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Vigilance for veterinary medicinal products

Annual report 2024

November 2025

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Credits

Publisher
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Summary of adverse reactions reported in Switzerland in 2024

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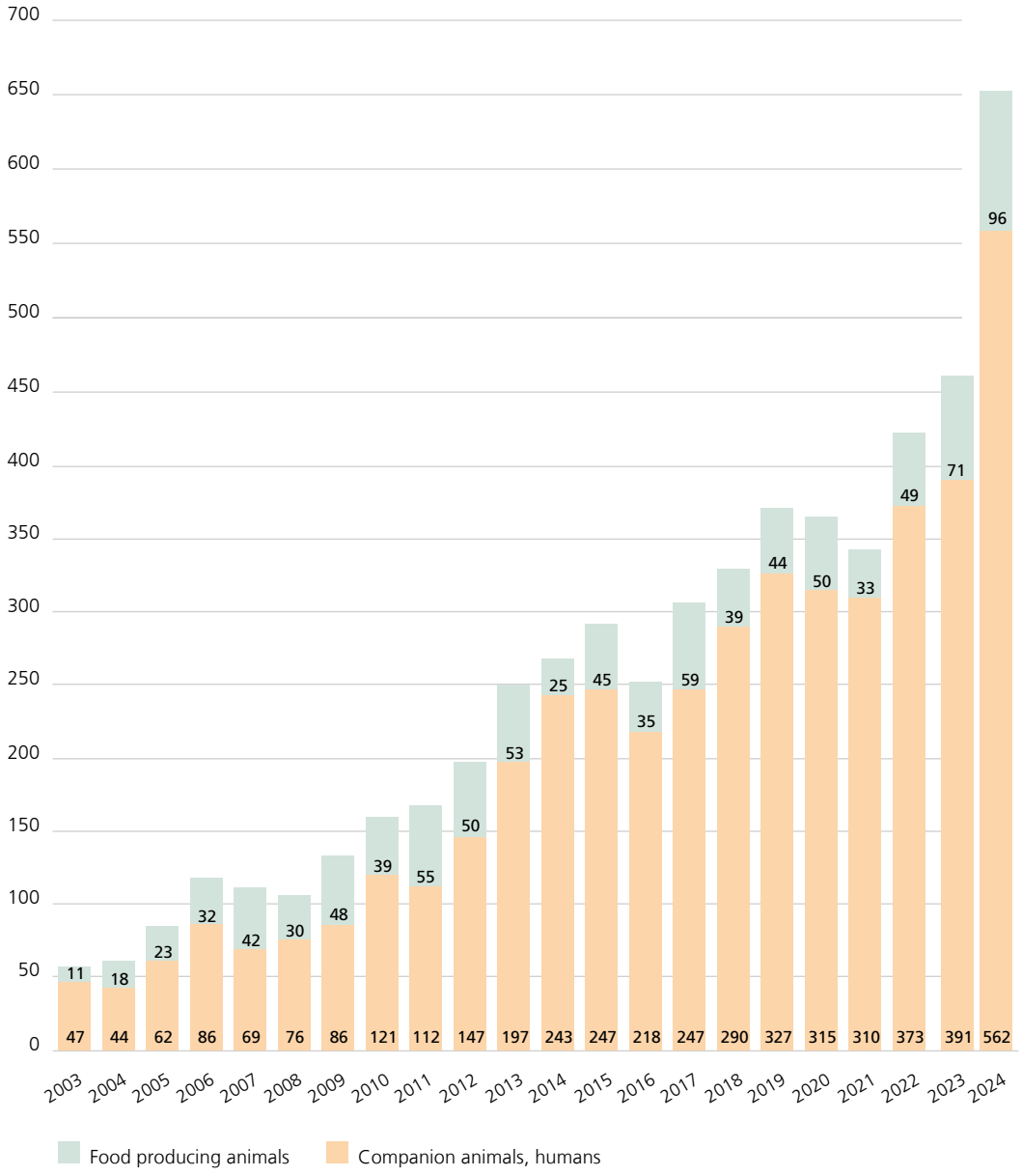
1 A summary of the main points

