99005023008000

Modul	Sachverhalt
Leistungsschlüssel	99005023008000
Leistungsbezeichnung I	
Leistungsbezeichnung II	Manufacture of medicinal products; notification of subsequent changes and change of qualified person
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	10.06.2025
Fachlich freigegen 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/__20.html https://www.gesetze-im-internet.de/amg_1976/__20.html https://www.gesetze-im-internet.de/amg_1976/__13.html https://www.gesetze-im-internet.de/amg_1976/__13.html https://www.gesetze-bayern.de/Content/Document/BayZustVAMUeB/true https://www.gesetze-bayern.de/Content/Document/BayZustVAMUeB/true
Teaser	Changes to a manufacturing authorization in accordance with Section 13 of the German Medicinal Products Act must be notified.
Volltext	If there are changes to a manufacturing authorization issued in accordance with Section 13 of the German Medicinal Products Act (AMG), these must be notified immediately in advance (Section 20 AMG). The notification can be sent informally by e-mail to the responsible 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	• Depending on the facts reported, the documents to be submitted may differ considerably.Please check with the appropriate authority for the required documentation.
Voraussetzungen	Depending on the nature of the notified change, the authorization pursuant to Section 13 AMG may have to be amended by the drug regulatory authority.

Modul	Sachverhalt
Kosten	A fee of between €500 and €50,000 is set on the basis of the administrative work and time involved and the importance of the matter for the applicant (according to the schedule of costs - tariff no. 7.IX.8/tariff item 1.1).
Verfahrensablauf	The notification must be made informally to the responsible government.
Bearbeitungsdauer	The statutory processing period is a maximum of three months. The period begins when all documents and information are complete.
Frist	The notification must be made before the intended change.
weiterführende Informationen	
Hinweise	
Rechtsbehelf	Administrative court action
Kurztext	
Ansprechpunkt	
Zuständige Stelle	
Formulare	
Ursprungsportal	BayernPortal, BayernPortal