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Informing information officers for pharmaceutical companies

Heruntergeladen am 24.06.2025

<https://fimportal.de/xzufi-services/137645126/L100002>

Modul	Sachverhalt
Leistungsschlüssel	99005019261000, 99005019261000
Leistungsbezeichnung I	Informing information officers for pharmaceutical companies
Leistungsbezeichnung II	Informing information officers for pharmaceutical companies
Typisierung	2a - Bundesauftragsverwaltung: Regelung, Land: Vollzug, 3a - Bundesaufsichtsverwaltung: Regelung, Land: Vollzug
Quellredaktion	Nordrhein-Westfalen
Freigabestatus Katalog	fachlich freigegeben (silber)
Freigabestatus Bibliothek	fachlich freigegeben (gold)
Begriffe im Kontext	
Leistungstyp	Leistungsobjekt mit Verrichtung
Leistungsgruppierung	Arzneimittel (005)
Verrichtungskennung	Entgegennahme (261)
SDG-Informationsbereich	Vorschriften für und Anforderungen an Erzeugnisse,

Modul	Sachverhalt
	Erlangung von Lizenzen, Genehmigungen oder Zulassungen im Hinblick auf die Gründung und Führung eines Unternehmens
Lagen Portalverbund	Mitarbeiterbezogene Meldepflichten (2030400), Anmeldepflichten (2010100)
Einheitlicher Ansprechpartner	Nein
Fachlich freigegeben am	28.03.2024
Fachlich freigegeben durch	Federal Ministry of Health (BMG)
Handlungsgrundlage	https://www.gesetze-im-internet.de/amg_1976/_74a.html https://www.gesetze-im-internet.de/amwhv/_12.html
Teaser	If you are a pharmaceutical entrepreneur and place finished medicinal products on the market, you must notify the competent authority of an information officer. In addition, any changes must be reported immediately.
Volltext	Information officers must have the necessary expertise and reliability in accordance with the Medicinal Products Act. Among other things, they are responsible for ensuring that the following complies with the content of the marketing authorization or registration of the medicinal products: • the labeling, • the package leaflet, • the information for healthcare professionals and • the advertising. You must send your notification to the competent authority in the respective federal state.
Erforderliche Unterlagen	• Employment references (copy) • Proof of training (copy) • Curriculum vitae • Certificate of good conduct (copy) • Form "Declaration of nomination"

Modul	Sachverhalt
	• Declaration of commitment
Voraussetzungen	• Information officers must have the necessary expertise and reliability. • Have the necessary expertise: Pharmacists Persons who have completed a university degree including a certificate of examination in pharmacy, chemistry, biology, human or veterinary medicine Pharmacy assistants Persons who have completed training as technical assistants in pharmacy, chemistry, biology, human or veterinary medicine Pharmaceutical sales representatives
Kosten	
Verfahrensablauf	You can notify information officers by post: • Send your notification with the required documents to the competent authority. • The authority will check the notification formally and for completeness. • If your documents are incomplete, the authority will ask you to submit missing documents. • Once the formal check has been passed, the authority will decide whether to confirm or reject the notification. • The authority will inform you of its decision. • The authority will then draw up a list of fees and send it to you with a request for payment.
Bearbeitungsdauer	
Frist	You must notify new information officers and any changes in advance. You must notify us immediately of any unforeseen changes.
weiterführende Informationen	
Hinweise	A fine may be imposed in the event of a violation.
Rechtsbehelf	• Objection You will receive information on how to lodge an objection with the decision on your complaint.
Kurztext	• Notification of information officer • Pharmaceutical companies that place finished

Modul	Sachverhalt
	medicinal products on the market must appoint an information officer. The competent authority must be notified of this person and of any changes. • Information officers must have the necessary expertise and reliability. • Companies submit the notification by post. • Responsible: competent authority of the federal state
Ansprechpunkt	
Zuständige Stelle	
Formulare	
Ursprungsportal	Informing information officers for pharmaceutical companies, Informationsbeauftragte für Pharmazieunternehmen mitteilen