99110048261000

Meldung an das Tierarzneimittelabgabemengenregister (TAM-R) Entgegennahme

Modul	Sachverhalt
Leistungsschlüssel	99110048261000
Leistungsbezeichnung I	Meldung an das Tierarzneimittelabgabemengenregister (TAM-R) Entgegennahme
Leistungsbezeichnung II	Submit notification to the Veterinary Drug Dispensing Registry (TAR).
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	Entgegennahme (261)

Modul	Sachverhalt
SDG-Informationsbereich	Erlangung von Lizenzen, Genehmigungen oder Zulassungen im Hinblick auf die Gründung und Führung eines Unternehmens
Lagen Portalverbund	Statistische Erhebungen und Meldepflichten (2090200)
Einheitlicher Ansprechpartner	Nein
Fachlich freigegeben am	27.03.2023
Fachlich freigegen durch	Federal Ministry of Food and Agriculture (BMEL)
Handlungsgrundlage	https://www.gesetze-im-internet.de/tamg/__45.html https://eur-lex.europa.eu/legal-content/DE/TXT/PDF/?uri=CELEX%3A32019R0006&from=it
Teaser	If you, as a pharmaceutical company or wholesaler, dispense certain veterinary drugs containing antimicrobials or certain substances to veterinary home pharmacies or other recipients, you must report the quantities annually to the Veterinary Drug Dispense Quantity Registry.
Volltext	When dispensing veterinary drugs to veterinary home pharmacies and other recipients with the following active ingredients, you as a pharmaceutical company or wholesaler must submit an annual notification to the Veterinary Drug Dispensing Registry (TAR): • antimicrobial active substances according to § 45 paragraph 6 number 1 Tierarzneimittelgesetz (TAMG). • Substances according to § 45 paragraph 6 number 2 of the German Veterinary Medicinal Products Act (TAMG). An updated list of veterinary medicinal products subject to notification is compiled each May and November by the Federal Office of Consumer Protection and Food Safety (BVL) from the official Medicines Information System (AmAnDa). This list contains information that is necessary in order to be able to assign the respective medicinal product individually without any problems:

Modul	Sachverhalt
	• Marketing authorization number (ZNR) • Unit of the reference quantity • All approved package sizes including the package size factor
Erforderliche Unterlagen	• Creation and upload of a complete XML schema according to concrete specifications for the web application "Tierarzneimittel-Abgabemengen-Register" (TAR)
Voraussetzungen	You are a pharmaceutical company or wholesaler and supply veterinary medicinal products with the following active substances to veterinary home pharmacies and other recipients: • Substances having antimicrobial activity according to point 1 and point 2, paragraph 5 and paragraphs 7 to 10 of the Annex to Delegated Regulation (EU) 2021/578 supplementing Regulation (EU) 2019/6. • Substances included in one of the appendices of the Ordinance on Substances with Pharmacological Activity in the version published on July 8, 2009 (Federal Law Gazette I page 1768) or Table 2 of the Annex to Regulation (EU) No. 37/2010
Kosten	There are no costs for you for reporting via the reporting portal "TAM-Abgabemengen-Register".
Verfahrensablauf	You can submit the notification for the Tierarzneimittel-Abgabemengen-Register (TAR) online to the Federal Office of Consumer Protection and Food Safety (BVL) as follows: • Call up the web application "Tierarzneimittel-Abgabemengen-Register" (TAR) . • To request access data, please send an e-mail to TAM-Abgabemengenregister@bvl.bund.de. • After receiving the access data, please perform a password reset. • After that, log in to the web application "Tierarzneimittel-Abgabemengen-Register" (TAR). • Upload the XML schema created in advance, according to the known specifications. • The web application validates and checks your file automatically. In case of error messages, make the appropriate correction. In case of unsolvable errors,

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	send a support request to TAM-Abgabemengenregister@bvl.bund.de. • The BVL checks the data at the end of the reporting period and contacts you in case of queries.
Bearbeitungsdauer	4 Monat(e) The data are reported in the reporting period from January 1 to March 31 of each year. The data are then validated, processed and evaluated by the BVL by August 1 of each year. The reporting parties do not receive any extra feedback on their reported data after submitting the report.
Frist	The reporting period starts at the beginning of January. The report must be submitted in electronic form as an XML file with a deadline of March 31 of each year.
weiterführende Informationen	https://www.bvl.bund.de/tar https://www.bvl.bund.de/tar-mitteilungspflichtige-AM-Stoffe https://www.bvl.bund.de/DE/Service/04_FAQ/02_FAQ-Unternehmer/03_Tierarzneimittel/_functions/faq_table-3-9-MeldungAbgabemenge.html?nn=12222456
Hinweise	
Rechtsbehelf	• No legal remedy is given.
Kurztext	• Notification to the Veterinary Medicinal Product Dispensing Quantity Register (TAM-R) Receipt. • Pharmaceutical companies and wholesalers are subject to an annual notification obligation for the Tierarzneimittel-Abgabemengen-Register (TAR) if they dispense veterinary drugs with the following active ingredients: antimicrobially active substances according to § 45 paragraph 6 number 1 Tierarzneimittelgesetz (TAMG). Substances according to § 45 paragraph 6 number 2 Veterinary Medicinal Products Act (TAMG) • an updated list of notifiable veterinary medicinal products is compiled each May and November by the Federal Office of Consumer Protection and Food Safety (BVL) from the official Medicines Information System (AmAnDa) • the list contains information that is necessary in order to be able to assign the medicinal product individually

Modul	Sachverhalt
	without any problems: Marketing authorization number (ZNR) unit of the reference quantity approved package sizes including the package size factor • Notification takes place online via web application "Tierarzneimittel-Abgabemengen-Register" (TAR) • responsible: Federal Office of Consumer Protection and Food Safety (BVL)
Ansprechpunkt	
Zuständige Stelle	
Formulare	• Forms available: No • Written form required: No • Informal application possible: No • Personal appearance required: No • Online service available: Yes
Ursprungsportal	Meldung an das Tierarzneimittelabgabemengenregister (TAM-R) Entgegennahme, Meldung an das Tierarzneimittelabgabemengenregister (TAM-R) Entgegennahme