- 658 reports, increase compared with 2023: 42.4%
- Most frequently affected species: 365 dogs, 197 cats, 45 cattle, 25 horses
- Most frequent medicinal product types: Antiparasitics (158 reports), immunological veterinary medicinal products (141), hormones (99), veterinary medicinal products to modulate the nervous system (89), veterinary medicinal products to treat the digestive tract (62)
- 188 cases of suspected lack of efficacy, largely for antiparasitics and hormones
- 206 cases passed on by Tox Info Suisse:
  - 73 cases of animal exposure to veterinary medicinal products, including 50 cases of accidental ingestion of flavoured tablets by dogs/cats
  - 133 cases of human exposure to veterinary medicinal products
- 16 signal procedures initiated

2 Evolution of the number of reports since 2003

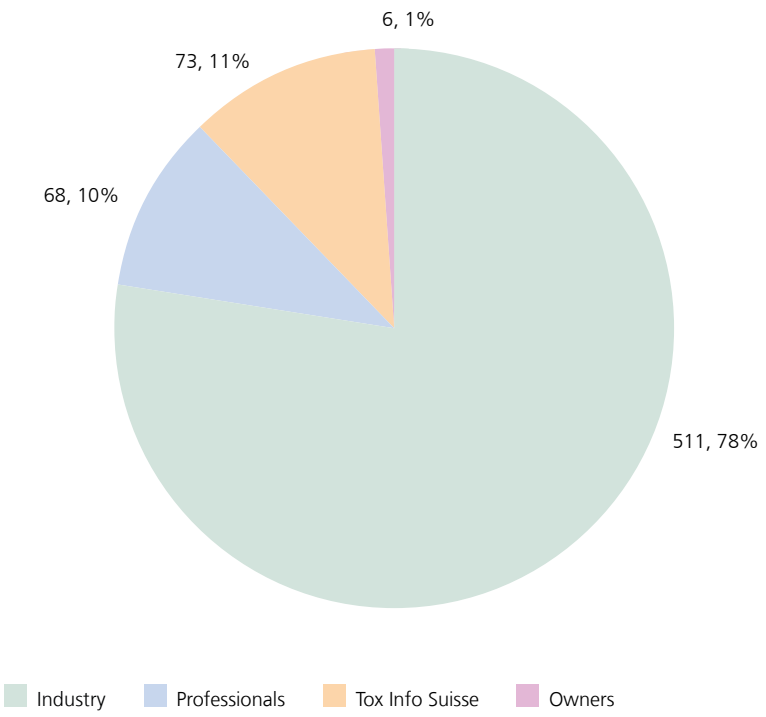


3 International comparison

- Switzerland: 658 reports (2024)
- Germany: 4,571 reports (2024)
- France: 6,762 reports (2023)
- Ireland: 883 reports (2024)
- Total EU: 30,677 reports (2024)

4 Distribution of the reports

4.1 Distribution of the reports by source



As in all previous years, the majority of these reports were submitted by marketing authorisation holders. These do not refer to cases from clinical trials, but rather to cases reported to marketing authorisation holders by practising veterinarians. A similar pattern has been observed for years both in Switzerland and various European countries.

4.2 Distribution of the reports by ATCvet code

	Number of reports and % of the respective total							
Medicine category by ATCvet code	**All species**		**Dog**		**Cat**		**Livestock**	
QA: Alimentary tract and metabolism	62	9.4%	14	3.8%	43	21.8%	5	5.2%
QC: Cardiovascular system	12	1.8%	9	2.5%	3	1.5%		
QD: Dermatologicals	9	1.4%	6	1.6%	3	1.5%		
QG: Genitourinary system, sex hormones	9	1.4%	7	1.9%	1	0.5%	1	1.0%
QH: Hormonal preparations (excl. sex hormones and insulins)	99	15.0%	84	23.0%	14	7.1%	1	1.0%
QI: Immunological veterinary medicinal products	141	21.4%	71	19.5%	30	15.2%	40	41.2%
QJ: Anti-infectives	24	3.6%	7	1.9%	5	2.5%	12	12.4%
QM: Musculoskeletal system	24	3.6%	11	3.0%	9	4.6%	3	3.1%
QN: Nervous system	88	13.4%	51	14.0%	25	12.7%	14	14.4%
QP: Antiparasitics	158	24.0 %	88	24.1%	59	29.9%	11	11.3%
QR: Respiratory system	2	0.3 %					2	2.1%
QS: Sensory organs	11	1.7%	11	3.0%				
QV: Various	1	0.2%			1	0.5%		
"QZ" Reclassified veterinary medicinal products	17	2.6%	5	1.4%	4	2.0%	8	8.2%
None	1	0.2%	1	0.3%				
	658	100.0%	365	100.0%	197	100.0%	97	100.0%

The total for all species may be higher than the total of the individual columns (dogs, cats, food producing animals) because reports of adverse reactions in exotic animals and humans were also submitted.

