertise and do not need to prove it again.</p> <p>For more details on this as well as on the requirements and the conduct of the examination, please refer to the "Ordinance on Proof of Expertise in the Retail Trade of Over-the-Counter Medicinal Products (AMSachKV)". (see -> Legal basis)</p>
Kosten	Procedural fee: Calculation according to the fee schedule of the IHK
Verfahrensablauf	<ul style="list-style-type: none"> • Inform the Landesdirektion Sachsen in an informal letter that you would like to sell over-the-counter medicinal products. • Enclose the necessary evidence (if available) proving your expertise or the expertise of your employees with your letter. <p>The IHK will confirm the date of the examination. The examination comprises 50 multiple-choice questions and five open questions, for example on</p> <ul style="list-style-type: none"> • the proper storage of over-the-counter medicines, • possible dangers in the event of overdosage of the active ingredients, and • legal regulations for handling and selling. <p>After successful completion of the examination, you will receive your certificate.</p>
Bearbeitungsdauer	You will usually receive the certificate a few days after passing the exam.
Frist	Report: before taking up the activity
weiterführende Informationen	
Hinweise	
Rechtsbehelf	Objection (details on the procedure in the decision)

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Kurztext	
Ansprechpunkt	
Zuständige Stelle	
Formulare	
Ursprungsportal	