

99005111169001

Production of medicinal products without a license Notification by persons authorized to practice medicine

Heruntergeladen am 10.06.2025

<https://fimportal.de/services/99005111169001>

Modul	Sachverhalt
Leistungsschlüssel	99005111169001
Leistungsbezeichnung I	Production of medicinal products without a license Notification by persons authorized to practice medicine
Leistungsbezeichnung II	Display the manufacture of medicinal products by persons authorized to practice medicine without a license
Typisierung	3 - Bundesaufsichtsverwaltung: Regelung
Quellredaktion	Baustein Leistungen
Freigabestatus Katalog	unbestimmter Freigabestatus
Freigabestatus Bibliothek	fachlich freigegeben (silber)
Begriffe im Kontext	
Leistungstyp	Leistungsobjekt mit Verrichtung

Modul	Sachverhalt
Leistungsgruppierung	Drugs (individuell, 005)
Verrichtungskennung	Anzeige (169)
SDG-Informationsbereich	Erlangung von Lizenzen, Genehmigungen oder Zulassungen im Hinblick auf die Gründung und Führung eines Unternehmens
Lagen Portalverbund	Berufszulassungen und Berechtigungen (1040500), Anmeldepflichten (2010100)
Einheitlicher Ansprechpartner	Nein
Fachlich freigegeben am	16.01.2025
Fachlich freigegeben durch	Ministry for Social Affairs, Youth, Family, Senior Citizens, Integration and Equality in Schleswig-Holstein
Handlungsgrundlage	https://www.gesetze-im-internet.de/amg_1976/_67.html https://www.gesetze-im-internet.de/amg_1976/_13.html
Teaser	If you, as a person authorized to practice medicine, wish to manufacture medicinal products under your direct professional responsibility for the purpose of personal use on a specific patient, you must register this activity with the competent authority.
Volltext	Every doctor and every dentist is personally obliged to report the manufacture of medicinal products for individual patients. This applies to every person who is authorized to practice medicine on humans, including alternative practitioners.
Erforderliche Unterlagen	<ul style="list-style-type: none"> • Notification with name and composition of the medicinal products • Approbation • Professional license for alternative practitioners
Voraussetzungen	<ul style="list-style-type: none"> • You have a license to practise as a doctor, dentist or alternative practitioner. • The medicinal products are prepared under your direct professional responsibility for the purpose of personal use on a specific patient.

Modul	Sachverhalt
Kosten	
Verfahrensablauf	You notify the competent authority of the manufacture of the medicinal products in writing with the self-declaration or online, stating the type of activity and the operating site as well as the name and composition of the medicinal products.
Bearbeitungsdauer	
Frist	You report the manufacture of medicinal products before you start the activity.
weiterführende Informationen	
Hinweise	<p>Special information on the manufacture subject to notification:</p> <p>The quality, efficacy and safety of medicinal products manufactured without a license must be ensured by the doctor or alternative practitioner. As the quality of a medicinal product is determined by the manufacturing process, manufacture must be carried out in accordance with the recognized pharmaceutical rules, in particular the European Pharmacopoeia.</p> <p>Therefore, appropriate and suitable spatial and hygienic environmental conditions are expected for the manufacturing process so that the quality of the manufactured medicinal product is not impaired. The traceability of the manufacture and, if necessary, testing and the use on the patient must be ensured by the available documentation.</p> <p>The manufacturing person is ultimately personally responsible for the quality of the medicinal product.</p>
Rechtsbehelf	<ul style="list-style-type: none"> • Objection <p>Further information on how to lodge an objection can be found in your cost assessment notice.</p>
Kurztext	<ul style="list-style-type: none"> • Written notification with the self-declaration or online

Modul

Sachverhalt

for the manufacture of medicinal products to the competent authority

- Details:
 - Type of activity and
 - the establishment and
 - the name and composition of the medicinal products.
- Other required documents:
 - License to practice medicine as a doctor, dentist or dentist or
 - Professional license for alternative practitioners.
 - The medicinal products are prepared under your direct professional responsibility for the purpose of personal use on a specific patient.

Ansprechpunkt

Zuständige Stelle

Formulare

Ursprungsportal