99005071261000

Reporting of emerging risks / coordination of measures to be taken with, among others, the competent state authorities / if necessary, informing the authorities of other Member States and the EMA of suspected cases of adverse reactions to veterinary medicinal products or human medicinal products in animals Receipt

Modul	Sachverhalt
Leistungsschlüssel	99005071261000

Modul	Sachverhalt
Leistungsbezeichnung I	Reporting of emerging risks / coordination of measures to be taken with, among others, the competent state authorities / if necessary, informing the authorities of other Member States and the EMA of suspected cases of adverse reactions to veterinary medicinal products or human medicinal products in animals Receipt
Leistungsbezeichnung II	Report an adverse reaction caused by veterinary medicinal products (in animals or humans) or by human medicinal products in animals
Typisierung	1 - Bund: Regelung und Vollzug
Quellredaktion	Bund
Freigabestatus Katalog	unbestimmter Freigabestatus
Freigabestatus Bibliothek	unbestimmter Freigabestatus
Begriffe im Kontext	
Leistungstyp	Leistungsobjekt mit Verrichtung
Leistungsgruppierung	
Verrichtungskennung	Entgegennahme (261)
SDG-Informationsbereich	nicht SDG-relevant
Lagen Portalverbund	Gesundheitsvorsorge (1130100)
Einheitlicher Ansprechpartner	Nein
Fachlich freigegeben am	04.11.2024
Fachlich freigegen durch	Federal Ministry of Food and Agriculture (BMEL), Federal Ministry of Health (BMG)
Handlungsgrundlage	https://www.gesetze-im-internet.de/tamg/__34.html https://eur-lex.europa.eu/legal-content/DE/TXT/PDF/?uri=CELEX%3A32019R0006&from=DE https://www.gesetze-im-internet.de/tierimpfstv_2006/__30.html
Teaser	If a veterinary medicinal product or vaccine is suspected of causing adverse effects in an animal, a human or the environment, report this to the

Modul	Sachverhalt
	competent authority. You can also proceed in the same way for a human medicinal product that has been used in an animal.
Volltext	In addition to the intended, i.e. desired effect, unintended, adverse events can also occur following the use of medicines. These "adverse events", or AEs for short, are generally referred to as "side effects". In the event of adverse events following the use of a veterinary medicinal product or veterinary vaccine, the competent authority should be informed. This also applies if adverse events occur in an animal following the use of a medicinal product authorized for human use. It is important to report adverse events following the use of veterinary medicinal products and veterinary vaccines, even if a connection with the use of one or more products is only suspected. Reports should be made in particular in the case of suspected • unknown/known suspected adverse reactions • Interactions with other medicinal products • lack of efficacy • reactions in persons who have had contact with the veterinary medicinal product • transmission of infectious agents • negative effects on the environment • Insufficient withdrawal period (residues in food) The Federal Office of Consumer Protection and Food Safety (BVL) is responsible for the approval of veterinary medicinal products in Germany. The BVL is also responsible for supervising and monitoring the safety of veterinary medicinal products after authorization. The Paul Ehrlich Institute (PEI) is responsible for the approval and post-approval monitoring of vaccines and serums for animals and immunological veterinary medicinal products in Germany. All AE reports from Germany are collected, evaluated and sent anonymously to the pharmacovigilance

