



Vigilance for veterinary medicinal products

Annual report 2023

Credits

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Annual report 2023

Summary of adverse reactions reported
in Switzerland in 2023

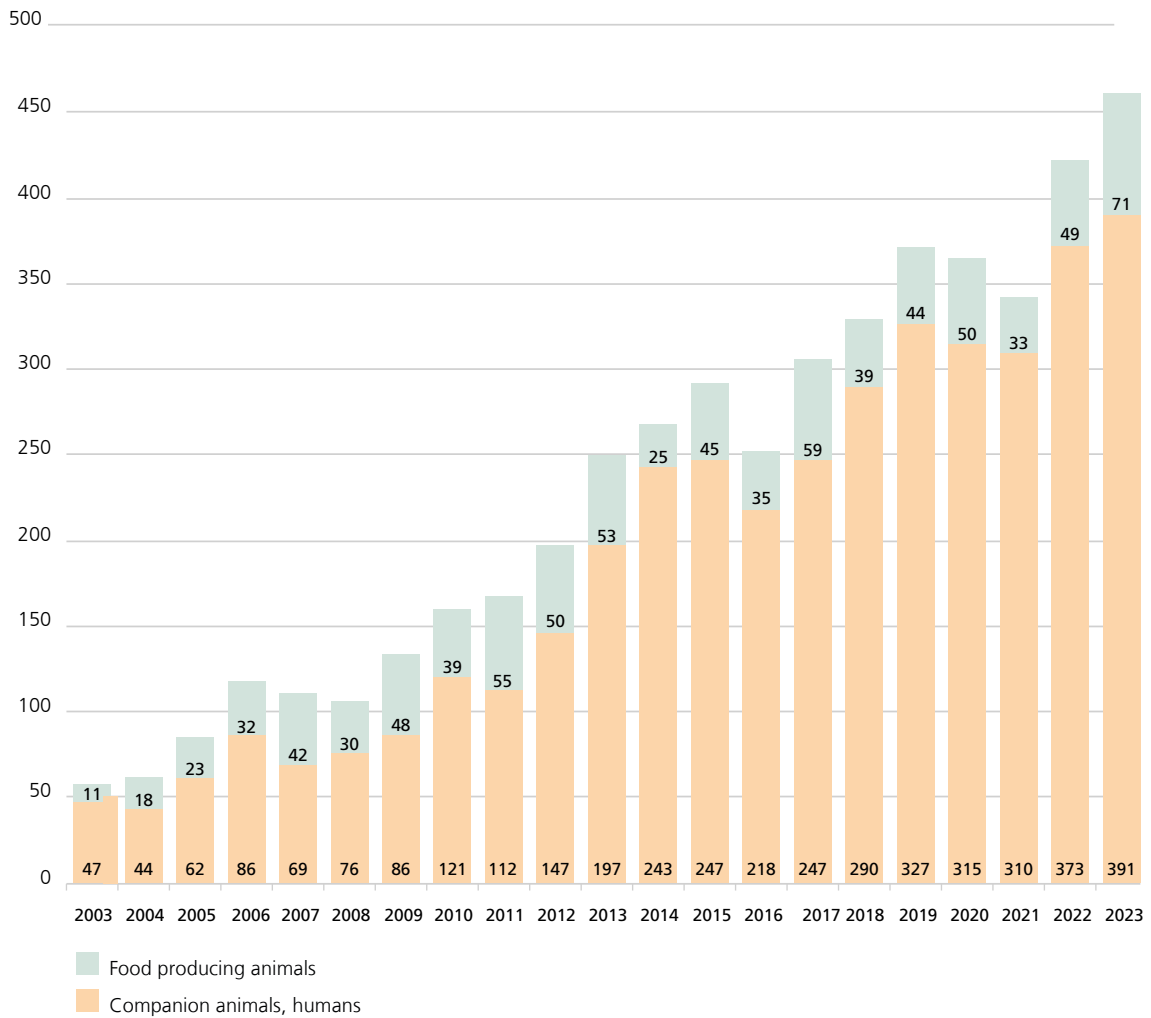
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1 A summary of the main points

