99005008005000

Import of medicinal products - apply for a licence

Modul	Sachverhalt
Leistungsschlüssel	99005008005000
Leistungsbezeichnung I	Import of medicinal products - apply for a licence
Leistungsbezeichnung II	Import of medicinal products - apply for a licence
Typisierung	2/3 - Bund: Regelung (2 oder 3), Land/Kommune: Vollzug
Quellredaktion	Baden-Württemberg
Freigabestatus Katalog	unbestimmter Freigabestatus
Freigabestatus Bibliothek	unbestimmter Freigabestatus
Begriffe im Kontext	
Leistungstyp	
Leistungsgruppierung	
Verrichtungskennung	
SDG-Informationsbereich	
Lagen Portalverbund	
Einheitlicher	

Modul	Sachverhalt
Ansprechpartner	
Fachlich freigegeben am	
Fachlich freigegen durch	
Handlungsgrundlage	Arzeimittelgesetz (AMG): • § 15 Sachkenntnis • § 72 Einfuhrerlaubnis Artikel 61 EU-Verordnung 536/2014 (Erlaubnis) Artikel 88 EU-Verordnung 2019/6 (Erlaubnis)
Teaser	You require authorisation for the import of
Volltext	You require authorisation for the import of • Medicinal products for human use, veterinary medicinal products, investigational medicinal products • Active substances of human, animal or microbial origin or which are produced by genetic engineering, or • other substances of human origin intended for the manufacture of medicinal products
Erforderliche Unterlagen	• Extract from the commercial register • Proof of availability of the premises, for example: • Copy of the rental agreement or • Extract from the land register • Floor plans of the company buildings and rooms for testing and storage • for external warehouses: floor plans • Proof of the required expertise and reliability of the competent person (certified copy of certificates, certificate of good conduct for official purposes) • current company description ("Site Master File"), quality assurance manual, list of procedural instructions
Voraussetzungen	• A qualified person is available • Suitable rooms and facilities are available for the activities intended with the import, testing and storage

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	of the medicinal products • It is ensured that the activities are carried out in accordance with the state of the art in science and technology
Kosten	Depending on the individual case
Verfahrensablauf	You can apply informally to the competent authority for authorisation. Your application must contain the following information: • exact name of the applicant and details of the legal form • Designation of the business premises (name, street, town) • Details of the activities planned at the business premises in connection with the import • Information on external warehouses • Name, telephone and fax number, e-mail address • a competent person • a responsible person in the case of the import of medicinal products of human origin for direct human use • tabular information on the medicinal products intended for import • Details of the organisations responsible for testing Tipcontact the competent authority before submitting the application to clarify the details. Once the complete documentation has been submitted, the competent authority will carry out a final inspection. Only then will it decide whether to grant the import licence or reject the application by issuing a decision.
Bearbeitungsdauer	Depending on, among other things • the type of medicinal products for which you are applying for authorisation and • whether an inspection abroad is required For new applications: at least 4 weeks from submission of the complete documentation, maximum 3 months For required foreign inspection minimum required lead time: 6 months

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Frist	The licence must always be applied for before starting the activity. The import activity may only commence once you have received the licence.
weiterführende Informationen	
Hinweise	none
Rechtsbehelf	Complaint to the competent administrative court
Kurztext	
Ansprechpunkt	
Zuständige Stelle	
Formulare	
Ursprungsportal	