Modul	Sachverhalt
	database of the European Medicines Agency (EMA) by the BVL or PEI in accordance with their responsibilities. The knowledge gained is used to minimize risks, for example warnings can be included in the package leaflet. In addition, the public is informed about safety-relevant drug issues. As a veterinarian, you should report adverse events following the use of a veterinary medicinal product to the marketing authorization holder or, alternatively, to the professional association (German Veterinary Association) or directly to the competent authority. If you as the animal owner suspect that you or your animal are affected by an adverse event, you should have this clarified by the attending veterinarian or your family doctor. You, your veterinarian or your doctor should then inform the competent authority directly if necessary. Based on the information available, the BVL or PEI will assess whether there is a causal link between the use of the (veterinary) medicinal product and the reported event. If an adverse reaction pattern for a (veterinary) medicinal product emerges as a result of frequent reports, measures to increase safety are initiated depending on the severity of the symptoms and the conditions under which they occurred, for example • Inclusion of warnings in the package leaflet • changes to the conditions of use • ordering the suspension of the marketing authorization in particularly serious cases until the safety-relevant defects have been have been eliminated.
Erforderliche Unterlagen	• You do not have to submit any documents. • However, you can upload documents such as laboratory findings or examination results.
Voraussetzungen	• According to the Veterinary Medicinal Products Act and the Veterinary Vaccines Ordinance, the BVL, PEI and the pharmaceutical industry are legally obliged to collect and evaluate reports on adverse events that

Modul	Sachverhalt
	have occurred in Germany. The reporting person must provide contact details (name and telephone number or e-mail address). Anonymous reports are not possible.
Kosten	Gebühr: Es fallen keine Kosten an There are no costs.
Verfahrensablauf	You can report an adverse event following the use of veterinary medicinal products or human medicinal products in animals to the competent authority using the online procedure, a reporting form or informally by post, e-mail, fax or telephone. Online procedure: • Go to the website "Online reporting of adverse drug reactions (ADR)". • This will guide you step by step through the necessary information. • At the end of the report, you can have an electronically generated confirmation of receipt sent to your e-mail address or postal address, which summarizes your details. • If you have provided an e-mail address or postal address, you will be given a case number after processing by the competent authority. By telephone: • Call the competent authority and describe your case. By post, e-mail or fax: • Go to the website of the competent authority. Call up the form for "Notification of adverse events (AEs) after use of veterinary medicinal products or after use of human medicinal products in animals". • You can either complete the form on your computer or print it out. • Send the completed form to the competent authority. Scientific staff at the competent authority will assess the severity of the adverse events and their connection with the use of the medicinal product(s). If necessary,

Modul	Sachverhalt
	the competent authority will contact you with any queries.
Bearbeitungsdauer	The suspected case is usually processed within 30 days. You will receive a confirmation of receipt.
Frist	
weiterführende Informationen	https://www.pei.de/DE/newsroom/hp-meldungen/2024/240119-flyer-meldung-tierarzneimittel.html https://www.bvl.bund.de/DE/Arbeitsbereiche/05_Tierarzneimittel/02_Verbraucher/02_UAW/tam_uaw_node.html
Hinweise	
Rechtsbehelf	There are no legal remedies.
Kurztext	• Should be reported: adverse events in animals or humans (e.g. animal caretakers and keepers) following the use of veterinary medicinal products adverse events following the use of human medicinal products in animals • Reporting even if a connection between the medicinal product and the event is only suspected • Reporting serves to systematically monitor the quality, efficacy and safety of (veterinary) medicinal products • Concerns: Veterinarians, pharmacists, employees in pharmacovigilance centers, animal owners • Responsible: for veterinary vaccines and immunological veterinary medicinal products: Paul-Ehrlich-Institut (PEI) for other veterinary medicinal products: Federal Office of Consumer Protection and Food Safety (BVL)
Ansprechpunkt	
Zuständige Stelle	
Formulare	
Ursprungsportal	Meldung von auftretenden Risiken / Koordination von zu ergreifenden Maßnahmen mit u.a. den zuständigen Landesbehörden / ggf. Unterrichtung der Behörden anderer Mitgliedsstaaten und der EMA über Verdachtsfälle von Nebenwirkungen durch

Modul	Sachverhalt
	Tierarzneimittel oder Humanarzneimittel am Tier Entgegennahme, Reporting of emerging risks / coordination of measures to be taken with, among others, the competent state authorities / if necessary, informing the authorities of other Member States and the EMA of suspected cases of adverse reactions to veterinary medicinal products or human medicinal products in animals Receipt