PHARMACOVIGILANCE

Summary of suspected adverse events, 2015

- **Decrease in number of reports for food-producing species**
- **Increase in number of pet animal reports**
- **Reports of dogs affected by medicines intended for large animals**

These are some of the results from surveillance work carried out by the pharmacovigilance team at the Veterinary Medicines Directorate (VMD) in 2015.

During 2015, the VMD's pharmacovigilance team received and assessed a total of 5674 reports of adverse events in animals, humans and the environment following the use of veterinary medicines. This was a slight decrease compared to the previous year. Many millions of doses of different types of veterinary medicines are manufactured, sold and used annually within the UK. In a relatively small number of cases, an adverse event (AE) occurs during, or a period of time after, the use of a medicine. Veterinary professionals, animal owners (including farmers) or anyone else who has reliable knowledge of the incident can report an AE either to the company marketing the medicine or to the VMD.

Of the 5674 reports received, 36 were associated with clinical trials or were extracted from articles in academic literature. These are called non-spontaneous reports. The remaining 5638 spontaneous reports, arising from everyday use of medicines, related to animals (5512 reports), humans (124 reports) or incidents in the environment (2 reports).

Figure 1 shows the numbers of different types of spontaneous reports received during 2015 and the animal species associated with those reports.

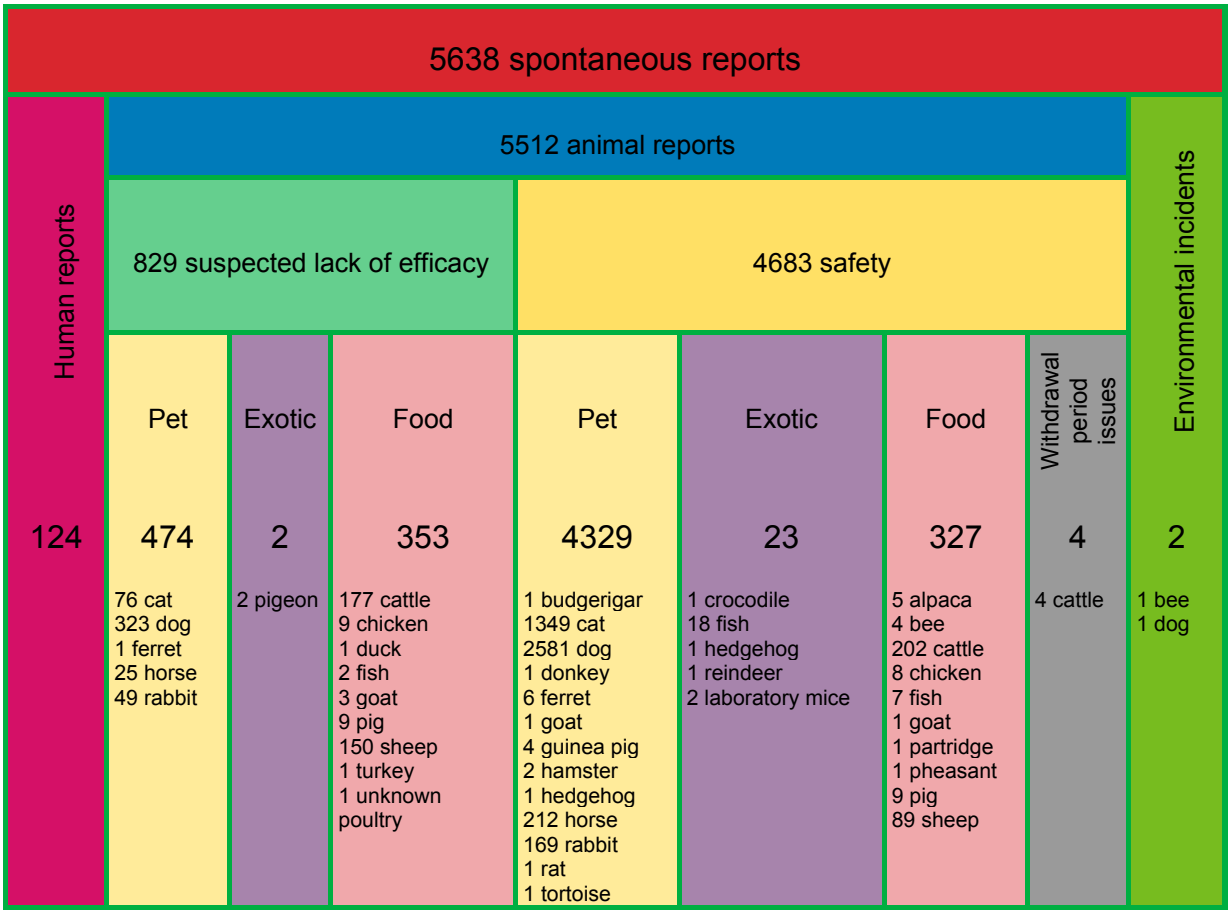

Figure 1 Number of spontaneous reports of different types received during 2015 and the animal species associated with them

