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Vigilance for veterinary medicinal products

Annual report 2022

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Summary of adverse reactions reported in Switzerland in 2022

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Contents

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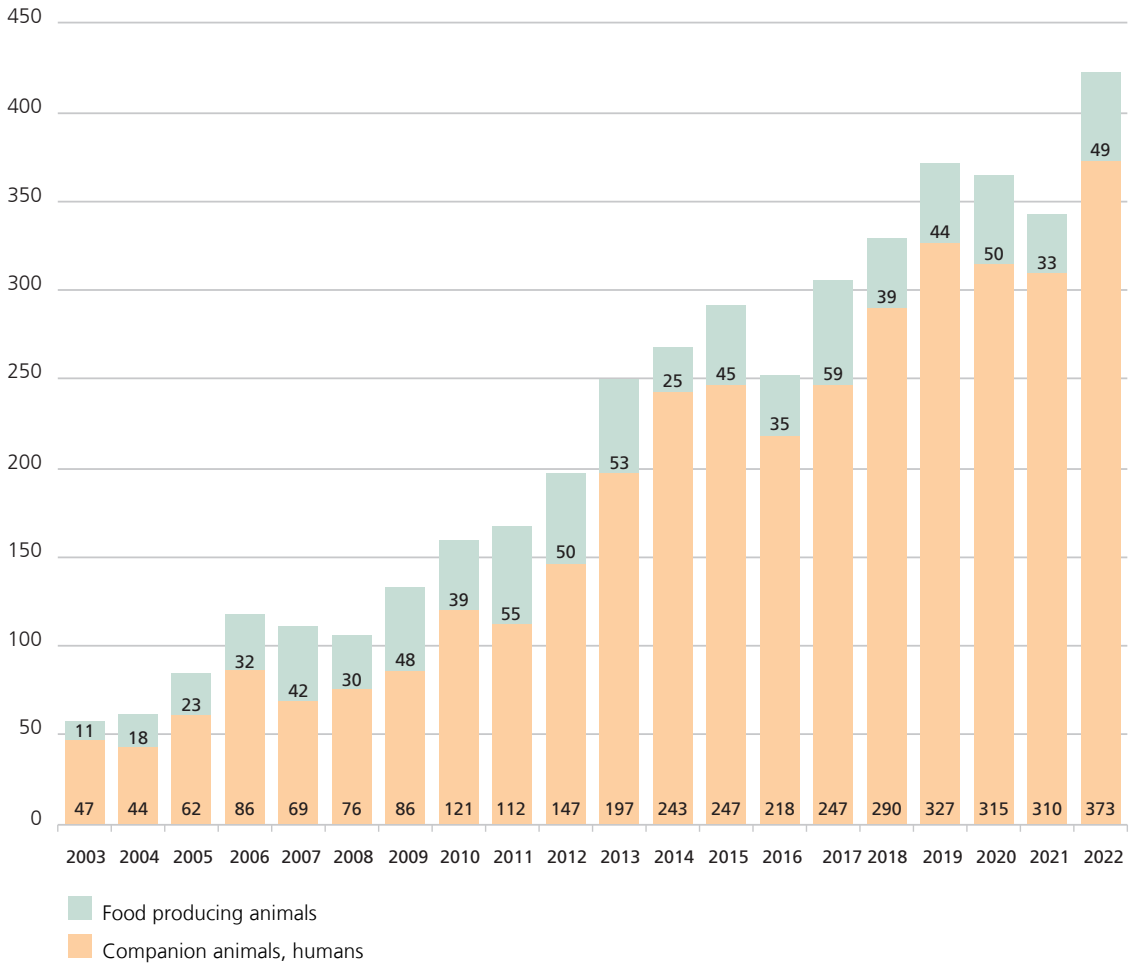
1 A summary of the main points

