HPRA Annual Pharmacovigilance report for 2024

Introduction

The Health Products Regulatory Authority (HPRA) regulates veterinary medicinal products (VMPs) in Ireland. Part of its role is to monitor the quality, safety, and efficacy of authorised VMPs, a process known as pharmacovigilance. This includes products authorised nationally by the HPRA or centrally by the European Commission following the opinion of the European Medicines Agency (EMA). Regulation 2019/6, introduced in 2022, changed how VMPs are regulated in the European Union insofar as adverse events are reported and monitored. Marketing authorisation holders (MAHs) must now record in the EU Pharmacovigilance database (UPhD) all suspected adverse events from anywhere in the world within 30 days of receipt of the report. MAHs must also conduct a signal management process for their products, and if a change to the benefit-risk balance of the product is found, they must notify it to the HPRA or EMA within 30 days.

Scope of Veterinary Pharmacovigilance

Veterinary pharmacovigilance involves monitoring:

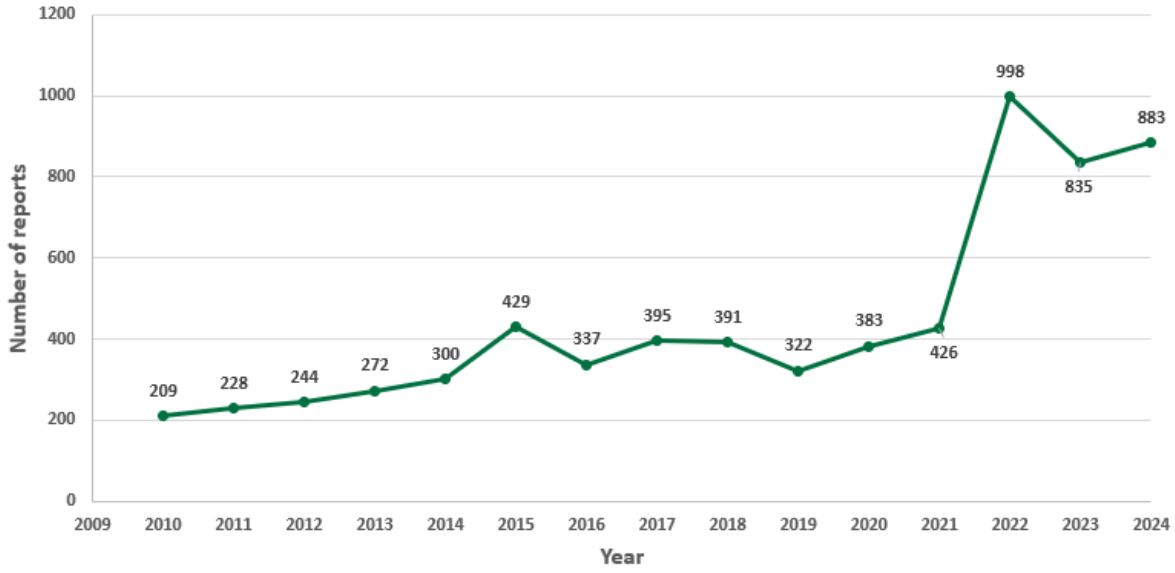
- Suspected adverse reactions (SAR) in animals to VMPs used under authorised conditions.
- Off-label use of VMPs in animals.
- Lack of expected efficacy (LEE) of VMPs.
- Reported violations of approved residue limits.
- Adverse reactions in humans related to the use of VMPs.
- Potential environmental problems.

These reports are collectively known as suspected adverse events (SAEs). Marketing authorisation holders (MAHs) must report all SAEs occurring in Ireland to the UPhD. Reports can also be submitted directly to the HPRA by veterinary healthcare professionals and animal owners.

National Pharmacovigilance Surveillance

In 2024, a total of 883 suspected adverse event (SAE) reports from Ireland were recorded in the Union Pharmacovigilance Database (UPhD), with 29 reported directly to the Health Products Regulatory Authority (HPRA) from various sources such as veterinarians, animal owners, and the Department of Agriculture, Food and the Marine (DAFM). Since 2022, all reports, including serious as well as non-serious ones, must be recorded in the UPhD, whereas previously only serious SAEs were reported. This change led to a significant increase in the number of adverse events reported in 2022 compared to previous years. Although the number of adverse events decreased in 2023, the trend of increasing reports continued in 2024 with a total of 883 reports (figure 1).

Figure 1: Total number of SAE Reports to the HPRA (2010-2021) and to the Union Pharmacovigilance Database (UPhD) (2022-2024)



During 2024, there were just over 73 adverse events occurring each month in Ireland, ranging from 49 to 1003. The highest number of adverse event reports occurred in dogs followed by cattle and cats (table 1).