Some of these reports describe reactions experienced by humans exposed to products used to treat animals. Most reports describe events that occurred in animals during or after the use of authorised veterinary or human medicines. Fewer reports were associated with other types of products. Many reports involved the use of a combination of products.

Others involved the detection of the residues of veterinary medicines in a food product intended for human consumption, usually milk, before it enters the food chain. There were also suspected exposures to veterinary medicines in the environment.

Human adverse events

Of the 124 human adverse event reports, 19 related to vets, 6 to other health professionals, usually vet nurses and 21 related to animal tenders, usually farm workers. The remaining 78 involved either pet or large animal owners or other people who came into contact with their animals.

Table 1 shows how many of different types of **authorised** medicines were associated with adverse reactions in different groups of people.

Administration route	Small animal owner	Large/food animal owner/handler	Veterinary professional	Total
Injection	14	16	21	51
Oral	8	2		10
Collar	4		1	5
Skin spot-on	33		2	35
Skin pour-on		12		12
Skin dip		2		2
Skin spray	1			1
Inhalation			2	2
Nasal	3			3
Ear	1			1
In hive		1		1

Table 1 Number of adverse reaction reports received for different groups of people following administration of authorised medicines by different routes

Animal adverse events

Figure 2 shows the distribution of adverse event reports across the most commonly reported species of animals. Reports of suspected lack of efficacy (SLE) and potential safety issues are shown.

