99005004023000

Erstzulassung (national), mit Bescheidabschluss Auskunft

Modul	Sachverhalt
Leistungsschlüssel	99005004023000
Leistungsbezeichnung I	Erstzulassung (national), mit Bescheidabschluss Auskunft
Leistungsbezeichnung II	Request information on medicinal products for human use authorised or registered in Germany and on immunological medicinal products for use in animals.
Typisierung	1 - Bund: Regelung und Vollzug
Quellredaktion	Bund
Freigabestatus Katalog	fachlich freigegeben (gold)
Freigabestatus Bibliothek	unbestimmter Freigabestatus
Begriffe im Kontext	
Leistungstyp	Leistungsobjekt mit Verrichtung
Leistungsgruppierung	
Verrichtungskennung	Auskunft (23)
SDG-Informationsbereich	nicht SDG-relevant
Lagen Portalverbund	Produkt- und Stoffzulassung (2120200)

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Einheitlicher Ansprechpartner	Nein
Fachlich freigegeben am	24.09.2020
Fachlich freigegen durch	Federal Ministry of Health (BMG)
Handlungsgrundlage	https://www.gesetze-im-internet.de/amg_1976/BJNR024480976.html
Teaser	If you would like information on the approval, testing and safety of a medicinal product for use in humans or immunological veterinary medicinal products, you can obtain information.
Volltext	The Federal Institute for Drugs and Medical Devices (BfArM) and the Paul Ehrlich Institute (PEI), Federal Institute for Vaccines and Biomedical Products, are responsible for this at national and European level, • the efficacy, • quality and • safety of new medicinal products for use in humans and for immunological veterinary medicinal products and to approve them. The PEI is responsible for vaccines and biomedical medicinal products, namely. • immunoglobulins, • monoclonal antibodies, • blood, bone marrow, tissue preparations, • allergens, • test sera, • test antigens, • gene transfer drugs, • somatic cell therapeutics, • xenogenic cellular therapeutics, and • genetically engineered blood components.

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	All other medicinal products for human use fall under the responsibility of the BfArM. The necessary documents for marketing authorisation are submitted by the pharmaceutical entrepreneur who wishes to place the medicinal product on the market. The BfArM or PEI can therefore provide you with the following information: • the receipt of an application for marketing authorisation of a medicinal product (the overview, which is updated once a month, can be found on the BfArM homepage), • the receipt of an application for approval of a clinical trial to confirm the quality, efficacy and safety of a medicinal product in a group of patients, and • the approval or rejection of a clinical trial intended to confirm the quality, efficacy and safety of a medicinal product in a group of patients. Notice: The BfArM or the PEI can also provide you with further information on the following topics: • Drug safety • Medical devices for use in humans; • Examples in the area of responsibility of BfArM: • implants, • dressing materials, • medical software, • medical instruments, • dental products • Examples in the area of responsibility PEI: • In vitro diagnostics for testing for high-risk pathogens such as HIV/AIDS, hepatitis, ZIKA or for determining blood groups • Reagents and reagent products • Medical classifications • Health care registries • Healthcare data • Training and access to health care professions

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Erforderliche Unterlagen	none
Voraussetzungen	none
Kosten	As a rule, none. In the case of information that involves a very high administrative burden in individual cases: between EUR 15.00 and EUR 500.00.
Verfahrensablauf	If you are looking for information on medicinal products that have already been authorised or were previously authorised, you can search for these medicinal products in the free public database of the Federal Institute for Drugs and Medical Devices (BfArM). If you would like to know whether a marketing authorisation for a medicinal product has been applied for at the BfArM, you can view this in a monthly updated list on the BfArM website. If you need further information, you can submit an inquiry online to the BfArM or to the Paul Ehrlich Institute - Federal Institute for Vaccines and Biomedical Products (PEI). BfArM: • You go to the BfArM website and call up the electronic contact form under the "Contact" tab. • You select your target group and follow the next steps of the contact form by selecting your request and entering your contact details. • After you have sent your request, you will receive information from the BfArM by e-mail. If you do not have an email address, you can also receive the answer by mail. PEI: • You go to the website of the Paul Ehrlich Institute on "Contact" on the top right of the entry page. • Under the tab "Contact form" you can enter your

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	question directly. Alternatively, you can also write an e-mail. • After you have sent your query, you will receive information from the PEI by e-mail.
Bearbeitungsdauer	• up to 4 weeks • Processing may take longer for difficult requests
Frist	none
weiterführende Informationen	https://www.pharmnet-bund.de/static/de/index.html https://www.bfarm.de/DE/Service/Statistiken/AM_statistik/_node.html https://www.bfarm.de/DE/Arzneimittel/Arzneimittelzulassung/_node.html https://www.pei.de/DE/arzneimittel/arzneimittel-node.html
Hinweise	
Rechtsbehelf	
Kurztext	• Medicinal product information • information on the authorisation of medicinal products can be obtained from • for use in humans and • immunological medicinal products for use in animals. • the following information is provided: • Receipt of an application for marketing authorisation of a medicinal product • Receipt of an application for authorisation of a clinical trial which tests the efficacy, quality and safety of a medicinal product in a large number of patients. • Approval or rejection of a clinical trial confirming the quality, efficacy and safety of a medicinal product in a large number of patients. • For information on approved or registered medicinal products, a public database is available at pharmnet-bund.de • Information online via contact form • the Paul Ehrlich Institute (PEI) for vaccines and biomedical drugs • on the website of the Federal Institute for Drugs and Medical Devices (BfArM) for all other medicinal products for human use

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	• responsible: Federal Institute for Drugs and Medical Devices (BfArM), Paul Ehrlich Institute - Federal Institute for Vaccines and Biomedical Medicinal Products (PEI).
Ansprechpunkt	
Zuständige Stelle	
Formulare	• Forms: no • Online procedure possible: yes • Written form required: no • Personal appearance required: no https://www.bfarm.de/DE/Servicefunktionen/Kontakt/_node.html https://www.pei.de/DE/service-navi/kontakt/kontakt_node.html
Ursprungsportal	Erstzulassung (national), mit Bescheidabschluss Auskunft, Erstzulassung (national), mit Bescheidabschluss Auskunft