- 462 reports, increase compared with 2022: 9.5%¹
- Most frequently affected species: 273 dogs, 115 cats, 41 cattle, 14 horses
- Most frequent medicinal product types: antiparasitics (142 reports), immunological veterinary medicinal products (111), hormone products (82), products to modulate the nervous system (38), anti-infectives (12)
- 125 cases of suspected lack of efficacy, largely for antiparasitics and hormone products
- 54 cases passed on by Tox Info Suisse
- 32 cases of accidental ingestion of flavoured tablets by dogs/cats
- 104 cases of human exposure to veterinary medicinal products
- 10 signal procedures initiated

¹ This increase is partly attributable to Swissmedic assuming responsibility for immunological veterinary medicinal products on 1 January 2023.

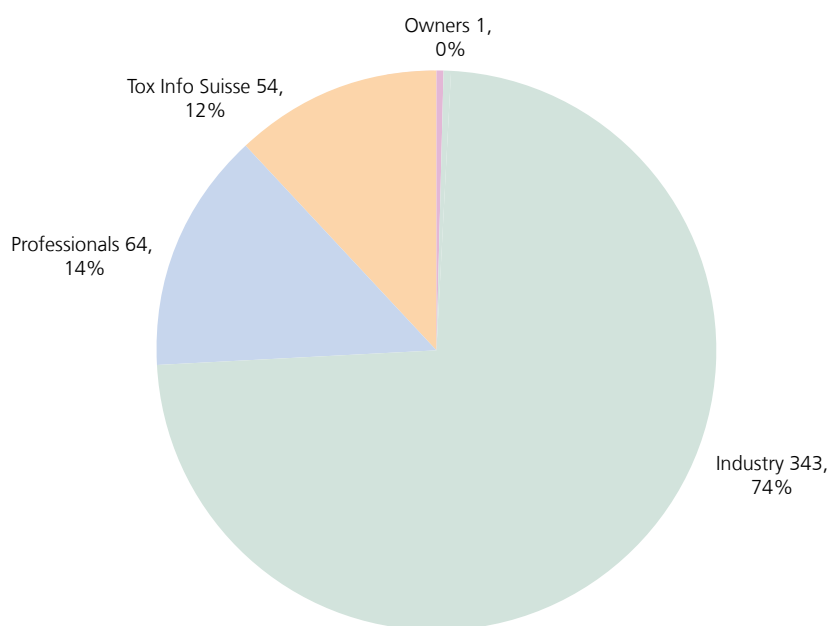


2 International comparison

- Switzerland: 462 reports (2023)
- Germany: 4,253 reports (2023)
- France: 4,887 reports (2022)
- Ireland: 998 reports (2022)
- Total EU: 27,518 reports (2023)

3 Distribution of the reports

3.1 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.

3.2 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	14	3.0%	9	3.3%	5	4.3%	0	0.0%	
QB: Blood and blood-forming organs	1	0.2%	0	0.0%	0	0.0%	1	1.4%	
QC: Cardiovascular system	13	2.8%	6	2.2%	7	6.1%	0	0.0%	
QD: Dermatologicals	6	1.3%	4	1.5%	1	0.9%	0	0.0%	
QG: Genitourinary system, sex hormones	6	1.3%	3	1.1%	2	1.7%	1	1.4%	
QH: Hormonal preparations (excl. sex hormones and insulins)	82	17.7%	64	23.4%	14	12.2%	4	5.6%	
QI: Immunological veterinary medicinal products	111	24.0%	66	24.2%	15	13.0%	30	42.3%	
QJ: Anti-infectives	12	2.6%	1	0.4%	1	0.9%	9	12.7%	
QL: Antineoplastic and immunomodulating agents	1	0.2%	1	0.4%	0	0.0%	0	0.0%	
QM: Musculoskeletal system	20	4.3%	12	4.4%	3	2.6%	5	7.0%	
QN: Nervous system	38	8.2%	12	4.4%	14	12.2%	12	16.9%	
QP: Antiparasitics	142	30.7%	87	31.9%	46	40.0%	8	11.3%	
QS: Sensory organs	5	1.1%	4	1.5%	1	0.9%	0	0.0%	
"QZ": Reconverted veterinary medicinal products	11	2.4%	4	1.5%	6	5.2%	1	1.4%	
	462	100.0%	273	100.0%	115	100.0%	71	100.0%	

