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Applying for an operating license for a hospital pharmacy

Heruntergeladen am 18.06.2025

<https://fimportal.de/xzufi-services/121296678/L100002>

Modul	Sachverhalt
Leistungsschlüssel	99004001005000, 99004001005000
Leistungsbezeichnung I	Applying for an operating license for a hospital pharmacy
Leistungsbezeichnung II	Applying for an operating license for a hospital pharmacy
Typisierung	2 - Bundesauftragsverwaltung: Regelung, 3 - Bundesaufsichtsverwaltung: Regelung
Quellredaktion	Nordrhein-Westfalen
Freigabestatus Katalog	fachlich freigegeben (gold)
Freigabestatus Bibliothek	fachlich freigegeben (gold)
Begriffe im Kontext	
Leistungstyp	Leistungsobjekt mit Verrichtung
Leistungsgruppierung	Apotheken (004)
Verrichtungskennung	Erlaubnis (005)
SDG-Informationsbereich	Erlangung von Lizenzen, Genehmigungen oder Zulassungen im Hinblick auf die Gründung und

Modul	Sachverhalt
	Führung eines Unternehmens
Lagen Portalverbund	Anmeldepflichten (2010100), Erlaubnisse und Genehmigungen (2010400)
Einheitlicher Ansprechpartner	Nein
Fachlich freigegeben am	26.08.2024
Fachlich freigegeben durch	Federal Ministry of Health (BMG)
Handlungsgrundlage	https://www.gesetze-im-internet.de/apog/_14.html https://www.gesetze-im-internet.de/apobetro_1987/BJNR005470987.html#BJNR005470987BJNG000301307
Teaser	You need a license to operate a hospital pharmacy. You can apply for this from the local competent authority.
Volltext	<p>If you want to operate a hospital pharmacy as the owner of a hospital, you must apply for a permit to do so.</p> <p>The hospital pharmacy is a functional unit of a hospital. It is responsible for the safe and proper supply of one or more hospitals with medicines and pharmacy-only medical products.</p> <p>It also informs and advises doctors, nursing staff and patients about the medicines and medical devices used.</p> <p>In order to obtain the operating license, you must provide evidence of the prescribed premises and employ a pharmacist who meets the requirements of the Pharmacy Act as a manager.</p> <p>A hospital does not necessarily need its own hospital pharmacy, but can also be supplied by the pharmacy of another hospital or a public pharmacy (hospital-supplying pharmacy) on a contractual basis.</p>
Erforderliche Unterlagen	<ul style="list-style-type: none"> • Floor plan of the pharmacy operating rooms • The size, location, furnishings and function designations of the individual pharmacy operating rooms must be visible • For new openings: copy of the building permit from the building supervisory authority • Proof of the rooms required for a hospital pharmacy:

Modul

Sachverhalt

- Notification of the number of employees, broken down into specialist staff and other staff
- The following documents must be submitted by the head of the hospital pharmacy:
 - Identity document, proof of nationality if applicable
 - Tabular proof of activity after licensure as a pharmacist
 - Certificate of licensure (certified copy or transcript)
 - Certificate of good conduct, document type 0 for submission to an authority
 - Medical certificate of suitability to properly manage a pharmacy (not older than 3 months)
 - legal capacity
 - any criminal proceedings, professional court proceedings and investigation proceedings as well as the authorization to practice the profession with regard to the reliability check
 - the operation of other pharmacies
 - the complete existence of all contracts and agreements relating to the establishment and operation of the pharmacy
 - the completeness and accuracy of the information
 - Declaration of

Voraussetzungen

- You must employ a pharmacist who fulfills the requirements of the Pharmacy Act
- Proof of the rooms required for hospital pharmacies in accordance with the Pharmacy Operating Regulations

Kosten

Different regulations in the countries.

Verfahrensablauf

- First, you should contact your competent authority to describe your project and discuss the scope of the documents to be submitted.
- Next, submit a complete written application.
- Your application will be reviewed by the competent authority.
- If necessary, the competent authority will request further documents.
- If the requirements of the Pharmacy Act are met, you will be issued an operating license.
- Pharmacy operations may only commence after an acceptance inspection by the competent authority.

Bearbeitungsdauer

Different regulations in the countries.

Modul	Sachverhalt
Frist	You may only start operating your hospital pharmacy once the competent authority has granted you permission to do so.
weiterführende Informationen	
Hinweise	
Rechtsbehelf	Action before the administrative court
Kurztext	<ul style="list-style-type: none"> • Operation of a hospital pharmacy Permit • A hospital pharmacy may only be operated after a permit has been issued • The written application must be submitted by the responsible body of the hospital • The head of the hospital pharmacy must be named in writing • A hospital does not necessarily need its own hospital pharmacy, but can also be supplied by the pharmacy of another hospital or a public pharmacy (hospital-supplying pharmacy) on a contractual basis
Ansprechpunkt	Different regulations in the countries.
Zuständige Stelle	You can find out the responsible authority in accordance with § 1 (2) of the Pharmacy Act from the Chamber of Pharmacists responsible for you.
Formulare	
Ursprungsportal	Applying for an operating license for a hospital pharmacy, Betriebserlaubnis für Krankenhausapotheke beantragen