The distribution across the affected animal species (see table) has remained almost unchanged in recent years. The largest group, with 562 reports (85.4%), is made up of small animals (dogs, cats). They are followed in descending order by cattle/cows/calves with 46 reports (7%) and horses with 25 reports (3.8%). The number of reports for all other animal species and for reactions in users was less than five in 2024.

As in previous years, the high number of reports in the hormones group can be explained by the large number of reported cases involving the suspected lack of efficacy of an implant that induces temporary infertility in male dogs (66 reports). These reports can be confirmed by measuring blood testosterone levels: In 23 cases, lack of efficacy was proven by a blood testosterone level in excess of the threshold, while in 28 cases it was refuted

by a very low level. No information regarding testosterone levels was available for the remaining cases, for example if the animal's owner did not want a blood sample to be taken or if a new implant was inserted with no prior testosterone measurement. In the case of antiparasitics, too, 46 out of the total of 158 reports submitted related to a suspected lack of efficacy, most commonly against ticks.

Reports involving immunological veterinary medicinal products mainly concerned frequently used vaccines, primarily in dogs and horses. Local and systemic reactions (including hypersensitivity reactions) in dogs following vaccination against serious diseases such as parvovirus or canine adenovirus infection, rabies or leptospirosis were most frequently reported. Local and systemic reactions following vaccination against influenza or tetanus were reported in horses.

In the 88 reports involving medicinal products to modulate the nervous system, two veterinary medicinal products containing anti-nerve growth factor (NGF) monoclonal antibodies are strongly represented with 54 reports. This figure is significantly higher than the 17 reports received in 2023. Since the distribution of the reported reactions (particularly hypersensitivity reactions, skin reactions, itching, anorexia, polyuria and polydipsia) was largely unchanged on previous years, it can be assumed that publications and media reports have increased awareness and, therefore, reporting rates. Three cases of suspected rapid progression of the osteoarthritis being treated with these two veterinary medicinal products were also reported. As there are still gaps in the available data for these cases, there is not yet any need for action. Such cases continue to be monitored and analysed.

The majority of reports involving veterinary medicinal products that act on the digestive tract were attributable to one oral antidiabetic (40 reports). The veterinary medicinal product in question was authorised in 2023 and offers a new option for treating diabetes mellitus in cats. However, its active substance, velagliflozin, is not interchangeable with insulin, and any change in treatment requires careful consideration and preparation. 17 of the reports received described a suspected lack of efficacy (hyperglycaemia); the remainder described lethargy, vomiting, diarrhoea or cystitis. Six cases described ketosis, which was asymptomatic in some animals, but very pronounced and fatal in others. As part of two signals, one of which was the subject of a Direct Healthcare Professional Communication (DHPC) to veterinarians, the key factors for safe treatment were highlighted and incorporated into the Information for healthcare professionals (section 4.5, Special precautions for use).

