

Apply for permission to ship pharmacy-only medicines

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Find out how to obtain a permit to ship pharmacy-only drugs and what requirements you must meet.

Competent Department

• <u>Die Senatorin für Gesundheit, Frauen und Verbraucherschutz | Referat 23 Pharmazie,</u> <u>Medizinprodukte und Umwelthygiene</u>

Basic information

For the granting of a permit to ship pharmacy-only drugs according to § 11a Pharmacy Act (ApoG), please submit a written, informal application.

This application must be submitted to the competent authority together with the necessary documents.

Requirements

- Applicant is the owner of a public pharmacy
- Dispatch may only be made from a public pharmacy, in addition to the usual
- · pharmacy operation
- The legal requirements for pharmacy operations apply
- A quality assurance system for the shipping operation must be in place

What documents do I need?

- Informal, written request
- Required documents result from § 11a Pharmacy Act (ApoG)

For more details on the type and scope of the documents, please refer to the leaflet "Application for permission to ship pharmacy-only drugs".

• Room details

If space outside the approved pharmacy premises is to be used for mail order operations: Details of the size, nature, furnishings, and function of the additional business premises, submitting floor plans to scale and the lease agreement.

Procedure

- You submit your written application for a mail order permit and all required documents to the competent authority.
- The authority may request additional documents.
- The mail order permit is to be issued when the competent authority determines that the legal requirements have been met.

Legal bases

- § 11a Apothekengesetz (ApoG)
- <u>§ 43 Absatz 1 Arzneimittelgesetz (AMG)</u>

More information

- All drug retailers operating a web store must be entered in a central register at the Federal Institute for Drugs and Medical Devices (BfArM).
- The BfArM maintains a mail-order pharmacy register in which all German pharmacies with a mail-order authorization are listed. The BfArM issues a safety logo to these retailers, which the providers can also display on their homepage. Consumers can view the mail-order pharmacy register on the BfArM website.
- For more information, please refer to the links "Registered drug distributors" and "Mail-order register".

What deadlines must be paid attention to?

4 weeks The application should be submitted at least 4 weeks before the pharmacy plans to begin mail order operations.

How long does it take to process

4 weeks

What are the costs?

Please note that there is a fee for issuance of the permit pursuant to Section 500.03 of the current Bremen Health Care Cost Ordinance.