99003096001000

Registration for trade in commodities Issue

Modul	Sachverhalt
Leistungsschlüssel	99003096001000
Leistungsbezeichnung I	Registration for trade in commodities Issue
Leistungsbezeichnung II	Apply for registration to trade in commodities
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	Erteilung (1)
SDG-Informationsbereich	nicht SDG-relevant
Lagen Portalverbund	Erlaubnisse und Genehmigungen (2010400), Import und Export (2070200)
Einheitlicher	

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Ansprechpartner	Nein
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 handle category 2 raw materials or export category 3 raw materials to countries outside the EU, you need a registration.
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 and 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 and pseudoephedrine or the salts of ephedrine or

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	pseudoephedrine If you export category 3 precursors to countries outside the EU, you also require a registration from the competent authority of the EU member state in which you are established. In Germany, the Federal Institute for Drugs and Medical Devices (BfArM) is responsible. To obtain a registration for basic substances of category 2A and 2B, you must also appoint a person as the responsible representative. This person • ensures that the applicable regulations on basic substances are complied with and • is the contact person for the BfArM. The representative must be authorized to represent you and make the necessary decisions to comply with the applicable regulations on basic substances. Customs agents and freight forwarders are exempt from the obligation to register if they act exclusively in this role. Registration is not required for the handling of category 2A and B commodities or for the export of category 3 commodities if you do not exceed certain quantities within one year. More detailed information and lists of the respective quantities can be found on the BfArM website.
Erforderliche Unterlagen	You must submit documents with the following complete details: • Name • your address • telephone number • Fax number, if available • e-mail address • Designation 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 the maximum possible content of such basic substances in the mixture

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	• Description of the operations envisaged, for example Trade in the European Union, further processing, import, export, mediation or brokerage • If you handle category 2 raw materials: completed declaration form for the appointment of the responsible representative(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 the location of your premises where you carry out the operations changes.
Kosten	Gebühr: 110€ Costs for registration per raw material and per operating site https://www.gesetze-im-internet.de/bmgbgebv/index.html Gebühr: 55€ Costs for registration per basic substance and per operating site for scientific or analytical purposes without economic purpose per basic substance and per operating site https://www.gesetze-im-internet.de/bmgbgebv/index.html
Verfahrensablauf	You can apply online or informally in writing to the Federal Institute for Drugs and Medical Devices (BfArM) for registration to handle basic substances in categories 2 and 3. Apply for 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

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	certificate to submit the application. 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 with a fee notice by post. • Pay the fees. Apply for registration informally in writing: • Compose an application with all the required information, print it out and sign it. • Attach the completed declaration form for the appointment of the responsible representative(s) to 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 registration, the BfArM will send you the registration certificate with a fee notice by post. • Pay the fees.
Bearbeitungsdauer	42 Tag(e) This is the average processing time.
Frist	You must submit the application before you start work.
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 initial registration.

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Kurztext	• Registration for trade in commodities Issue • Commodities 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 • Registration required for Handling of precursors (scheduled substances, drug precursors) of category 2 Export of precursors of category 3 to countries that do not belong to the European Union (EU) • Appointment of a responsible officer required for handling category 2 precursors • all applications must be submitted online or informally in writing • all initial applications are subject to a fee: EUR 110.00 per basic substance and per operating site • Processing time: on average around 42 days • Responsible: Federal Institute for Drugs and Medical Devices (BfArM)
Ansprechpunkt	
Zuständige Stelle	
Formulare	
Ursprungsportal	Registrierung für den Handel mit Grundstoffen Erteilung, Registration for trade in commodities Issue