- 422 reports, increase compared with 2021: 23%
- Most frequently affected species: 254 dogs, 104 cats, 31 cattle
- Most frequent medicinal product types: antiparasitics (141), hormone products (103), products to modulate the nervous system (76), antiinfectives (21)
- 139 cases of suspected lack of efficacy, largely for antiparasitics and hormone products
- 47 cases passed on by Tox Info Suisse
- 30 cases of accidental ingestion of flavoured tablets by dogs/cats
- 104 cases of human exposure to veterinary medicinal products
- 6 signal procedures initiated

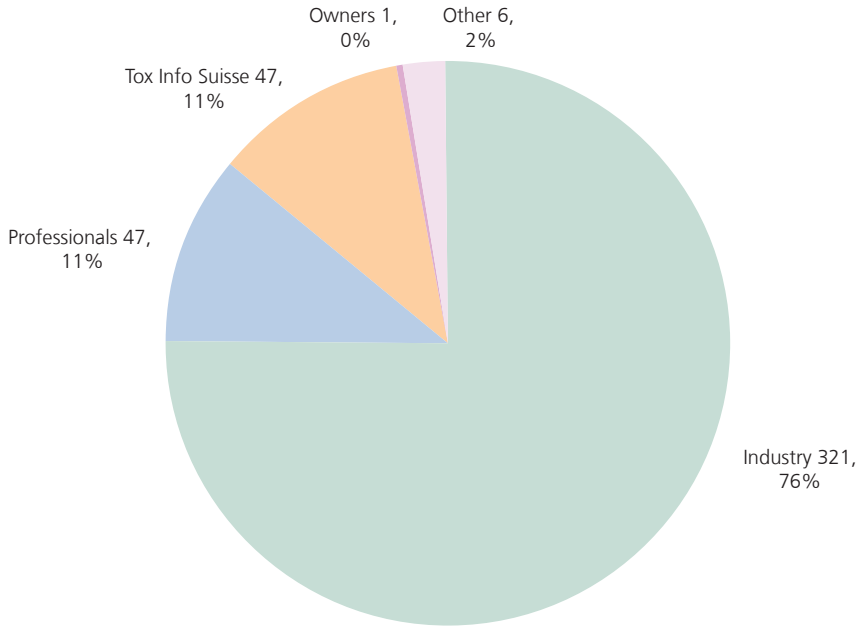


2 International comparison

- Switzerland: 422 reports (2022)
- Germany: 4086 reports (2022)
- United Kingdom: 6139 reports (2020)
- France: 4420 reports (2021)

3 Distribution of the reports

3.1 Distribution of the reports by source



Others: veterinary offices, official veterinarians

The majority of the reports were submitted by the marketing authorisation holders. These do not refer to cases from clinical trials, but rather to cases reported to marketing authorisation holders by practising veterinarians. This 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	8	1.9%	5	2.0%	1	1.0%	2	4.8%
QB: Blood and blood-forming organs	1	0.2%	0	0.0%	0	0.0%	1	2.4%
QC: Cardiovascular system	13	3.1%	10	3.9%	3	2.9%	0	0.0%
QD: Dermatologicals	4	0.9%	3	1.2%	1	1.0%	0	0.0%
QG: Genitourinary system, sex hormones	6	1.4%	3	1.2%	0	0.0%	3	7.1%
QH: Hormonal preparations (excl. sex hormones and insulins)	103	24.4%	86	33.9%	10	9.6%	3	7.1%
QJ: Anti-infectives	21	5.0%	2	0.8%	2	1.9%	16	38.1%
QL: Antineoplastic and immuno-modulating agents	2	0.5%	1	0.4%	1	1.0%	0	0.0%
QM: Musculoskeletal system	21	5.0%	9	3.5%	9	8.7%	3	7.1%
QN: Nervous system	76	18.0%	42	16.5%	25	24.0%	7	16.7%
QP: Antiparasitics	141	33.4%	80	31.5%	46	44.2%	5	11.9%
QR: Respiratory system	1	0.2%	0	0.0%	0	0.0%	1	2.4%
QS: Sensory organs	10	2.4%	9	3.5%	1	1.0%	0	0.0%
QV: Miscellaneous	1	0.2%	0	0.0%	1	1.0%	0	0.0%
«QZ» Reconverted veterinary medicinal products	14	3.3%	4	1.6%	4	3.8%	1	2.4%
	422	100.0%	254	100.0%	104	100.0%	42	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 companion animals (dogs, cats). They are followed in descending order by cattle with 31 reports, horses with 11 reports, and adverse reactions in users, which account for 5 reports. Fewer than five reports were received throughout the year for all other animal species.

