99005023008000

Notification of the competent person in accordance with the Medicinal Products Act Confirmation

Modul	Sachverhalt
Leistungsschlüssel	99005023008000
Leistungsbezeichnung I	Notification of the competent person in accordance with the Medicinal Products Act Confirmation
Leistungsbezeichnung II	Notify a competent person in accordance with the Medicinal Products Act
Typisierung	2a - Bundesauftragsverwaltung: Regelung, Land: Vollzug
Quellredaktion	Baustein Leistungen
Freigabestatus Katalog	fachlich freigegeben (gold)
Freigabestatus Bibliothek	fachlich freigegeben (silber)
Begriffe im Kontext	
Leistungstyp	Leistungsobjekt mit Verrichtung
Leistungsgruppierung	Drugs (individuell, 005)

Modul	Sachverhalt
Verrichtungskennung	Bestätigung (008)
SDG-Informationsbereich	Vorschriften für und Anforderungen an Erzeugnisse, Erlangung von Lizenzen, Genehmigungen oder Zulassungen im Hinblick auf die Gründung und Führung eines Unternehmens
Lagen Portalverbund	Mitarbeiterbezogene Meldepflichten (2030400), Anmeldepflichten (2010100)
Einheitlicher Ansprechpartner	
Fachlich freigegeben am	06.05.2022
Fachlich freigegen durch	Ministry of Justice and Consumer Protection of the Free and Hanseatic City of Hamburg
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
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" • Declaration of commitment
Voraussetzungen	• Qualified persons must have the necessary expertise

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	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 authority. • The authority checks the notification formally and for completeness. • If the check reveals missing documents, the person who made the report is 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 report can be confirmed or rejected. • The decision will be communicated to the person making the notification. • A statement of fees will then be drawn up and also sent to the person making the report with a request for payment.
Bearbeitungsdauer	1 - 4 Woche(n)
Frist	Fictitious approval: To be notified immediately upon change.
weiterführende Informationen	
Hinweise	A fine may be imposed in the event of a violation.
Rechtsbehelf	• Objection • Information on how to lodge an objection will be sent with the decision on your complaint.
Kurztext	• Notification of the competent person in accordance with Section 14 of the Medicinal Products Act • The Medicinal Products Act describes the

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	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	
Zuständige Stelle	
Formulare	Forms available: Written form required: Yes Informal application possible: Yes Personal appearance necessary: No Online services available: Yes
Ursprungsportal	