

99005019261000

Show information officers for pharmaceutical companies

Heruntergeladen am 24.06.2025

<https://fimportal.de/xzufi-services/6018991/L100022>

Modul	Sachverhalt
Leistungsschlüssel	99005019261000
Leistungsbezeichnung I	Show information officers for pharmaceutical companies
Leistungsbezeichnung II	Show information officers for pharmaceutical companies
Typisierung	3a - Bundesaufsichtsverwaltung: Regelung, Land: Vollzug, 2a - Bundesauftragsverwaltung: Regelung, Land: Vollzug
Quellredaktion	Baden-Württemberg
Freigabestatus Katalog	unbestimmter Freigabestatus
Freigabestatus Bibliothek	unbestimmter Freigabestatus
Begriffe im Kontext	
Leistungstyp	
Leistungsgruppierung	
Verrichtungskennung	
SDG-Informationsbereich	

Modul	Sachverhalt
Lagen Portalverbund	
Einheitlicher Ansprechpartner	
Fachlich freigegeben am	
Fachlich freigegeben durch	
Handlungsgrundlage	Arzneimittelgesetz (AMG) • § 74a Arzneimittel- und Wirkstoffherstellungsverordnung (AMWHV) • § 12
Teaser	If you operate a pharmaceutical company that places finished medicinal products on the market, you must notify the competent authority of an information officer. Any changes must also be reported immediately.
Volltext	If you operate a pharmaceutical company that places finished medicinal products on the market, you must notify the competent authority of an information officer. Any changes must also be reported immediately. The information officer must have the appropriate expertise and reliability . They are responsible, among other things, for ensuring that medicinal products are correctly registered, properly labelled and not misleadingly advertised.
Erforderliche Unterlagen	• Employment references (copy) • Proof of training (certified copy) • Curriculum vitae • Certificate of good conduct (document type O for direct transmission from authority to authority) • Form "Declaration of nomination" • Declaration of commitment
Voraussetzungen	• Information officers must have the necessary

Modul	Sachverhalt
	expertise and reliability (see Section 74a of the German Medicinal Products Act)
Kosten	There are no costs for the advert.
Verfahrensablauf	You can notify an information officer in writing or online: • You notify the information officer by means of a written application or using the online service. Proof of the person's expertise must be attached to the notification. • Upon receipt, the authority checks the notification formally and for completeness. • If the check reveals that documents are missing, the person making the notification will be contacted and asked to provide the missing documents. • Once the missing documents have been submitted or the formal check has been passed, the competent authority will make a decision. • The notification can be confirmed or rejected. • You will be informed of the decision. • A statement of fees will then be drawn up and sent to you with a request for payment.
Bearbeitungsdauer	
Frist	Any change must be notified in advance. In the event of an unforeseen change of information officer, notification must be given immediately.
weiterführende Informationen	
Hinweise	A fine may be imposed if the obligation to notify is violated.
Rechtsbehelf	• Objection • Information on how to lodge an objection will be sent with the decision on your advert.
Kurztext	
Ansprechpunkt	
Zuständige Stelle	

Modul	Sachverhalt
-------	-------------

Formulare	
-----------	--

Ursprungsportal	
-----------------	--