Three cases of adverse reactions in persons using the products involved contact with the solution of a spot-on antiparasitic product. This veterinary medicinal product is a solution in a pipette that leaves a «sticky feeling» on the fingers upon contact with the skin due to its formulation. Wearing gloves is expressly advised in the product's Information for healthcare professionals and package leaflet due to the risk of (potentially serious) reactions in users.

The high number of reports in the group of hormone products can be explained by a large number of reported cases regarding a suspected lack of efficacy of an implant inducing temporary infertility in male dogs (68 reports). Suspected lack of efficacy can be confirmed by measuring testosterone levels: in 21 cases the lack of efficacy was proven, while in 33 cases it was refuted. No information regarding testosterone levels was available for the remaining cases. In the case of antiparasitics, too, 48 out of a total of 141 reports were submitted due to a suspected lack of efficacy, primarily against ticks.

Regarding products to modulate the nervous system, 43 reports related to two new authorisations of monoclonal antibodies to control pain associated with osteoarthritis in dogs and cats dating from 2020. The largest number of reports is generally expected within the first two to five years following the authorisation of new active substances.

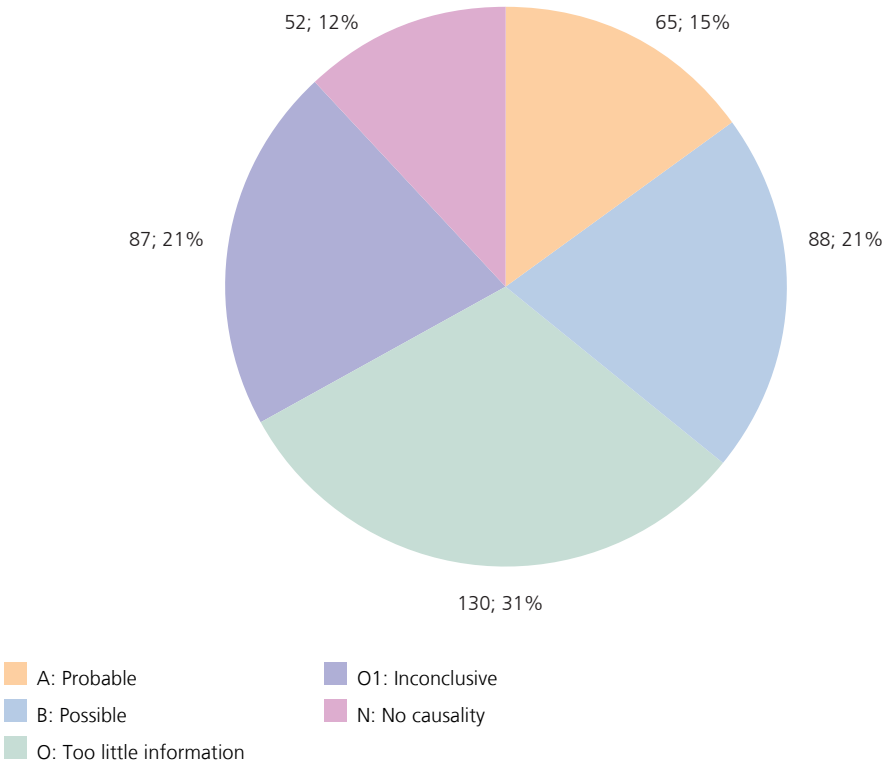
Notable cases

- Increased drinking (polydipsia) and more frequent urination (polyuria) in dogs following the use of bedinvetmab (a monoclonal antibody used to control pain associated with osteoarthritis). Modification of the «Side effects» section in the Information for healthcare professionals.