Table 1. Breakdown of reports recorded in 2024

Species	Total number reports	Total number of animals reacting
Food producing animals		
Cattle	228	6830
Sheep	50	696
Horses	25	72
Pigs	3	28
Poultry	2	1860
Bees	1	3 hives
Companion Animals		
Dogs	440	483
Cats	119	150
Rabbits	2	2
Donkeys	1	2
Other		
Chimpanzee	1	3
Humans		
Humans	11	11
Total	**883**	**10,137***

* Excluding the number of bees

In relation to reports in dogs, the clinical signs most frequently reported following the use of all VMPs are listed in Table 2.

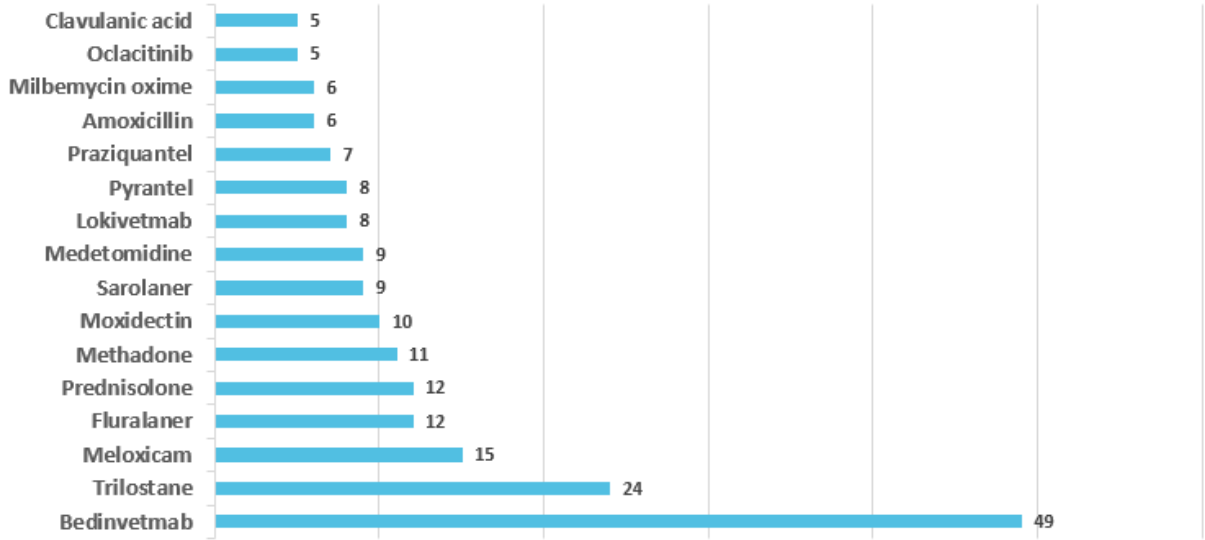
Table 2. Most frequently reported medically important terms for dogs in 2024

Clinical signs reported	Number of reports	Number of animals affected
Death	40	45
Seizure	16	17
Collapse	12	12
Apnoea	8	8
Thrombocytopenia (low platelet count)	7	7
Paralysis	7	7
Paresis (muscle weakness)	6	6
Deafness/Loss of hearing	5	5
Anaphylaxis (severe allergic reaction)	5	5

Multiple active substances can be included in the same report, so the total below does not equate to the total number of reports.

The most frequently reported active substances associated with reports in dogs are listed in figure 2.

Figure 2: Most frequently reported active substances concerning reports in dogs in 2024



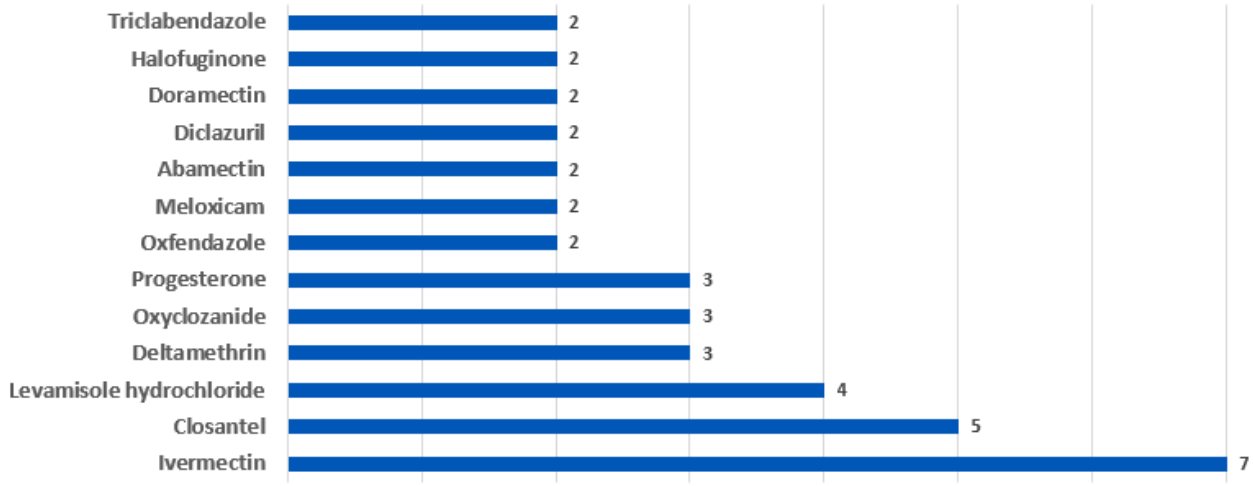
The medically important terms reported most frequently in cattle following the use of all VMPs are listed in Table 3.

