99005023008000

Notification of the competent person according to §14 Drugs Act Confirmation

Modul	Sachverhalt
Leistungsschlüssel	99005023008000
Leistungsbezeichnung I	Notification of the competent person according to §14 Drugs Act Confirmation
Leistungsbezeichnung II	Notify a competent person according to the Medicines Act
Typisierung	2a - Bundesauftragsverwaltung: Regelung, Land: Vollzug
Quellredaktion	Hamburg
Freigabestatus Katalog	unbestimmter Freigabestatus
Freigabestatus Bibliothek	unbestimmter Freigabestatus
Begriffe im Kontext	Pharmaceuticals , Medicines Act , advertisement , AMG , Qualified Person , pharmaceutical manufacturer , drug

Modul	Sachverhalt
	manufacturer
Leistungstyp	
Leistungsgruppierung	
Verrichtungskennung	
SDG-Informationsbereich	
Lagen Portalverbund	
Einheitlicher Ansprechpartner	Nein
Fachlich freigegeben am	06.05.2022
Fachlich freigegen durch	
Handlungsgrundlage	• [§ 14 Medicines Act (AMG)](https://www.gesetze-im-internet.de/amg_1976/__14.html) • [§ 15 Medicines Act (AMG)](http://www.gesetze-im-internet.de/amg_1976/__15.html) • [§ 20 Medicines Act (AMG)](http://www.gesetze-im-internet.de/amg_1976/__20.html)
Teaser	If you operate a pharmaceutical company that markets finished medicinal products, you must notify the competent authority of a qualified person. You must also notify them immediately of any changes to the qualified person.
Volltext	The Medicines Act sets out the requirements for various responsible persons. To obtain permission to manufacture medicines, you must report a competent person with the appropriate qualifications and reliability to the competent authority.
Erforderliche Unterlagen	• Job references (copy) • Training certificate (copy) • CV • Certificate of good conduct (copy) • Declaration of designation form • commitment declaration

Modul	Sachverhalt
Voraussetzungen	• Competent persons must have the necessary expertise and reliability. • You need 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	The amount of the fees depends on the administrative effort.
Verfahrensablauf	• You can notify a competent person in writing or electronically. • Submit the competent person's report with all required documents to the competent authority. • The authority will examine your report and the documents submitted. If necessary, it will request further documents or information from you. • Once all the necessary documents and information have been provided, the responsible authority will decide on your report. • You will be informed of the decision. • The ad can be confirmed or rejected. • You will receive a fee statement with a request for payment.
Bearbeitungsdauer	The processing time depends on the administrative effort and is approximately 1 to 4 weeks.
Frist	You need the certification of your qualified person from the competent authority in order to obtain permission to manufacture medicinal products and to manufacture medicinal products. Report any changes affecting the Qualified Person immediately.
weiterführende Informationen	https://www.hamburg.de/pharmaziewesen/2131596/arzneimittelhersteller/ https://www.hamburg.de/pharmaziewesen/2131596/arzneimittelhersteller/
Hinweise	If you manufacture medicinal products without a qualified person confirmed by the competent authority, or if you do not immediately report changes that affect the qualified person, you are violating the Medicines Act. This can lead to a fine.

Modul	Sachverhalt
Rechtsbehelf	• contradiction • Information on how you object will be transmitted with the decision on your ad.
Kurztext	• Notification of the competent person according to Section 14 of the Medicines Act • The Medicines Act describes the requirements for various responsible persons. • In order for a pharmaceutical company to obtain a manufacturing license, a competent person with appropriate qualifications and reliability must be reported to the responsible supervisory authority. • To notify us of responsibility, please use the online service or submit the document in writing.
Ansprechpunkt	
Zuständige Stelle	Justice and Consumer Protection Authority
Formulare	
Ursprungsportal	Behördenfinder Hamburg, Authority finder Hamburg (Currently this link is only available in german)