- Use of a deslorelin implant in female dogs, accumulation of pus in the uterus (pyometra). Off-label use; in 2022 the veterinary medicinal product was authorised only for inducing temporary infertility in male dogs. No modification of the Information for healthcare professionals due to the off-label use.

- In the case of one dog, licking an oestrogen-containing gel (a human medicinal product) led to alterations in its coat and enlargement of its mammary chain (effect of oestrogen).

3.3 Distribution of the reports by causality

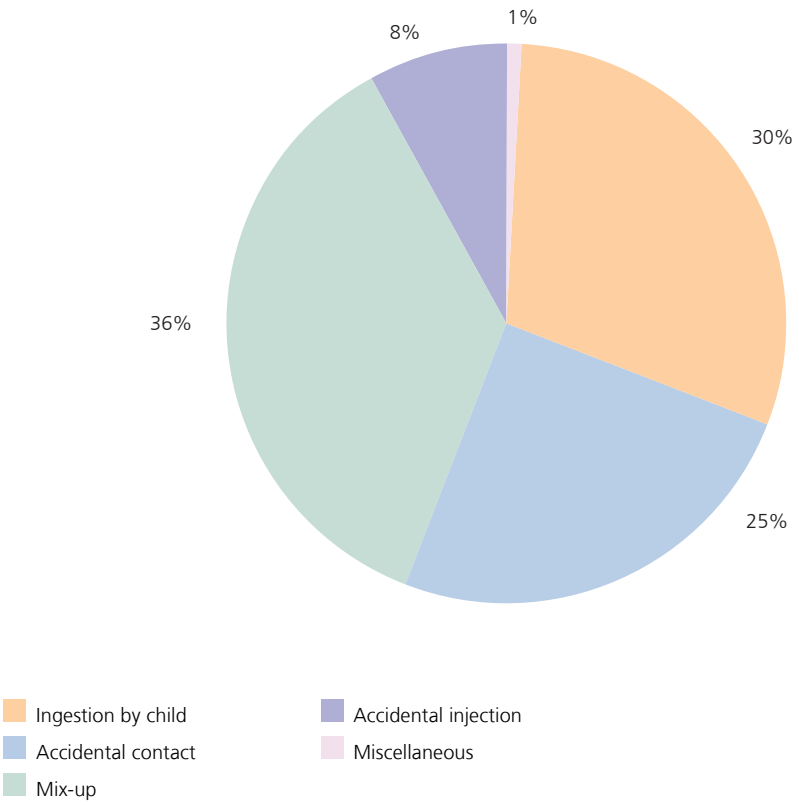


4 Reports from Tox Info Suisse

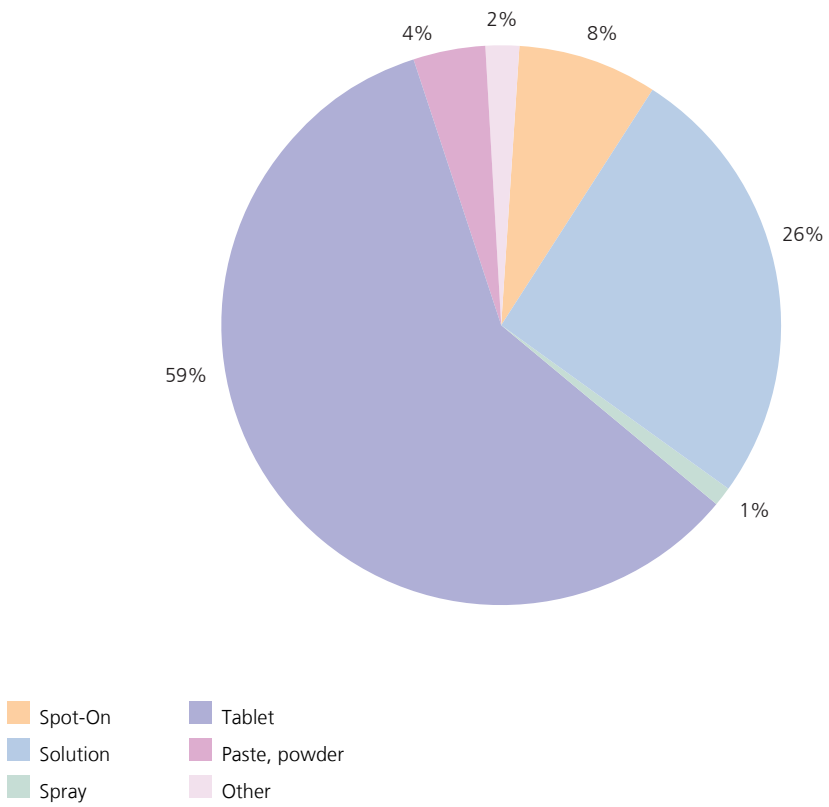
4.1 Adverse reactions to veterinary medicinal products in animals

Overall, 47 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. These primarily involved veterinary medicinal products for administration over a prolonged period such as anti-inflammatory drugs, products for the treatment of hypo- or hyperthyroidism, and antiparasitics. Although overdoses can be substantial (e.g. a 25-fold overdose of the anti-inflammatory active ingredient carprofen), they are often without consequence. In one case, a dog ingested 6 antibiotic tablets and 5 anti-inflammatory tablets as well as around 130g of milk chocolate (chocolate can be toxic to dogs depending on its theobromine content).

4.2 Human exposure to veterinary medicinal products



104 cases were recorded: as in previous years, mix-ups, accidental contact with veterinary medicinal products, and ingestion of veterinary medicinal products by children each made up a third of cases. In addition, there were 9 cases of accidental self-injection. These cases cover a very broad spectrum of veterinary medicinal products, with those for long-term treatments – such as anti-inflammatories, veterinary medicinal products to treat hypo- or hyperthyroidism, and antiparasitics – being reported more frequently. In most cases there were no symptoms, and the calls to Tox Info Suisse were primarily made as a precautionary measure.



