

99005006005000

Heruntergeladen am 08.06.2025

<https://fimportal.de/xzufi-services/55045/L100042>

Modul	Sachverhalt
Leistungsschlüssel	99005006005000
Leistungsbezeichnung I	
Leistungsbezeichnung II	Pharmaceutical legislation; import permits and certificates for tissues and certain tissue preparations
Typisierung	2/3 - Bund: Regelung (2 oder 3), Land/Kommune: Vollzug
Quellredaktion	Bayern
Freigabestatus Katalog	unbestimmter Freigabestatus
Freigabestatus Bibliothek	unbestimmter Freigabestatus
Begriffe im Kontext	
Leistungstyp	
Leistungsgruppierung	
Verrichtungskennung	
SDG-Informationsbereich	
Lagen Portalverbund	
Einheitlicher Ansprechpartner	

Modul	Sachverhalt
Fachlich freigegeben am	17.04.2025
Fachlich freigegeben durch	Bayerisches Staatsministerium für Gesundheit, Pflege und Prävention (Bavarian State Ministry of Health, Care and Prevention)
Handlungsgrundlage	https://www.gesetze-im-internet.de/amg_1976/_72b.html https://www.gesetze-im-internet.de/amg_1976/_72b.html true">https://www.gesetze-bayern.de/Content/Document/BayZustVAMUeB>true true">https://www.gesetze-bayern.de/Content/Document/BayZustVAMUeB>true
Teaser	The import of tissue / tissue preparations from a third country is subject to authorization.
Volltext	Tissues within the meaning of Section 1a number 4 of the Transplantation Act or tissue preparations within the meaning of Section 20c paragraph 1 sentence 1 or sentence 2 of the German Medicinal Products Act (AMG) may only be imported with a permit. The competent authority of the federal state in which the establishment of the importing tissue establishment is located shall decide on the granting of the permit in consultation with the competent higher federal authority (Paul Ehrlich Institute). The permit can be applied for informally by e-mail to the competent government. • Government of Upper Franconia: responsible for the administrative districts of Upper Palatinate, Upper Franconia, Middle Franconia and Lower Franconia • Government of Upper Bavaria: responsible for the administrative districts of Upper Bavaria, Lower Bavaria and Swabia
Erforderliche Unterlagen	
Voraussetzungen	The requirements result from § 72 b AMG.
Kosten	A fee of between €200 and €20,000 is set on the basis of the administrative work and time involved and the importance of the matter for the applicant (according

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	to the list of costs - tariff no. 7.IX.8/tariff item 6.4 and 6.5). This also includes expenses for necessary on-site inspections by our pharmaceutical officials (according to the list of costs - tariff no. 7.IX.8/tariff item 6.9).
Verfahrensablauf	The notification must be made informally to the responsible government.
Bearbeitungsdauer	The statutory processing period is a maximum of 3 months. The period begins when all documents and information are complete.
Frist	
weiterführende Informationen	https://formularserver.bayern.de/intelliform/forms/stmi+regierungen/rof/b5/53.2/rof_53.2-066/index https://formularserver.bayern.de/intelliform/forms/stmi+regierungen/rof/b5/53.2/rof_53.2-066/index
Hinweise	
Rechtsbehelf	Administrative court action
Kurztext	
Ansprechpunkt	
Zuständige Stelle	
Formulare	
Ursprungsportal	BayernPortal, BayernPortal