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Show retail sale of non-prescription medicines

Heruntergeladen am 10.06.2025

<https://fimportal.de/xzufi-services/244604712/L100012>

Modul	Sachverhalt
Leistungsschlüssel	99005072261000, 99005072261000
Leistungsbezeichnung I	Show retail sale of non-prescription medicines
Leistungsbezeichnung II	
Typisierung	3 - Bundesaufsichtsverwaltung: Regelung
Quellredaktion	Schleswig-Holstein
Freigabestatus Katalog	unbestimmter Freigabestatus
Freigabestatus Bibliothek	fachlich freigegeben (gold)
Begriffe im Kontext	
Leistungstyp	Leistungsobjekt mit Verrichtung
Leistungsgruppierung	Arzneimittel (005)
Verrichtungskennung	Entgegennahme (261)
SDG-Informationsbereich	Erlangung von Lizenzen, Genehmigungen oder Zulassungen im Hinblick auf die Gründung und Führung eines Unternehmens
Lagen Portalverbund	Erlaubnisse und Genehmigungen (2010400)

Modul	Sachverhalt
Einheitlicher Ansprechpartner	Nein
Fachlich freigegeben am	13.07.2023
Fachlich freigegeben durch	Ministry of Justice and Health of the State of Schleswig-Holstein
Handlungsgrundlage	https://www.gesetze-im-internet.de/amg_1976/_44.html https://www.gesetze-im-internet.de/amg_1976/_50.html https://www.gesetze-im-internet.de/amg_1976/_52.html https://www.gesetze-im-internet.de/amg_1976/_67.html https://www.gesetze-im-internet.de/amg_1976/_51.html
Teaser	If you wish to sell over-the-counter medicines outside of pharmacies, you must register this with the competent authority.
Volltext	<p>If you wish to trade in over-the-counter medicines, you do not require a license; all you need to do is register with the competent authority.</p> <p>All companies in which over-the-counter medicines are manufactured, stored, packaged or placed on the market are subject to supervision by the competent authorities.</p> <p>The competent authority must ensure that the relevant legal standards are observed. This is carried out by means of regular unannounced inspections for which a fee is charged or inspections on an ad hoc basis.</p> <p>The facilities, companies or other persons have a far-reaching obligation to tolerate and cooperate. If they do not comply with the statutory regulations, the competent authority can initiate appropriate measures in accordance with the Medicinal Products Act.</p> <p>This includes verbal or written orders to prevent or eliminate deficiencies, and violations can also be</p>

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	punished as an administrative offense with a warning, warning fine, fine or as a criminal offense.
Erforderliche Unterlagen	<ul style="list-style-type: none"> • Completed notification form • Certificate of competence or comparable professional qualification
Voraussetzungen	<p data-bbox="507 613 815 649">**Proof of expertise**</p> <p data-bbox="507 689 1209 913">Over-the-counter medicines may be sold outside pharmacies provided that the person operating the business, the legal representative or the person responsible for the management or sale of the over-the-counter medicines has the necessary expertise and can provide proof of this.</p> <p data-bbox="507 954 1262 1256">A competent person must be present at each establishment and must also be present during normal sales hours so that qualified advice and proper sales can be guaranteed. If this is not possible, the medicinal products must be suitably withdrawn from the customer's access and sale for the duration of the absence of the competent person (e.g. via lockable shelf cabinets).</p> <p data-bbox="507 1296 1251 1554">The details of the scope and proof of expertise are regulated. The expertise includes knowledge and skills regarding the proper filling, packaging, labeling, storage and placing on the market of medicinal products that are approved for sale outside pharmacies and knowledge of the regulations applicable to these medicinal products.</p> <p data-bbox="507 1594 1251 1818">Expertise is not required when placing finished medicinal products on the retail market that may be dispensed in tourist traffic, that are used to prevent pregnancy or sexually transmitted diseases in humans or certain disinfectants that are intended exclusively for external use or oxygen in oxygen cylinders.</p> <p data-bbox="507 1859 1251 2004">The required expertise can be demonstrated either by a corresponding examination, by examination certificates for relevant professional training or in some other way.</p>

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	<p>The examination certificates for the specializations</p> <ul style="list-style-type: none"> • pharmacy • chemistry • biology • human or veterinary medicine <p>from universities as well as the professional training</p> <ul style="list-style-type: none"> • to become a trainee pharmacist • as a pharmaceutical-technical assistant • to become a druggist • to become a pharmaceutical engineer • to become a pharmacy assistant • to become a pharmacy assistant • to become a pharmaceutical and commercial assistant <p>are recognized as proof of competence.</p>
Kosten	<p>Gebühr: 50€ - 4.000€</p> <p>The competent authorities charge fees for \- the confirmation of notifications (50 to 2000 euros) \- the monitoring of establishments (50 to 4000 euros) \- sampling (50 to 1000 euros) \- measures (20 to 4000 euros)</p> <p>https://www.gesetze-rechtsprechung.sh.juris.de/perma?j=VwGebV_SH</p>
Verfahrensablauf	<ul style="list-style-type: none"> • As a rule, you can register trade in over-the-counter medicinal products with the competent authority by e-mail or in writing by post. • Further information on the procedure can be found on the websites of the competent authorities.
Bearbeitungsdauer	There are no statutory processing deadlines.
Frist	You must register the sale before starting the activity.
weiterführende Informationen	

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Hinweise	<p>Trade in over-the-counter medicines outside of pharmacies is not subject to authorization.</p> <p>**Some tips on handling medicines**</p> <p>Stocks of medicines must be stored in accordance with the regulations and the manufacturer's storage instructions must be observed. Over-the-counter medicines are usually stored at room temperature (15-25 degrees Celsius). Document compliance with the prescribed temperature. Protect the medicines from direct sunlight or indirect heat. In addition, you should avoid storing medicines next to odorous products, perishable foods or on the floor. The expiry date ("use by ...") must be strictly observed.</p>
Rechtsbehelf	You can lodge an appeal against the fee notices.
Kurztext	<ul style="list-style-type: none"> • Notification Retail sale of over-the-counter medicines Receipt • Monitoring the retail trade in over-the-counter medicines • Registration in accordance with the Medicinal Products Act • Proof of expertise in accordance with the Medicinal Products Act • Responsible: Health authorities of the districts and independent cities
Ansprechpunkt	Please contact the public health department of your district or city.
Zuständige Stelle	The health authorities of the districts and independent cities are responsible.
Formulare	
Ursprungsportal	Einzelhandel mit verschreibungsfreien Arzneimitteln anzeigen, Show retail sale of non-prescription medicines