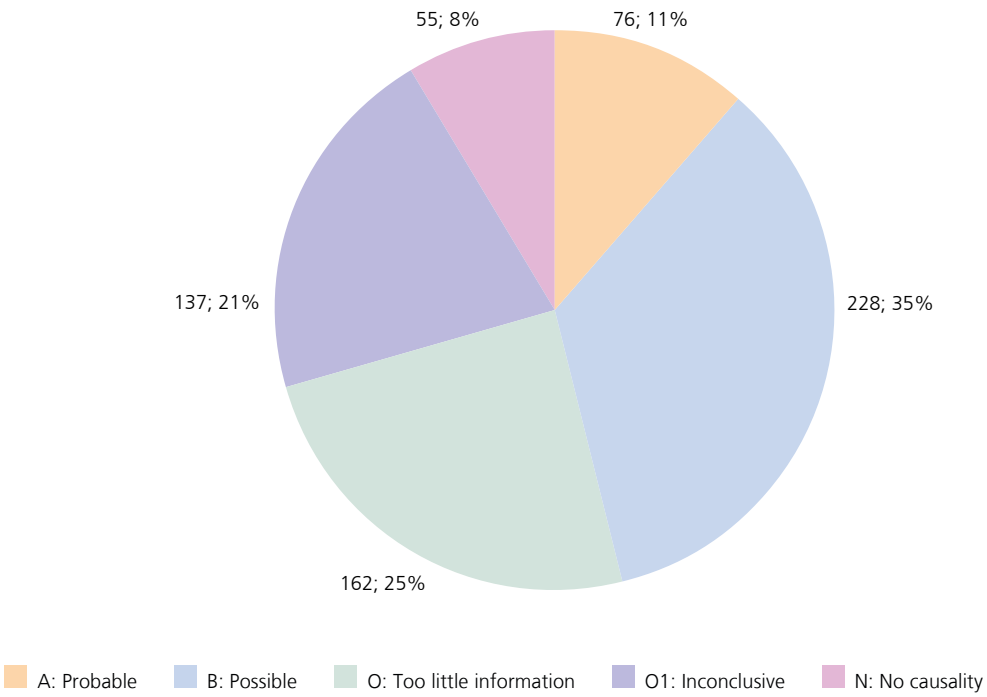
The same group of veterinary medicinal products contains nine reports involving an insulin product for which reports of pain and defensive reactions in the dogs treated with the product increased following a change in one of its excipients. A link between the new excipient and the reactions is suspected [1].

Notable...

- Use of a caninised anti-nerve growth factor (NGF) monoclonal antibody in a mini pig. The animal exhibited an anaphylactic reaction. Monoclonal antibodies are species-specific and their safety and efficacy in other species cannot be guaranteed.
- Use of the felinised equivalent, frunevetmab, in a leopard. Treatment was not effective. However, there are also reports attesting to efficacy in big cats.
- A cat was treated by its owner with oral and systemic ivermectin (2 mg/kg) for a suspected lung neoplasm, after which it presented with ataxia, tremors, hypothermia, anorexia and blindness. Symptomatic treatment was successful. The owner had found "information" on the Internet...
- Subcutaneous administration of a vaccine for intranasal use in a dog. The animal developed an infection with swelling and bleeding at the injection site. The dog was treated successfully.
- 35% overdosage of an oral non-steroidal anti-inflammatory in powder form led to the death of 13 of the 226 pigs that had been treated. The animals' owner had calculated the dose incorrectly.

[1] *www.gov.uk/government/news/caninsulin-40-iuml-suspension-for-injection-adverse-events*

