

99005002005000

Heruntergeladen am 18.06.2025

<https://fimportal.de/xzufi-services/106451/L100042>

Modul	Sachverhalt
Leistungsschlüssel	99005002005000
Leistungsbezeichnung I	
Leistungsbezeichnung II	Pharmacy-only medicines; application for a permit for shipping
Typisierung	2/3 - Bund: Regelung (2 oder 3), Land/Kommune: Vollzug
Quellredaktion	Bayern
Freigabestatus Katalog	unbestimmter Freigabestatus
Freigabestatus Bibliothek	unbestimmter Freigabestatus
Begriffe im Kontext	
Leistungstyp	
Leistungsgruppierung	
Verrichtungskennung	
SDG-Informationsbereich	
Lagen Portalverbund	
Einheitlicher Ansprechpartner	

Modul	Sachverhalt
Fachlich freigegeben am	05.09.2024
Fachlich freigegeben durch	Bayerisches Staatsministerium für Gesundheit, Pflege und Prävention (Bavarian State Ministry of Health, Care and Prevention)
Handlungsgrundlage	https://www.gesetze-im-internet.de/apog/_11a.html https://www.gesetze-im-internet.de/apog/_11a.html https://www.gesetze-im-internet.de/apobetro_1987/_4.html https://www.gesetze-im-internet.de/apobetro_1987/_4.html https://www.gesetze-im-internet.de/apobetro_1987/BjNR005470987.html https://www.gesetze-im-internet.de/apobetro_1987/BjNR005470987.html https://www.gesetze-im-internet.de/amg_1976/_43.html https://www.gesetze-im-internet.de/amg_1976/_43.html https://www.gesetze-bayern.de/Content/Document/BayZustVAMUeB https://www.gesetze-bayern.de/Content/Document/BayZustVAMUeB
Teaser	If pharmacies want to ship pharmacy-only medicines, they need a permit to do so.
Volltext	Pharmacies that are in possession of a mail-order license are permitted to market medicinal products by mail order. These pharmacies are authorized to send medicines to patients in Germany and other EU member states. In doing so, the supplying pharmacy must comply with the applicable law in the country of destination.
Erforderliche Unterlagen	<ul style="list-style-type: none"> • Informal application for a mail order permit according to § 11 a ApoG with information on the planned scope of the mail order business • Written or electronic assurance of compliance with the requirements of Section 11a ApoG and Section 17 (2) ApoBetrO Information on the planned scope of mail order business • If premises outside the approved pharmacy premises are to be used for the mail order business: Site plan on

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a scale of 1:100 and, if applicable, rental agreement.

Voraussetzungen

Mail order may only be carried out from a public pharmacy for which an operating license has been issued, in addition to the usual pharmacy operations. Pure mail-order pharmacies are not permitted. The statutory regulations for pharmacy operations apply. The mail-order premises from which the mail-order business is to be operated must be located in reasonable proximity to the other operating premises of the pharmacy.

A quality assurance system for the mail order process must be in place. This ensures that

- the medicinal product to be dispatched is packaged, transported and delivered in such a way that its quality and efficacy are maintained; in particular, the temperature requirements applicable to the medicinal product must be complied with during transportation until delivery to the recipient,
- the dispatched medicinal product is delivered to the person notified to the pharmacy by the person placing the order. This specification may in particular include delivery to a named natural person or a named group of persons,
- the patient is informed of the need to contact the attending physician if problems arise with the medication, and
- the advice will be provided by pharmaceutical staff in German.

The holder of the pharmacy operating license must also ensure that

- the ordered medicinal product is dispatched within two working days of receipt of the order, insofar as the medicinal product is available within this period, unless other arrangements have been made with the person who ordered the medicinal product; if it is apparent that the ordered medicinal product cannot be dispatched within the aforementioned period, the customer must be informed of this in an appropriate manner,
- all ordered medicinal products are delivered, insofar as they may be placed on the market within the scope of the Medicinal Products Act and are available,
- a suitable system is available for the reporting of such risks by customers, for informing customers about

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such risks and for internal defensive measures in the event that risks become known with medicinal products,

- the person receiving treatment is informed that, as a prerequisite for the supply of medicinal products, they must provide a telephone number with their order, under which they can be advised by the pharmacy's pharmaceutical staff, including by means of telecommunications facilities, at no additional charge; they must be informed of the possibilities and times of the consultation,
- a second delivery is arranged free of charge,
- a shipment tracking system is maintained and
- transportation insurance is taken out.

If the planned mail-order pharmacy is to be an "Internet pharmacy" - as is generally the case - the pharmacy must also have the facilities and equipment suitable for e-commerce.

Kosten

Verfahrensablauf

- You submit your informal application for a mail-order permit in accordance with Section 11 a ApoG and all the necessary documents to the district administrative authority responsible for the location of the main pharmacy.
- The authority may request further documents.
- The mail-order permit is issued if the competent authority determines that the legal requirements have been met.
- As a rule, a fee-based inspection of the pharmacy is carried out by the responsible honorary pharmacist of the government of Upper Bavaria or the government of Upper Franconia.

Bearbeitungsdauer

Frist

- The permit must be applied for before starting the activity. The application should be submitted at least 4 weeks before the planned start of the pharmacy's mail-order business.
- The processing time depends on the completeness and scope of the documents submitted. It can therefore vary from case to case.
- The permit can only be issued once all the necessary documents have been submitted and any outstanding issues have been clarified.
- Mail-order business may

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	only be commenced once the permit has been issued.
weiterführende Informationen	https://www.bfarm.de/DE/Arzneimittel/Arzneimittelinformationen/Versandhandels-Register/_node.html https://www.bfarm.de/DE/Arzneimittel/Arzneimittelinformationen/Versandhandels-Register/_node.html
Hinweise	The mail-order register of the Federal Institute for Drugs and Medical Devices (BfArM) lists pharmacies and other retailers that are officially authorized to sell medicinal products for human use online. Since October 2015, all registered distributors must display the EU safety logo on their websites, in each case with the flag of the Member State in which the company is based.
Rechtsbehelf	Administrative court action
Kurztext	
Ansprechpunkt	
Zuständige Stelle	
Formulare	
Ursprungsportal	BayernPortal, BayernPortal