Table 3. Most frequently reported medically important for cattle in 2024

Clinical signs reported	Number of reports	Number of animals affected
Death	61	170
Recumbency/Lying down	8	148
Blindness	3	31
Anaphylaxis (severe allergic reaction)	2	2
Abortion	2	20
Hypersensitivity reaction	2	5

The most frequently reported active substances associated with reports in cattle are listed in figure 3.

Figure 3: Most frequently reported active substances in cattle in 2024



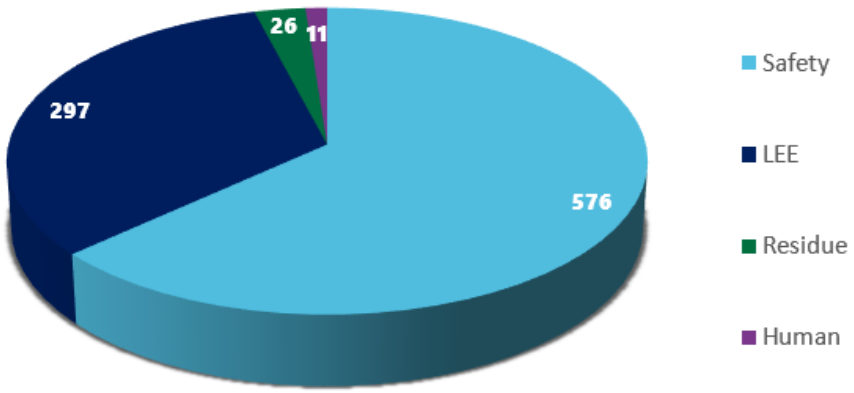
Discussion

Of the 29 adverse event reports submitted directly to the HPRA in 2024, 15 reports were submitted by veterinarians, representing 52% of all reports. Eight reports were submitted by animal owners, five reports by the DAFM, and one report by a marketing authorisation holder.

Of the reports that were recorded during 2024, 576 involved SARs; 297 reports related to a lack of expected efficacy (LEE); 26 reports related to possible residue violations; and 11 reports involved human reactions, representing approximately 63%, 33%, 3% and 1% respectively of all reports (see Figure 3 below).

Note that 27 reports related to both adverse reactions and a lack of expected efficacy, so these reports have been counted twice and therefore the number of reports is higher than 883.

Figure 3: Number and type of adverse event reports received in 2024



Eleven reports of human exposure to VMPs were received during 2024 which is a significant increase compared to 2023 when just 6 reports were received. Seven of them were following exposure to immunological products and four reports arose from exposure to a pharmaceutical product. The most common clinical symptom reported was injection site swelling following accidental self-injection and the next most common symptom was eye irritation.

There were 297 reports relating to lack of expected efficacy (LEE) reported in 2024 which is similar to the number of reports in 2023 (309). Of these reports, 162 relate to cattle, 72 relate to dogs, 37 relate to sheep, 10 relate to cats, 9 relate to horses, 3 relate to pigs, 2 relate to chickens, 1 relates to donkeys and 1 relates to chimpanzees.

During 2024, the HPRA became aware of adverse event reports where residues of closantel above the Maximum Residue Limit (MRL) were detected post-slaughter. The HPRA published a safety advisory notice about this matter in April 2024. On the European front, regulatory action was taken in respect of an intraruminal bolus product for cattle due to deficiencies in the quality of the VMP. The marketing authorisation was suspended, and a recall of the product was initiated.

Conclusion

The HPRA works to ensure the safety and efficacy of VMPs in Ireland. The significant increase in adverse event reports highlights the importance of continuous monitoring and reporting by veterinary professionals and animal owners. By working together, we can ensure that any potential issues are identified and addressed promptly, safeguarding the health and well-being of both animals and humans.

Veterinary professionals and those licensed to sell or supply animal remedies are reminded to notify the HPRA or the relevant marketing authorisation holder of all suspected adverse events. Your reports are vital in helping us maintain the safety and efficacy of veterinary medicinal

products. Together, we can continue to protect and promote the health and welfare of animals across Ireland.

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