99005008005000

Import of medicinal products permit

Modul	Sachverhalt
Leistungsschlüssel	99005008005000
Leistungsbezeichnung I	Import of medicinal products permit
Leistungsbezeichnung II	Import of medicinal products, certain active substances or investigational medicinal products for clinical trials - apply for permission
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 substances or investigational medicinal products for clinical trials from non-EU member states or contracting states of the European Economic Area on a commercial or professional basis, you require a permit from the competent authority.
Volltext	You require a permit for the commercial import of medicinal products, active ingredients 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 from countries that are not members of the European Union or the European Economic Area. You do not need a permit in this sense for the import of: • Active substances that are manufactured using a process described in the Homeopathic Part of the Pharmacopoeia and are intended for the manufacture of medicinal products • Active ingredients of purely chemical or plant origin You need another import permit (§ 72b and § 72c AMG)

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	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 using industrial processes and whose essential processing or treatment processes are sufficiently known in the European Union
Erforderliche Unterlagen	• Your application must contain the following information: • 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 (Please note that an 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 statement on criminal proceedings of the expert person • Statement on criminal proceedings against the

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	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	• Its headquarters are in Hamburg. • Your business has a qualified person in accordance with the Medicines Act. • They have suitable premises and facilities for the activities intended for import, including the testing and storage of medicinal products. • The activities within the scope of import are carried out in accordance with the state of the art in science and technology. • The product to be imported is a medicinal product, active substance of human, animal or microbial origin or produced by genetic engineering, or another substance of human origin intended for 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 an application for approval has been verifiably initiated. • In the case of investigational medicinal products, the clinical study has been approved or demonstrably applied for. • The establishment in the third country has a mutually recognized GMP certificate (except for investigational medicinal products). • Further information can be found on the website of the Department of Pharmacy and Medical Devices.
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	• 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

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	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. • If all the documentation is available, the responsible authority will carry out an acceptance inspection. • They will then 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/arzneimittel/ https://www.hamburg.de/arzneimittel/ https://www.hamburg.de/pharmaziewesen/2136682/einfuhrerlaubnis/ https://www.hamburg.de/pharmaziewesen/2136682/einfuhrerlaubnis/
Hinweise	To clarify details, you can contact the responsible authority before submitting your application.
Rechtsbehelf	Contradiction
Kurztext	• Import of medicinal products, certain active substances or investigational medicinal products for clinical trials - apply for permission • Apply 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 • commercial import of medicinal products from non-EU countries that are not contracting states of the

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	European Economic Area, apply for the import of: • Medicines, • Active substances of human, animal or microbial origin or which are produced by genetic engineering, • other substances of human origin intended for 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 intended for the manufacture of medicinal products • Active ingredients of purely chemical or plant origin • You need another import permit (§ 72b and § 72c AMG) for: • Tissue within the meaning of Section 1a number 4 of the Transplantation Act, • Autologous blood for the production of biotechnologically processed tissue products • Tissue preparations within the meaning of Section 20c of the German Medicines Act (AMG)
Ansprechpunkt	
Zuständige Stelle	Justice and Consumer Protection Authority
Formulare	
Ursprungsportal	Behördenfinder Hamburg, Authority finder Hamburg (Currently this link is only available in german)