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Show information officer according to the Medicinal Products Act

Heruntergeladen am 24.06.2025

<https://fimportal.de/xzufi-services/222694147/L100038>

Modul	Sachverhalt
Leistungsschlüssel	99005019261000, 99005019261000
Leistungsbezeichnung I	Show information officer according to the Medicinal Products Act
Leistungsbezeichnung II	Informing information officers for pharmaceutical companies
Typisierung	2a - Bundesauftragsverwaltung: Regelung, Land: Vollzug, 3a - Bundesaufsichtsverwaltung: Regelung, Land: Vollzug
Quellredaktion	Thüringen
Freigabestatus Katalog	unbestimmter Freigabestatus
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	27.05.2025
Fachlich freigegeben durch	Thuringian Ministry for Social Affairs, Health, Labor and Family (TMSGAF)
Handlungsgrundlage	https://www.gesetze-im-internet.de/amg_1976/_74a.html https://www.gesetze-im-internet.de/amg_1976/_74a.html
Teaser	If you as a pharmaceutical company place finished medicinal products on the market, you must appoint a person with the necessary expertise and reliability to be responsible for providing scientific information about the medicinal products.
Volltext	Information officers must have the necessary expertise and reliability in accordance with the Medicinal Products Act. In particular, they are responsible for ensuring that no medicinal products are placed on the market with misleading names, information or presentation and that • the labeling, • the package leaflet, • the information for healthcare professionals and • the advertising complies with the content of the marketing authorization or registration of the medicinal products.
Erforderliche Unterlagen	• Employment references (copy) • Training certificates (copy) • Curriculum vitae

Modul	Sachverhalt
	• Certificate of good conduct (sent directly to the authority by the Federal Office of Justice)
Voraussetzungen	• Information officers must have the necessary expertise and reliability. • No specific proof of expertise is required. • A (relevant) scientific background is required in order to be able to fulfill the task of providing scientific information on medicinal products.
Kosten	Gebühr: 57€ - 400€ https://landesrecht.thueringen.de/bsth/document/jlr-VwKostOTHV10Anlage
Verfahrensablauf	You can notify a competent person in writing or online. • You notify the information officer(s) by means of a written application or using the online service. • The authority will check the notification formally and for completeness. • If any documents are found to be missing during the check, the missing documents will be requested. • Once the formal check has been passed, the competent authority will make a decision. • The notification can be confirmed or rejected. The decision on costs is also issued with this letter.
Bearbeitungsdauer	2 - 4 Woche(n)
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 medicinal products on the market must appoint an information officer. The competent authority must be notified of this person and of any changes.

Modul	Sachverhalt
	• Information officers must have the necessary expertise and reliability. • Companies submit the notification by post. • Responsible: competent authority of the federal state
Ansprechpunkt	Please contact the Thuringian State Office for Consumer Protection, Department 24.
Zuständige Stelle	
Formulare	
Ursprungsportal	Informationsbeauftragte nach dem Arzneimittelgesetz anzeigen, Show information officer according to the Medicinal Products Act