99003096011000

Registration for trade in commodities Amendment

Modul	Sachverhalt
Leistungsschlüssel	99003096011000
Leistungsbezeichnung I	Registration for trade in commodities Amendment
Leistungsbezeichnung II	Change registration for handling basic substances
Typisierung	1 - Bund: Regelung und Vollzug
Quellredaktion	Bund
Freigabestatus Katalog	unbestimmter Freigabestatus
Freigabestatus Bibliothek	unbestimmter Freigabestatus
Begriffe im Kontext	
Leistungstyp	Leistungsobjekt mit Verrichtung
Leistungsgruppierung	
Verrichtungskennung	Änderung (11)
SDG-Informationsbereich	nicht SDG-relevant
Lagen Portalverbund	Import und Export (2070200)
Einheitlicher Ansprechpartner	Nein

Modul	Sachverhalt
Fachlich freigegeben am	13.12.2024
Fachlich freigegen durch	Federal Ministry of Health (BMG)
Handlungsgrundlage	https://eur-lex.europa.eu/legal-content/DE/ALL/?uri=CELEX%3A32004R0273 https://eur-lex.europa.eu/legal-content/DE/ALL/?uri=CELEX%3A32015R1011 https://eur-lex.europa.eu/legal-content/DE/TXT/PDF/?uri=CELEX%3A32015R1013&from=DE https://eur-lex.europa.eu/legal-content/DE/ALL/?uri=CELEX%3A32005R0111
Teaser	If you wish to change the registration for the trade in basic substances or for the use of basic substances of category 2A, you must apply to the Federal Institute for Drugs and Medical Devices.
Volltext	For transportation within the European Union (EU), the basic substances of category 2 are divided into subcategories 2A and 2B. If you • trade them or supply them to third parties, • arrange transactions with them, • carry out drop shipments with them, even if the precursors do not touch the territory of the EU, or • import them into or export them from the EU, you must submit an application for registration to the competent authority of the EU Member State in which you are established. Registration is also required if you possess or use category 2A precursors. Precursors are divided into the following categories: • Category 1: Precursors that can potentially be converted into drugs with a high potential for dependence and abuse • Category 2: Substances that can be used for the illicit manufacture of narcotics • Category 3: Solvents and acids • Category 4: Medicinal products and veterinary medicinal products containing ephedrine or pseudoephedrine or the salts of ephedrine or pseudoephedrine

Modul	Sachverhalt
	If you wish to change this registration because • another basic substance is added, • a new operation is to be included or • the location of your premises changes, please contact the Federal Institute for Drugs and Medical Devices (BfArM). You must notify the BfArM of any change in the responsible representative(s) or the name of the company.
Erforderliche Unterlagen	You must submit documents with the following complete details: • Name • telephone number • Fax number, if available • e-mail address • Name and CN code of the required raw materials and their salts • for mixtures: the name of the mixture, the name and CN codes of all the basic substances contained in the mixture, and indication of the maximum possible content of such basic substances in the mixture • Description of the operations envisaged, for example Trade in the European Union (EU), further processing, import, export, brokerage or intermediary transactions • in the event of a change in the responsible officer(s) for the handling of category 2 precursors, a completed declaration form for the appointment of the responsible officer(s)
Voraussetzungen	• You must be resident in Germany. • The Federal Institute for Drugs and Medical Devices (BfArM) will check your application for completeness and plausibility. In addition, the BfArM will check whether there are justified grounds for doubting the suitability and reliability of the applicant or the responsible representative(s) before issuing a registration for handling basic substances. • You must apply for a new registration if another basic substance is added, a new process is to be included or

Modul	Sachverhalt
	the location of your premises where you carry out the operations changes. • If the responsible representative or the name of the company changes, you must notify us.
Kosten	There are no costs.
Verfahrensablauf	You can apply online or informally in writing to the Federal Institute for Drugs and Medical Devices (BfArM) to change the registration for handling basic substances of categories 2 A and B and 3. Change registration online: • Go to the website of the federal portal verwaltung.bund.de and call up the online application. This will guide you step by step through the necessary information, which you can enter electronically. You will need an Elster company account and an Elster certificate for the change. • Upload the required documents as a file (PDF, PNG, JPEG, maximum 10 megabytes per file) and send the application. • The BfArM will check your details. If any of your details or documents are incomplete, you will receive a request to submit them within a deadline set by the BfArM. • If you are granted registration, the BfArM will send you the registration certificate by post. Apply informally in writing for a change of registration: • Compose an application with all the required information, print it out and sign it. • Enclose the completed declaration form for the appointment of the responsible representative(s) with the application. • Send your informal application by post to the BfArM. • The BfArM will check your details. If any of your details or documents are incomplete, you will receive a request to submit them within a deadline set by the BfArM. • If you are granted the change of registration, the BfArM will send you the registration certificate by post.

Modul	Sachverhalt
Bearbeitungsdauer	42 Tag(e) This is the average processing time.
Frist	The application for the inclusion of a new substance, a new process or a change in the location of your business premises must be submitted before you commence your activities. If the name or legal form of your company changes, if you appoint a new responsible representative or if their name or address changes, you must inform the BfArM electronically or in writing within 10 working days.
weiterführende Informationen	https://www.bfarm.de/DE/Bundesopiumstelle/Grundstoffe/Erlaubnis/_node.html https://www.bfarm.de/DE/Bundesopiumstelle/_FAQ/Grundstoffe/Erlaubnis-und-Registrierungspflicht/faq-liste.html
Hinweise	There are no indications or special features.
Rechtsbehelf	• Contradiction You will find detailed information on how to lodge an objection in the notification of your application for a change of registration.
Kurztext	• Raw materials are divided into the following categories: Category 1: precursors that can potentially be converted into drugs with a high potential for dependence and abuse Category 2: Substances that can be used for the illicit manufacture of narcotics Category 3: Solvents and acids Category 4: Medicinal products and veterinary medicinal products containing ephedrine or pseudoephedrine or the salts of ephedrine or pseudoephedrine • Change of registration required if another basic substance is added, a new operation is to be included or the location of your business premises where you carry out the operations changes • Changes are free of charge • Changes to the responsible representative(s) or the name of the company must be notified • Processing time: on average around 42 days • Responsible: Federal Institute for Drugs and Medical Devices (BfArM)
Ansprechpunkt	

Modul	Sachverhalt
Zuständige Stelle	
Formulare	
Ursprungsportal	Registration for trade in commodities Amendment, Registrierung für den Handel mit Grundstoffen Änderung