The classification of exposures by dosage form shows that tablets, solutions and spot-on pipettes were most frequently involved. This largely refers to veterinary medicinal products that are administered by the animal owners themselves, e.g. antiparasitics and 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 2022

- Toxic effects of flunixin in carrion-eating birds: modification of the «Special warnings for each target species» and «Environmental compatibility» sections in the Information for healthcare professionals.

- Black spots in cheese following the use of bismuth subnitrate-based teat sealants: modification of the «Special warnings for use», «Amounts to be administered and administration route» and «withdrawal times» sections in the Information for healthcare professionals

- Use of isoflurane for the castration of piglets, risks for users and the environment: modification of the «Special warnings for each target species», «Special warnings for use», «Amounts to be administered and administration route» and «Environmental compatibility» sections in the Information for healthcare professionals

- Paradoxical excitation following the administration of detomidine in horses: modification of the «Side effects» section in the Information for healthcare professionals

- Local reactions following the use of deltamethrin 'pour-on' in cattle: modification of the «Side effects» section in the Information for healthcare professionals

- Pulmonary oedema following the use of xylazine in calves: modification of the «Side effects» section in the Information for healthcare professionals

6 Conclusion

The number of reports in 2022 showed a marked increase compared with 2021, which can be explained by the natural fluctuations of a spontaneous reporting system. It cannot be ascribed to any specific circumstances. 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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