The distribution across the affected animal species (**table**) has remained almost unchanged in recent years. The largest group (84% of all reports) is made up of small animals (dogs, cats). They are followed in descending order by cattle/cows/calves with 41 reports, and horses with 14 reports. The number of reports for all other animal species and for undesirable effects in users was less than five in 2023.

The high number of reports in the group of hormone products can be explained by a large number of reported cases regarding suspected lack of efficacy of an implant to induce temporary infertility in male dogs (62 reports). Suspected lack of efficacy can be confirmed by measuring testosterone levels: in 20 cases, lack of efficacy was proven by a blood testosterone level in excess of the threshold, while in 26 cases it was refuted by a very low level. No information regarding testosterone levels was available for the remaining cases. In the case of antiparasitics, too, 43 out of the total of 142 reports submitted related to a suspected lack of efficacy, most commonly against ticks.

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

Regarding products to modulate the nervous system, 17 reports related to monoclonal antibodies to control pain associated with osteoarthritis in dogs and cats. The veterinary medicinal products were authorised in 2020 and the number of reports in 2023 declined by around 60% compared with 2022. This is a well known phenomenon following initial authorisation of a medicinal product (known as the Weber effect²). The reported incidents were comparable with 2022 and are in line with the known risk-benefit profiles of the two veterinary medicinal products.

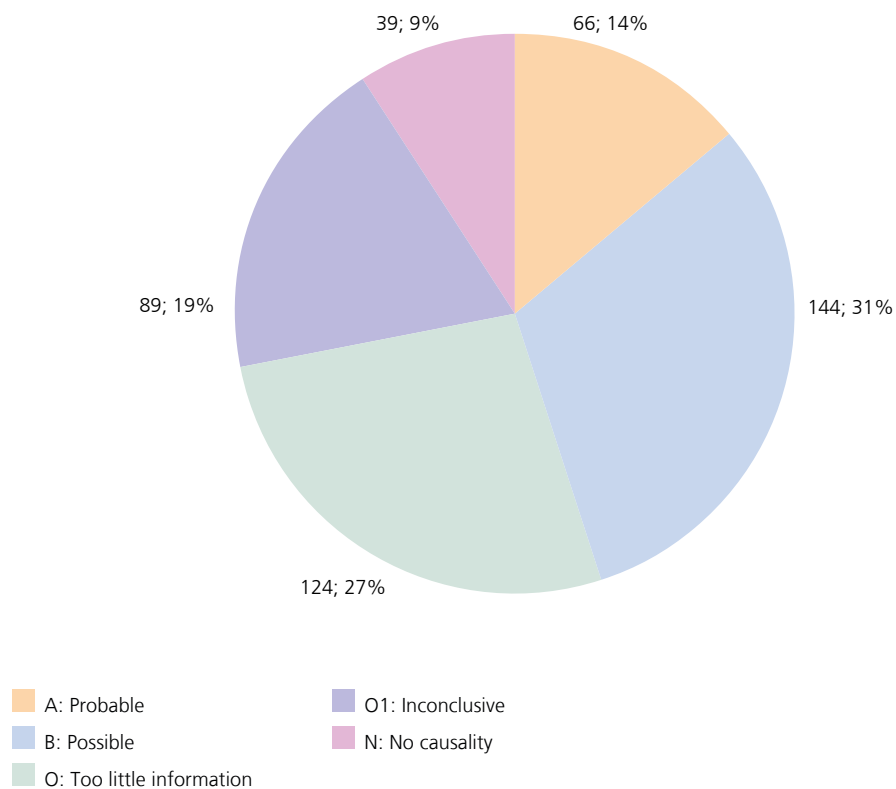
Notable...

