99005023008000

Notify a competent person in accordance with the Medicinal Products Act

Modul	Sachverhalt
Leistungsschlüssel	99005023008000
Leistungsbezeichnung I	Notify a competent person in accordance with the Medicinal Products Act
Leistungsbezeichnung II	Notify a competent person in accordance with the Medicinal Products Act
Typisierung	2a - Bundesauftragsverwaltung: Regelung, Land: Vollzug, 3a - Bundesaufsichtsverwaltung: Regelung, Land: Vollzug
Quellredaktion	Sachsen-Anhalt
Freigabestatus Katalog	unbestimmter Freigabestatus
Freigabestatus Bibliothek	unbestimmter Freigabestatus
Begriffe im Kontext	
Leistungstyp	Leistungsobjekt mit Verrichtung
Leistungsgruppierung	
Verrichtungskennung	Bestätigung (8)

Modul	Sachverhalt
SDG-Informationsbereich	
Lagen Portalverbund	Anmeldepflichten (2010100), Mitarbeiterbezogene Meldepflichten (2030400)
Einheitlicher Ansprechpartner	Nein
Fachlich freigegeben am	16.11.2023
Fachlich freigegen durch	Ministry of Justice and Consumer Protection of the Free and Hanseatic City of Hamburg Ministry of Labor, Social Affairs, Health and Equality of the State of Saxony-Anhalt
Handlungsgrundlage	https://www.gesetze-im-internet.de/amg_1976/__14.html https://www.gesetze-im-internet.de/amg_1976/__15.html https://www.gesetze-im-internet.de/amg_1976/__20.html https://www.gesetze-im-internet.de/amg_1976/__14.html https://www.gesetze-im-internet.de/amg_1976/__15.html https://www.gesetze-im-internet.de/amg_1976/__20.html
Teaser	If you operate a pharmaceutical company that places finished medicinal products on the market, you must notify the competent authority of a qualified person. Any changes must also be reported immediately.
Volltext	The requirements for various responsible persons are described in the Medicinal Products Act. It stipulates that you must notify the competent authority of a competent person with appropriate qualifications and reliability for the decision on manufacturing authorization. Any changes must also be reported immediately.
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 Please submit certified copies. The certificate of good conduct must be suitable for submission to an authority (document type O). It must not be older than 3 months.
Voraussetzungen	• Qualified persons must have the necessary expertise and reliability. • They require a university degree in pharmacy, chemistry, biology, human or veterinary medicine, • Alternatively, completed training in the aforementioned areas or proof of employment as a pharmaceutical representative.
Kosten	
Verfahrensablauf	You can notify a qualified person in writing or online. • You notify the competent person by means of a written application or using the online service. • The notification is then received by the competent authority. • The competent authority checks the notification formally and for completeness. • If any documents are found to be missing during the check, you will be notified. • Once the missing documents have been submitted or the formal check has been passed, the competent authority will make a decision. • The competent authority can confirm or reject your notification. • The authority will inform the pharmaceutical company of its decision. The pharmaceutical company will receive a notification of costs.
Bearbeitungsdauer	3 Monat(e)
Frist	Fictitious approval: To be notified immediately upon change.
weiterführende Informationen	

Modul	Sachverhalt
Hinweise	A fine may be imposed in the event of a violation.
Rechtsbehelf	You can file a lawsuit.
Kurztext	• Notification of the competent person in accordance with Section 14 of the Medicinal Products Act • The Medicinal Products Act describes the requirements for various responsible persons. • In order to obtain a manufacturing authorization as a pharmaceutical company, a competent person with the appropriate qualifications and reliability must be notified to the competent supervisory authority. • For the corresponding notification of responsibility, please use the online service or submit the document in writing. • Competent authority:
Ansprechpunkt	Saxony-Anhalt State Administration Office
Zuständige Stelle	
Formulare	Forms available: Written form required: Yes Informal application possible: Yes Personal appearance necessary: No Online services available: Yes
Ursprungsportal	Eine sachkundige Person nach dem Arzneimittelgesetz anzeigen, Notify a competent person in accordance with the Medicinal Products Act