4.3 Distribution of the reports by causality



5 Reports from Tox Info Suisse

5.1 Adverse reactions to veterinary medicinal products in animals

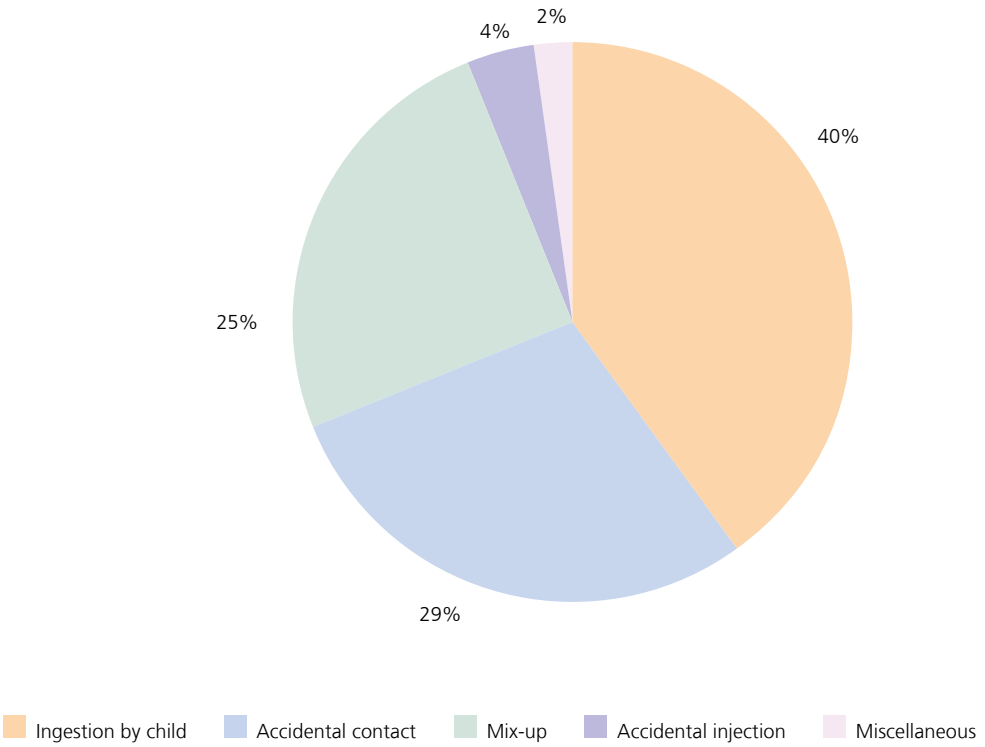
Tox Info Suisse passed 73 cases on to Swissmedic in 2024. In 50 cases, the reports involved the accidental ingestion of veterinary medicinal products by animals, very frequently in the form of flavoured tablets. All veterinary medicinal products intended to be administered over a protracted period may be affected if they contain flavourings (including anti-inflammatories, products for the treatment of hypo- or hyperthyroidism, and antiparasitics). Although the overdoses were substantial in some cases (e.g. a 10-fold overdose of the anti-inflammatory product carprofen), they were often without consequence.

Notable...

- A dog ate a flea collar containing pyrethroids and subsequently exhibited weakness for several hours. The animal recovered.
- An antiparasitic containing an isoxazoline for application on the skin (spot-on) was administered orally to two cats. In both cases, the animals displayed no symptoms apart from hypersalivation.
- A dog was accidentally given an influenza and tetanus vaccine intended for horses. The animal was not exhibiting symptoms at the time the report was submitted.
- A cat bit into a tube containing an ointment for the treatment of skin infections and displayed no symptoms apart from hypersalivation.

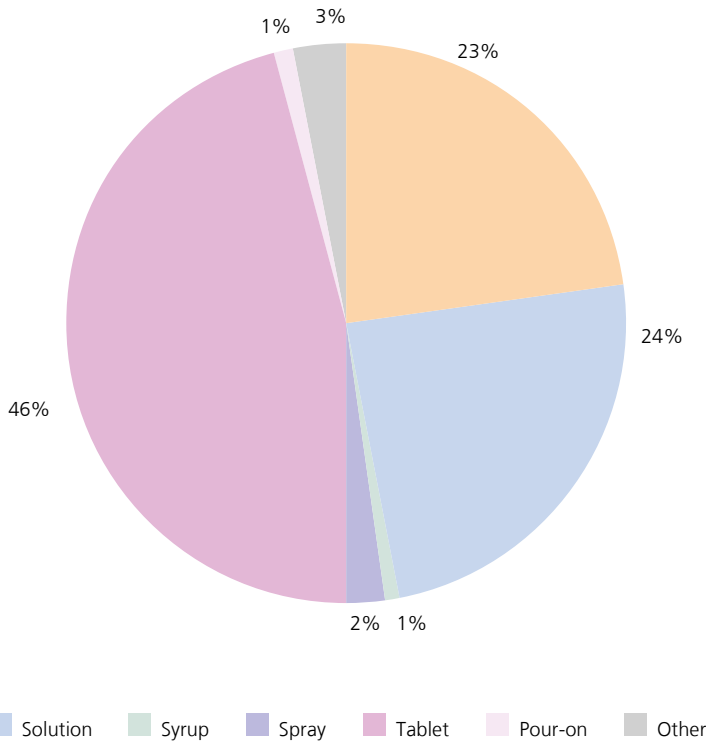
5.2 Human exposure to veterinary medicinal products

Breakdown by type of human exposure to veterinary medicines



133 cases were recorded: As in previous years, the cases affecting humans involved mistaking a veterinary medicinal product for a human one (25%), accidental contact with veterinary medicinal products (29%), and ingestion of veterinary medicinal products by children (40%). These cases cover a very broad spectrum of veterinary medicinal products, with human exposure to veterinary medicinal products for long-term treatments – such as anti-inflammatories, veterinary medicinal products to treat hypo- or hyperthyroidism, and antiparasitics – being reported more frequently. There were frequently no symptoms at the time of reporting, and the calls to Tox Info Suisse were primarily made as a precautionary measure.