- The successful resuscitation of a dog following pentobarbital overdosage (Iannucci et al., 2023³). The dog was treated first with phenobarbital and then with pentobarbital for idiopathic epilepsy. The pentobarbital was overdosed and blood levels were close to LD50. Normal circulation was restored after seven minutes of cardiopulmonary resuscitation and the dog was discharged from hospital after seven days. Because of their high active substance concentration, veterinary medicinal products containing pentobarbital are only authorised in Switzerland for euthanasia.

² Weber JCP. Epidemiology of adverse reactions to nonsteroidal anti-inflammatory drugs. In: Rainsford KD, Velo GD, editors. *Side-effects of Anti-inflammatory Drugs, Advances in Inflammation Research*. New York: Raven Press; 1984: 1–7

³ *J Vet Emerg Crit Care*. 2023; 33: 393–400. DOI: 10.1111/vec.13283

3.3 Distribution of the reports by causality



4 Reports from Tox Info Suisse

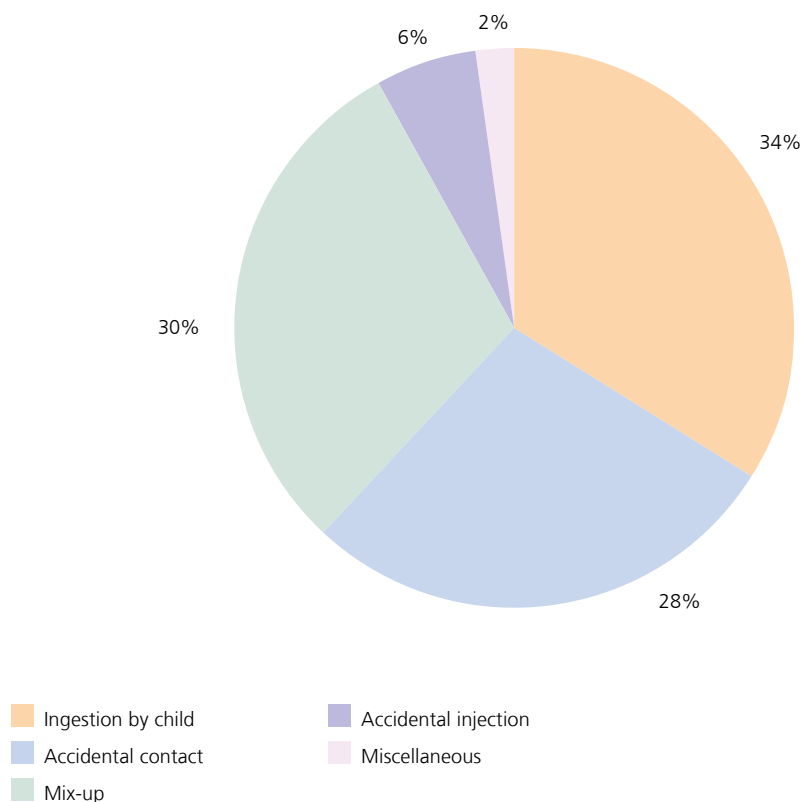
4.1 Adverse reactions to veterinary medicinal products in animals

Overall, 54 cases satisfied the minimum criteria for reports (unambiguous identification of the patient, veterinary medicinal product and reaction) and were passed on to Swissmedic by Tox Info Suisse as part of a contractual agreement. 30 cases involved the accidental ingestion of veterinary medicinal products by animals, 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 (anti-inflammatories, products for the treatment of hypo- or hyperthyroidism, antiparasitics). Although the overdoses were substantial in some cases (e.g. a 5- to 10-fold overdose of the anti-inflammatory product carprofen), they were often without consequence.

