99005008005000

Import of medicinal products permit

Modul	Sachverhalt
Leistungsschlüssel	99005008005000
Leistungsbezeichnung I	Import of medicinal products permit
Leistungsbezeichnung II	Apply for permission to import medicinal products, active substances or investigational medicinal products
Typisierung	2/3 - Bund: Regelung (2 oder 3), Land/Kommune: Vollzug
Quellredaktion	Hamburg
Freigabestatus Katalog	unbestimmter Freigabestatus
Freigabestatus Bibliothek	unbestimmter Freigabestatus
Begriffe im Kontext	Import permits for active ingredients and pharmaceuticals , Medicines import permits , Medicines import permits , Import of active substances , Import of preparations
Leistungstyp	

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Leistungsgruppierung	
Verrichtungskennung	
SDG-Informationsbereich	
Lagen Portalverbund	
Einheitlicher Ansprechpartner	Nein
Fachlich freigegeben am	20.03.2024
Fachlich freigegen durch	
Handlungsgrundlage	[Law on the trade in medicinal products (Medicines Act - AMG) § 72 Import permit](https://www.gesetze-im-internet.de/amg_1976/__72.html)
Teaser	If you wish to import medicinal products, certain active ingredients or investigational medicinal products for clinical trials into Germany from countries outside the EU or the European Economic Area for professional or commercial purposes, you require permission from the responsible authority.
Volltext	You need a permit for commercial import from countries outside the EU or the European Economic Area for: • drug • Active ingredients of human, animal or microbial origin • Genetically engineered active ingredients • other substances of human origin intended for use in the manufacture of medicinal products • Investigational medicinal products You do not need a permit in this sense for the import of: • Active substances which are manufactured according to a process technology described in the Homeopathic Part of the Pharmacopoeia and are

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	intended for the manufacture of medicinal products • Active ingredients of purely chemical or plant origin You need a different import permit for: • Tissue within the meaning of the Transplantation Act • Autologous blood for the production of biotechnologically processed tissue products • Tissue preparations which are not processed or treated by industrial processes and whose essential processing or treatment processes are known in the EU
Erforderliche Unterlagen	• Please provide the following information in your application: • exact name of the applicant and information on the legal form • Name of the establishment (name, street, place) • Information on the activities planned for the import at the facility (note that a foreign inspection of the manufacturer in the third country may be required to issue a Section 72a certificate). • If applicable, information on other external warehouses • Name, telephone and fax number, e-mail address of a qualified person according to Section 15 of the Medicines Act or • a responsible person in the case of imports of medicinal products of human origin for direct use in humans • Tabular information on medicinal products intended for import • Where applicable, information on the companies commissioned to carry out tests outside the premises • Further information can be found on the website of the Department of Pharmacy and Medical Devices. • Extract from the commercial register • Proof of availability of the rooms, for example: • Copy of the rental agreement or • Land register extract • Floor plans of the operating buildings and rooms for testing and storage • For off-site warehouses: floor plans • Proof of the required expertise of the competent person (certified copy) • Curriculum vitae, declaration of commitment and

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	statement on criminal proceedings of the expert person • Statement on criminal proceedings against the management • Certificate of good conduct of the management and the competent person (certificate type O) • Current company description ("Site Master File"), quality assurance manual, list of procedural instructions • Further information can be found on the website of the Department of Pharmacy and Medical Devices.
Voraussetzungen	• Their company is located in Hamburg. • Your business has a qualified person in accordance with the Medicines Act. • They have suitable premises and facilities for the planned import, including testing and storage of the medicinal products. Their import activities correspond to the current state of science and technology. • The product you wish to import is a medicinal product, an active substance of human, animal or microbial origin, an active substance produced by genetic engineering, another substance of human origin intended for use in the manufacture of medicinal products or an investigational medicinal product for clinical trials. • The medicinal product to be imported is approved in Germany or the EU, or it can be proven that an application for approval has been submitted. • In the case of investigational medicinal products, the clinical study has been approved or the application for approval has been verifiably submitted. • The manufacturing facility in the third country has a mutually recognized GMP (Good Manufacturing Practice) certificate. This certificate is not required for investigational medicinal products.
Kosten	Fees apply. These depend on the individual case and are based, among other things, on the time required to process the application, including the acceptance inspection.
Verfahrensablauf	• To clarify details, you can contact the responsible authority before submitting your application.

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	• Submit an informal application for permission to import medicinal products, active substances of human, animal or microbial origin or produced by genetic engineering, or other substances of human origin intended for the manufacture of medicinal products or investigational medicinal products for clinical trials to the competent authority and submit it with all the necessary documents. • The responsible authority will examine your application and your documents. • If necessary, she will request further documents or information from you. • Once all required documentation has been submitted, the responsible authority will carry out an acceptance inspection. • The responsible authority will decide on your application. • You will receive a notification.
Bearbeitungsdauer	The processing time depends on the individual case. Once all the required documents are available, it is at least 12 weeks; for foreign inspections, it is at least 12 months.
Frist	You need permission before you can import the relevant medicines. Apply for permission at least 12 weeks before the planned import, or at least 12 months in the case of foreign inspections.
weiterführende Informationen	https://www.hamburg.de/politik-und-verwaltung/behoerden/bjv/themen/verbraucherschutz/medizinprodukte https://www.hamburg.de/arzneimittel/ https://www.hamburg.de/politik-und-verwaltung/behoerden/bjv/themen/verbraucherschutz/pharmaziewesen/einfuhrerlaubnis-88994 https://www.hamburg.de/pharmaziewesen/2136682/einfuhrerlaubnis/
Hinweise	No.
Rechtsbehelf	Contradiction
Kurztext	Permission required for commercial import from non-EU/EEA countries for:

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	• drug • Active ingredients of human, animal or microbial origin • Genetically engineered active ingredients • other substances of human origin intended for use in the manufacture of medicinal products • Investigational medicinal products No permit required for import of: • Active substances manufactured according to the homeopathic part of the pharmacopoeia and intended for the manufacture of medicinal products • Active ingredients of purely chemical or plant origin Other import permit required for: • Tissue according to the Transplantation Act • Autologous blood for the production of biotechnologically processed tissue products • Tissue preparations which are not processed or treated by industrial processes and whose essential processing or treatment processes are known in the EU
Ansprechpunkt	
Zuständige Stelle	Justice and Consumer Protection Authority
Formulare	
Ursprungsportal	Hamburg Service, Hamburg Service (Currently this link is only available in german)