

99005065261000

Sunset clause: (notification obligation for AM for placing on the market and discontinuation of placing on the market) Receipt

Heruntergeladen am 08.07.2025

<https://fimportal.de/xzufi-services/103668704/B100019>

Modul	Sachverhalt
Leistungsschlüssel	99005065261000
Leistungsbezeichnung I	Sunset clause: (notification obligation for AM for placing on the market and discontinuation of placing on the market) Receipt
Leistungsbezeichnung II	Registration and deregistration of medicinal products with the Federal Institute for Drugs and Medical Devices
Typisierung	1 - Bund: Regelung und Vollzug
Quellredaktion	Bund
Freigabestatus Katalog	fachlich freigegeben (gold)
Freigabestatus Bibliothek	unbestimmter Freigabestatus
Begriffe im Kontext	
Leistungstyp	Leistungsobjekt mit Verrichtung

Modul	Sachverhalt
Leistungsgruppierung	
Verrichtungskennung	Entgegennahme (261)
SDG-Informationsbereich	Erlangung von Lizenzen, Genehmigungen oder Zulassungen im Hinblick auf die Gründung und Führung eines Unternehmens
Lagen Portalverbund	Produkt- und Stoffzulassung (2120200)
Einheitlicher Ansprechpartner	Nein
Fachlich freigegeben am	20.01.2022
Fachlich freigegeben durch	Federal Ministry of Health
Handlungsgrundlage	https://www.gesetze-im-internet.de/amg_1976/_29.html
Teaser	If you want to offer a medicinal product or if you withdraw it from the market, you must report this.
Volltext	As a pharmaceutical entrepreneur, you are obliged to register and deregister medicinal products with the Federal Institute for Drugs and Medical Devices (BfArM). • Registration means the notification of the placing on the market of a medicinal product for which you have a marketing authorization. Placing on the market means making a product available for sale or use. • Deregistration means the notification of the end of placing on the market. The procedure is also known as the "sunset clause". Even if you no longer produce a medicinal product, you must report this. The marketing authorization loses its validity if • a medicinal product is not placed on the market within 3 years of authorization or • if a medicinal product is no longer on the market for 3 consecutive years, i.e. has been withdrawn from the market.

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Erforderliche Unterlagen	You do not need to submit any documents.
Voraussetzungen	• Authorization or registration for medicinal products • Valid authorization as a pharmaceutical entrepreneur
Kosten	EUR 100.00 per registration or deregistration
Verfahrensablauf	Registration and deregistration with the Federal Institute for Drugs and Medical Devices is done online. • If necessary, register on the online platform PharmNet.Bund. Authentication takes place centrally via the registration and user administration (RuBen). • Select the "Sunset Clause" display procedure. • Follow the menu navigation to register or deregister for medicinal products. The procedure allows both individual and collective notifications. • You can check the status of your notifications using an overview list.
Bearbeitungsdauer	• immediately
Frist	• Notification: immediately after the business decision has been made, but not earlier than 4 weeks before you place the medicinal product on the market - Deregistration: • 2 months before the end of placing on the market • The expiration date of the last batch placed on the market must not be more than 10 years in the future.
weiterführende Informationen	https://www.bfarm.de/DE/Arzneimittel/Zulassung/Folgevverfahren/Sunset-Clause/_node.html https://www.bfarm.de/DE/Arzneimittel/_FAQ/Zulassung/Aenderungsanzeigen-Variations/Anzeigeverfahren-Sunset-Clause/_node.html
Hinweise	
Rechtsbehelf	"Sunset Clause" is a pure notification procedure, so there are no legal remedies.
Kurztext	• Placing on the market and discontinuation of placing on the market (sunset clause) Notification, receipt • Registration and deregistration with the Federal Institute for Drugs and Medical Devices (BfArM) required if medicinal product a product is to be made

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	available for sale or use (placing on the market) or are withdrawn from the market (discontinuation of placing on the market) • Registration and deregistration via online platform • Costs: EUR 100.00 per notification • Responsible: Federal Institute for Drugs and Medical Devices (BfArM)
Ansprechpunkt	Federal Institute for Drugs and Medical Devices (BfArM) - Marketing Authorization Division 1 Address Kurt-Georg-Kiesinger-Allee 3 53175 Bonn, City Telephone +49 228 99307-4310 E-Maile-sunset-clause@bfarm.de
Zuständige Stelle	Federal Institute for Drugs and Medical Devices (BfArM) - Marketing Authorization Division 1 Address Kurt-Georg-Kiesinger-Allee 3 53175 Bonn, City Telephone +49 228 99307-4310 E-mailsunset-clause@bfarm.de
Formulare	Forms: yes Online procedure possible: yes Written form required: no Personal appearance required: no https://www.pharmnet-bund.de/static/de/unternehmen/sunset-clause/index.html
Ursprungsportal	Sunset-Clause: (Anzeigepflicht für AM für das Inverkehrbringen und die Einstellung des Inverkehrbringens) Entgegennahme, Sunset clause: (notification obligation for AM for placing on the market and discontinuation of placing on the market) Receipt