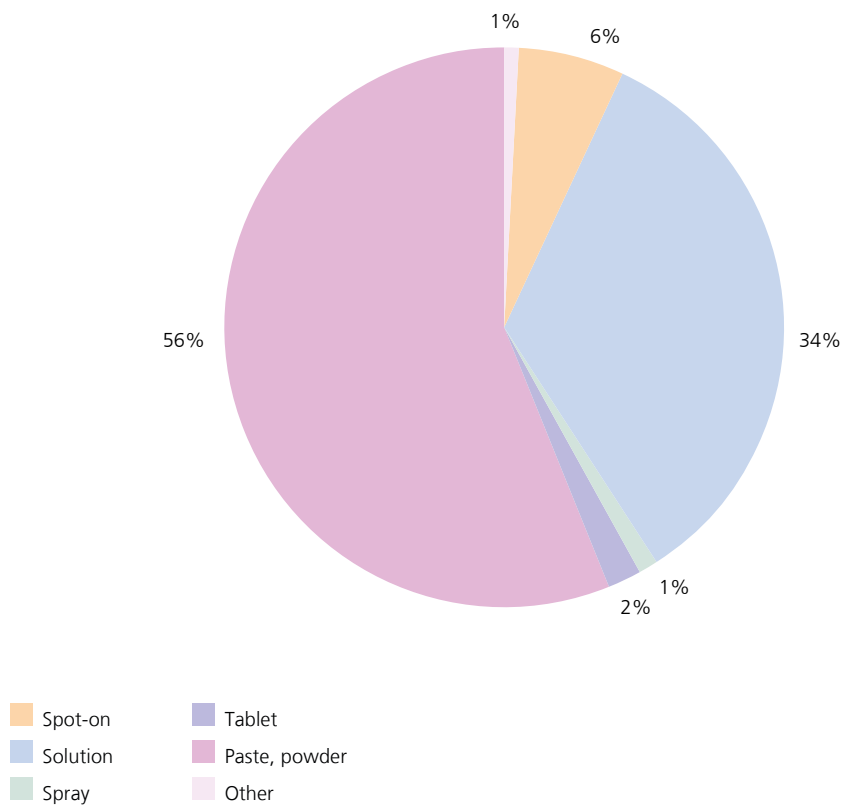
Notable...

- A dog owner’s daughter fed the animal eight tablets of two different anti-parasitics while playing with it. The dog displayed no symptoms.
- Incorrect use of an oral applicator resulted in a horse receiving double the dose of ivermectin. The horse displayed no symptoms.
- A dog ate its pyrethroid flea collar and exhibited vomiting and tremor.
- A dog chewed a bottle of ear drops and was inappotent afterwards.
- Incorrect dilution of a phosphoric acid ester (50-fold overdose) caused miosis, anorexia and apathy in goats. One animal had to be euthanised.

4.2 Human exposure to veterinary medicinal products



104 cases were recorded: as in previous years, mix-ups in humans, accidental contact with veterinary medicinal products, and ingestion of veterinary medicinal products by children each made up about one third of cases. In addition, there were 6 cases of accidental self-injection. 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.



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.

5 Signals

5.1 Signals in 2023

- Potential risk to female users and pregnant animals when using veterinary medicinal products containing the excipient N-methyl-pyrrolidone: modification of the “Special warnings for each target species”, “Special warnings for use” and “Use during pregnancy and lactation” sections of the Information for healthcare professionals.
- Hypersensitivity reactions to various influenza vaccines in horses: modification of the “Side effects” section of the Information for healthcare professionals
- Anaphylaxis following use of a vaccine against distemper, canine adenovirus, parvovirus and parainfluenza virus infections: modification of the “Side effects” section of the Information for healthcare professionals
- Polyuria/polydipsia, incontinence during treatment with lotilaner: modification of the “Side effects” section of the Information for healthcare professionals

6 Conclusion

The number of reports in 2023 increased slightly from 2022. There were an extra 111 reports resulting from Swissmedic's assumption of responsibility for monitoring immunological veterinary medicinal products on 1 January 2023, which accounted for 24% of the year's reports. Furthermore, a need to update the Information for healthcare professionals for some immunological veterinary medicinal products was identified. The information texts were updated accordingly as part of signal processing.

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.

Many reports of exposure passed on by Tox Info Suisse may appear anecdotal, but these should be viewed in the context of improving safety for the users and their families. They 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.

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



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