

99005001005000

Herstellung von Arzneimitteln Erlaubnis

Heruntergeladen am 16.06.2025

<https://fimportal.de/xzufi-services/S1000030001877131/S100003>

Modul	Sachverhalt
Leistungsschlüssel	99005001005000
Leistungsbezeichnung I	Herstellung von Arzneimitteln Erlaubnis
Leistungsbezeichnung II	Production of medicinal products without permission
Typisierung	2/3 - Bund: Regelung (2 oder 3), Land/Kommune: Vollzug
Quellredaktion	Bremen
Freigabestatus Katalog	unbestimmter Freigabestatus
Freigabestatus Bibliothek	unbestimmter Freigabestatus
Begriffe im Kontext	Medicine, Duty of disclosure
Leistungstyp	
Leistungsgruppierung	
Verrichtungskennung	
SDG-Informationsbereich	
Lagen Portalverbund	Patente und geistiges Eigentum (2100500), Produkt- und Stoffzulassung (2120200)

Modul	Sachverhalt
Einheitlicher Ansprechpartner	
Fachlich freigegeben am	29.02.2024
Fachlich freigegeben durch	
Handlungsgrundlage	https://www.gesetze-im-internet.de/amg_1976/__13.html https://www.gesetze-im-internet.de/amg_1976/__20d.html https://www.gesetze-im-internet.de/amg_1976/__67.html
Teaser	In certain cases, physicians, dentists and non-medical practitioners may manufacture medicinal products without a license, i.e. without having a manufacturing authorization. There are certain regulations for this, and the competent authority must be notified before the activity is commenced.
Volltext	Anyone who intends to manufacture medicinal products generally requires a manufacturing license in accordance with Section 13 (1) of the German Medicines Act (AMG). For physicians, dentists and non-medical practitioners, the law describes an exception under certain conditions under § 13 para. 2b or § 20d. Anyone wishing to make use of this exemption must notify the competent authority in accordance with Section 67 (1) and (2) AMG.
Erforderliche Unterlagen	No documents required.
Voraussetzungen	You have a license as a (dental) physician or a license as a non-medical practitioner and the production of the medicinal product takes place • under your direct professional responsibility and • for the purpose of personal use by you on a specific patient. The notification to the competent authority must be

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	made before the start of the activity.
Kosten	The notification is usually free of charge. In the case of more complex tests and monitoring measures, costs may be incurred in accordance with the Bremen Health Costs Ordinance.
Verfahrensablauf	After you have completed the online form, the competent authority will be informed about the notification. The authority checks the notification and contacts you with queries in the event of ambiguities or discrepancies. You will receive a notification from the competent authority that the notification has been received.
Bearbeitungsdauer	3 Woche(n)
Frist	
weiterführende Informationen	2-3 weeks. The processing time and the extent of the inquiries depend on the quality of the information submitted and may entail an on-site monitoring measure if necessary.
Hinweise	
Rechtsbehelf	
Kurztext	
Ansprechpunkt	
Zuständige Stelle	
Formulare	
Ursprungsportal	Serviceportal der Freien Hansestadt Bremen, Service portal of the Free Hanseatic City of Bremen