Freie Hansestadt Bremen

Over-the-counter medicines

Businesses and establishments dealing in over-the-counter medicines must register them with the regulatory authority.

Competent Department

- Ordnungsamt | Referat 10 & 13 - Allgemeine Ordnungsangelegenheiten

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Basic information

Over-the-counter drugs may be sold outside pharmacies. Drugs are considered over-the-counter if they do not require a prescription and are not available at pharmacies.

Any retail business wishing to place medicines on the market must notify the competent supervisory authority of this activity in advance in accordance with Section 67 of the German Medicines Act (AMG). This also applies, for example, to supermarkets and drugstores. Subsequent changes must also be notified.

Information on handling medicinal products:

- Medicinal products must be stored in accordance with regulations. The manufacturer's storage instructions must be observed.
- The commonly offered over-the-counter medicines are to be stored at room temperature. This corresponds to a temperature of 15-25 degrees Celsius. Compliance with the temperature must be documented.
- The expiration date must be checked regularly. Medicinal products with an expired expiry date must be removed from circulation immediately so that access by customers is no longer possible.
- Medicines must be stored separately from perishable goods.
- The storage place must be dry. Storage on the floor is not permitted.

Requirements

According to Section 50 of the German Medicines Act, the prerequisite for trading in over-the-counter medicinal products outside pharmacies is proof of the required expertise.

However, expert knowledge is not required for anyone who places finished medicinal products on the market in the retail trade which

- may be supplied in tourist traffic
- are intended for the prevention of pregnancy or sexually transmitted diseases in humans,
- disinfectants intended exclusively for external use, or
- oxygen

are.

Certificates of the following degrees are considered proof of expertise:

- Pharmacist
- druggist
- Pharmacy assistant
- Pharmacy engineer
- Pharmacy assistant
- Pharmaceutical-technical:r Assistant:in
- Pharmaceutical-commercial:r employee:r
- Certificate of competence with successful examination before the Chamber of Industry and Commerce.

In order to monitor the proper marketing of the medicinal products and to be available to customers for advice, at least one competent person must be present during the opening hours of the establishment. If this cannot be ensured, the medicinal products may not be sold for the duration of the absence of the competent person.

Procedure

Trade in over-the-counter medicinal products can be notified using the attached form. The notification must state the type of activity and the business premises; if medicinal products

are collected, details of the type of collection and the storage location must be provided. In addition to the notification form, we require a scan/copy of your certificate of competence.

You are welcome to send us the documents by e-mail.

According to § 64 AMG, establishments and facilities in which medicinal products are manufactured, tested, stored, packaged or placed on the market, or in which they are otherwise traded, are subject to supervision by the competent authority. The competent authority must therefore satisfy itself that the regulations on the marketing of medicinal products, on advertising in the field of medicine and on pharmacy are being observed.

The Bremen Regulatory Authority therefore intends to carry out regular inspections at your premises and will, if necessary, have any pharmaceutical items officially inspected.

Legal bases

- Arzneimittelgesetz

More information

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What deadlines must be paid attention to?

Not specified

How long does it take to process

Not specified

What are the costs?

Both the examination and confirmation of a notification pursuant to Section 67 AMG and the examination of the trade in medicinal products in the establishments (pursuant to Sections 64 ff. AMG) are subject to a fee.
The fees are charged within the specified cost framework for the item 100.00 of the General Schedule of Costs (AllKostV) according to the average time required and taking into account the regulations in item 103.00 of the AllKostV and in Section 5 (1) of the Bremen Fees and Contributions Act (BremGebBeitrG).