

99005111169000

Heruntergeladen am 10.06.2025

<https://fimportal.de/xzufi-services/55291/L100042>

Modul	Sachverhalt
Leistungsschlüssel	99005111169000
Leistungsbezeichnung I	
Leistungsbezeichnung II	Medicinal products; notification of manufacture without authorization
Typisierung	3 - Bundesaufsichtsverwaltung: Regelung
Quellredaktion	Bayern
Freigabestatus Katalog	unbestimmter Freigabestatus
Freigabestatus Bibliothek	unbestimmter Freigabestatus
Begriffe im Kontext	
Leistungstyp	
Leistungsgruppierung	
Verrichtungskennung	
SDG-Informationsbereich	
Lagen Portalverbund	
Einheitlicher Ansprechpartner	
Fachlich freigegeben am	17.04.2025

Modul	Sachverhalt
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/amg_1976/_67.html https://www.gesetze-im-internet.de/amg_1976/_67.html https://www.gesetze-im-internet.de/amg_1976/_13.html https://www.gesetze-im-internet.de/amg_1976/_13.html https://www.gesetze-bayern.de/Content/Document/BayZustVAMUeB-2 https://www.gesetze-bayern.de/Content/Document/BayZustVAMUeB-2
Teaser	If the manufacture of medicinal products for which a license is not required in accordance with Section 13 of the German Medicinal Products Act (AMG) is intended, the medicinal products must be notified together with their name and composition.
Volltext	A license pursuant to Section 13 (1) of the German Medicinal Products Act (AMG) is not required for physicians or alternative practitioners if the medicinal products are manufactured under their direct professional responsibility for the purpose of personal use on a specific patient. However, the manufacture of medicinal products must be notified in accordance with Section 67 Para. 2 AMG. The persons concerned must notify the competent authority of their planned activity. The authority will check whether the activity may require a license.
Erforderliche Unterlagen	• Description of the production activities (if possible, please PDF file) • Proof of qualification as a doctor or non-medical practitioner • Information on rooms and facilities
Voraussetzungen	The notifying party must be a doctor, dentist or

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	alternative practitioner.
Kosten	Costs for the notification confirmation: 50 to 5,000 € (according to the list of costs - tariff no. 7.IX.8 / tariff item 1.1.4.3) They are to be borne by the notifying party.
Verfahrensablauf	The informal notification must be sent to the responsible government with the required information and documents (see information sheet under "Further links").
Bearbeitungsdauer	Depending on the questions to be clarified, processing may take some time.
Frist	The notification can only be confirmed after all the necessary documents have been submitted and any unanswered questions have been clarified and a professional assessment has been carried out. The Medicinal Products Act does not set any deadlines.
weiterführende Informationen	https://formularserver.bayern.de/intelliform/forms/stmi+regierungen/rof/b5/53.2/rof_53.2-063/index https://formularserver.bayern.de/intelliform/forms/stmi+regierungen/rof/b5/53.2/rof_53.2-063/index
Hinweise	
Rechtsbehelf	
Kurztext	
Ansprechpunkt	
Zuständige Stelle	
Formulare	
Ursprungsportal	BayernPortal, BayernPortal