Breakdown of human exposure according to dosage form



The classification of exposures by dosage form shows that tablets and solutions were most frequently involved. Tablets, oral solutions and spot-ons are the dosage forms most frequently administered by the animal owners themselves, for example as antiparasitics or anti-inflammatories.

Exposures to solutions for injection tended to occur in a veterinary practice or during administration by a veterinarian, and more rarely by animal owners. Ten cases of self-injection were reported. If a case of self-injection involves a vaccine that contains mineral oil (e.g. paraffin oil, "oil adjuvant"), the wound **must be treated surgically without delay**, even if it appears small and insignificant to begin with. Even without injection, the small residual quantities on the needle are sufficient to trigger necrosis. In one case, the patient waited six hours before presenting at a hospital emergency department. Although the original lesion on the patient's finger was no bigger than a scratch, it subsequently developed into osteomyelitis and necrosis that required several operations. The patient almost lost the finger and was subsequently unable to work for one year.

Notable...

- A cat owner with earache and a sore throat took their pet's antibiotic (amoxicillin and clavulanic acid) instead of an anti-inflammatory.
- A cat owner was unable to open a pipette of spot-on antiparasitic using their hands, so used their teeth instead. Two to three drops entered their mouth. There were no symptoms apart from a "strange taste".
- A young man "mistook" a bottle of anti-inflammatory medicine intended for dogs for a cough syrup and took about 70 ml. In another case, a three-year-old child took 15–20 ml of the same solution. There were no symptoms in either case at the time the reports were submitted.
- Instead of a "spagyric spray for sore throats", a dog owner took an oral dose (three pumps) of an antibiotic spray intended for application on the skin. He was not exhibiting symptoms at the time the report was submitted.

Many of these reports of exposure appear anecdotal, but these should be viewed in the context of improving safety for the users and their families. The cases show that elementary safety precautions, such as separating human and veterinary medicines, storing them out of reach of children and administering veterinary medicinal products as soon as the blister pack or packaging has been opened, are not always observed. The cases are important for an efficient pharmacovigilance system because they cover an additional spectrum of incidents with veterinary medicinal products. For example, they help identify possible risks to those in close contact with animal patients arising from incorrect uses or abuses of veterinary medicinal products.

6 Safety signals

A safety signal is an indication of a possible new or modified risk associated with the use of a medicinal product. Pharmacovigilance reports play a crucial role in identifying safety signals. During 2024, safety signals were identified that resulted in the modification of the medicinal product information for the veterinary medicinal products in question.

6.1 Some signals from 2024

- Anaphylaxis following the use of solutions for injection containing ketoprofen
- Stricter warnings and safety precautions for the use of velagliflozin in cats
- Risks to wild animals of the corpses of animals euthanised with pentobarbital
- Modification of the indications, dosage and waiting times for suspensions for injection containing procaine penicillin
- Anorexia, ataxia and incontinence following bedinvetmab administration in dogs

7 Conclusion

The number of reports in 2024 increased significantly – by more than 40% – from 2023. Given the spontaneous nature of a pharmacovigilance system, it is not always possible to identify the causes of a fluctuation of this magnitude. As regards 2024, the new authorisation of an oral antidiabetic for cats and publications on anti-NGF monoclonal antibodies certainly played a role, but the increase in reported adverse reactions was observed across all medicinal product groups and all sources. It can be concluded from this that the increase is attributable in general to greater awareness of the reporting system and to greater participation by veterinarians in the monitoring of veterinary medicinal products.

Pharmacovigilance for veterinary medicinal products remains an important tool for improving the safety of such products and for reducing the risks to the individuals who use them. Every report submitted can make a crucial contribution to this end.

To conclude this report, we would like to thank all practising veterinarians and all other reporters who took the time to submit reports on observed adverse reactions during the course of the year.

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