

99005019261000

Heruntergeladen am 24.06.2025

<https://fimportal.de/xzufi-services/135824/L100042>

Modul	Sachverhalt
Leistungsschlüssel	99005019261000
Leistungsbezeichnung I	
Leistungsbezeichnung II	Medicinal products; notification of the information officer
Typisierung	2 - Bundesauftragsverwaltung: 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	17.10.2024

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/_74a.html https://www.gesetze-im-internet.de/amg_1976/_74a.html https://www.gesetze-bayern.de/Content/Document/BayZustVAMUeB-2 https://www.gesetze-bayern.de/Content/Document/BayZustVAMUeB-2
Teaser	Pharmaceutical companies that place finished medicinal products on the market must notify the competent authority of an information officer. Any change must be reported immediately.
Volltext	Any pharmaceutical entrepreneur who places finished medicinal products on the market must appoint a person with the necessary expertise and the reliability required to perform their duties to be responsible for providing scientific information on the medicinal products. The information officer is responsible in particular for ensuring that • the prohibition of § 8 para. 1 no. 2 of the German Medicinal Products Act (AMG) (publication of misleading information) is observed and • the labeling, package leaflet, expert information and advertising comply with the content of the marketing authorization or registration or, if the medicinal product is exempt from marketing authorization or registration, with the content of the ordinances on exemption from marketing authorization or registration pursuant to Section 36 or Section 39 para. 3 AMG. The information officer may also be the graduated plan officer pursuant to Section 63a AMG.
Erforderliche Unterlagen	• Appointment of the information officer - Specification of name and contact details (telephone/fax number;

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	e-mail address) is required. The designation must be dated and signed by both parties. • Proof of expertise through signed curriculum vitae, certified certificates of education/studies, relevant qualified references • personal reliability Official certificate of good conduct of document type O (original, not older than 3 months). Please indicate the person applying for the certificate, the company name and location, and the file number.
Voraussetzungen	The information officer must demonstrate the necessary expertise and the reliability required to perform the task of providing scientific information on medicinal products responsibly Information officers require a university degree in pharmacy, chemistry, biology, human or veterinary medicine or completed training in the aforementioned fields.
Kosten	Fee for advertisement confirmation: EUR 150
Verfahrensablauf	The notification of the information officer can be made informally in writing or online (see "Online procedure"). It must be sent with the necessary documents to prove the expertise to • the government of Upper Bavaria for the administrative districts of Upper Bavaria, Lower Bavaria and Swabia, • the government of Upper Franconia for the administrative districts of Upper, Middle and Lower Franconia and Upper Palatinate. Upon receipt, the authority checks the notification for completeness, content and technical aspects. Missing documents will be requested. If all the necessary evidence and documents are available, the notification will be confirmed.
Bearbeitungsdauer	The processing time depends on the completeness and scope of the documents submitted. It can therefore vary individually.
Frist	The pharmaceutical entrepreneur must notify the competent authority in advance of the information

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	officer and of any change. In the event of an unforeseen change of information officer, notification must be made immediately. A confirmation of the notification can only be issued after all necessary documents have been submitted and any open questions have been clarified.
weiterführende Informationen	
Hinweise	
Rechtsbehelf	Administrative court action
Kurztext	
Ansprechpunkt	
Zuständige Stelle	
Formulare	
Ursprungsportal	BayernPortal, BayernPortal