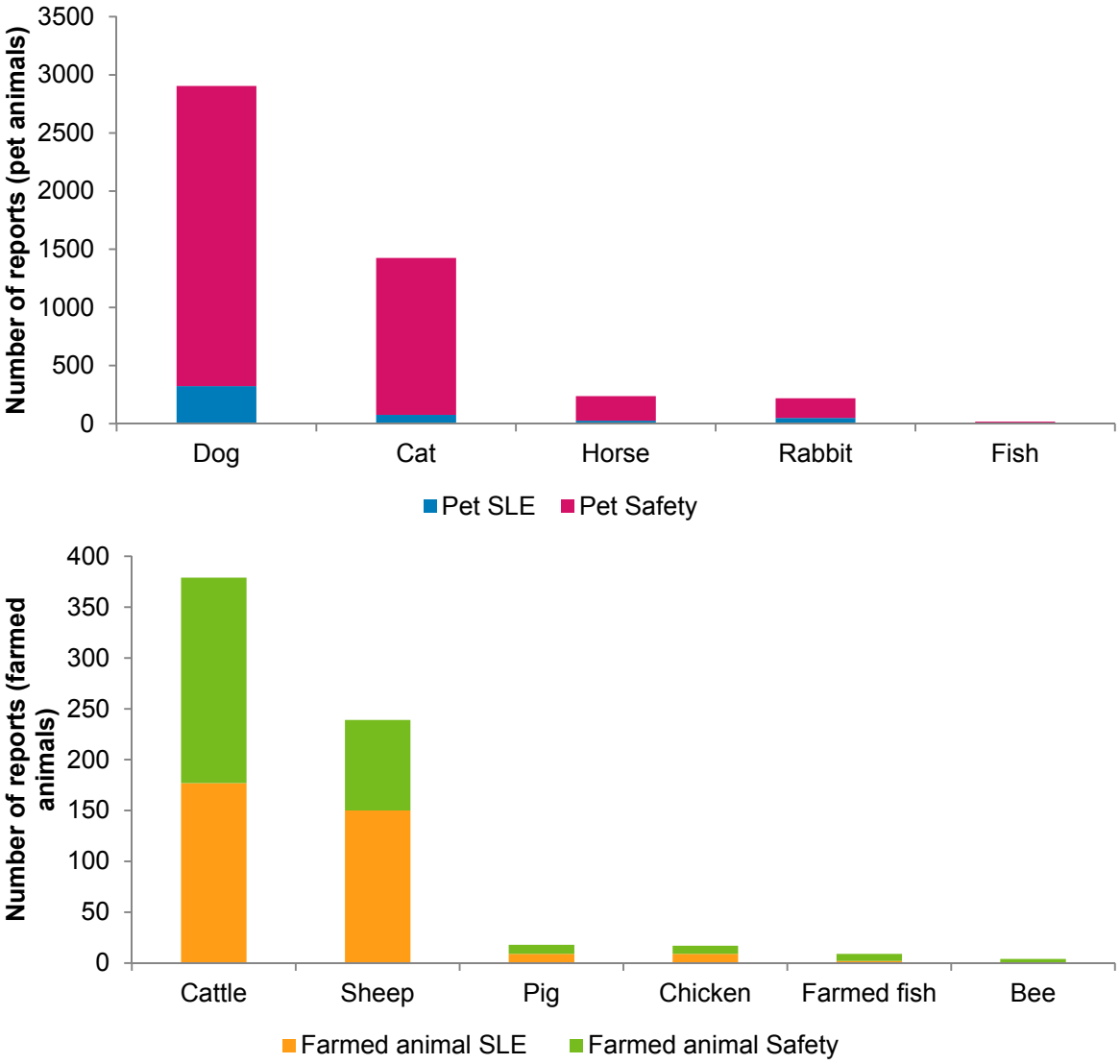

Figure 2 Number of reports received in 2015 for the most commonly reported species of pet and farmed animal

Less commonly reported species include: ferret (7), goat (5), alpaca (5), and other small rodents, birds, wildlife and laboratory animals.

Figure 3 shows the generally upward trend in the number of reports for pet animals, including horses, and the simultaneous downward trend in the number of reports for food-producing species, particularly for cattle and sheep.

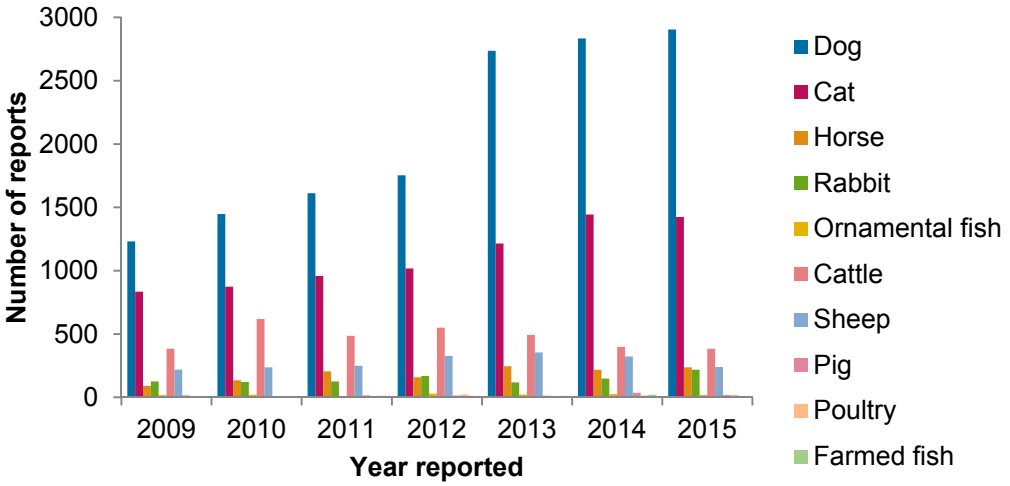

Figure 3 Number of reports received for different animal species from 2009 to 2015

Using Defra's farming statistics ('Livestock Populations at December 1, 2015, United Kingdom'), for cattle the number of adverse event reports received represents a rate of one report per 26,000 animals. For sheep it represents a rate of one report per 97,000 animals, and for pigs it represents a rate of one report per 246,000 animals.

Using figures from the Pet Food Manufacturer's pet animal population survey for 2015[1], for dogs the number of reports received represents a rate of one report per 2,900 animals. For cats and rabbits the rate are one report per 5,200 and 4,600 animals respectively.

Using figures from the British Equestrian Trade Association's National Equestrian Survey 2015, for horses the number of reports received represents a rate of one report per 4,000 animals.

For both pet animal and food-producing animals, vaccines were the products most likely to be associated with adverse event reports.

[1] Pet Population 2015, www.pfma.org.uk/pet-population-2015

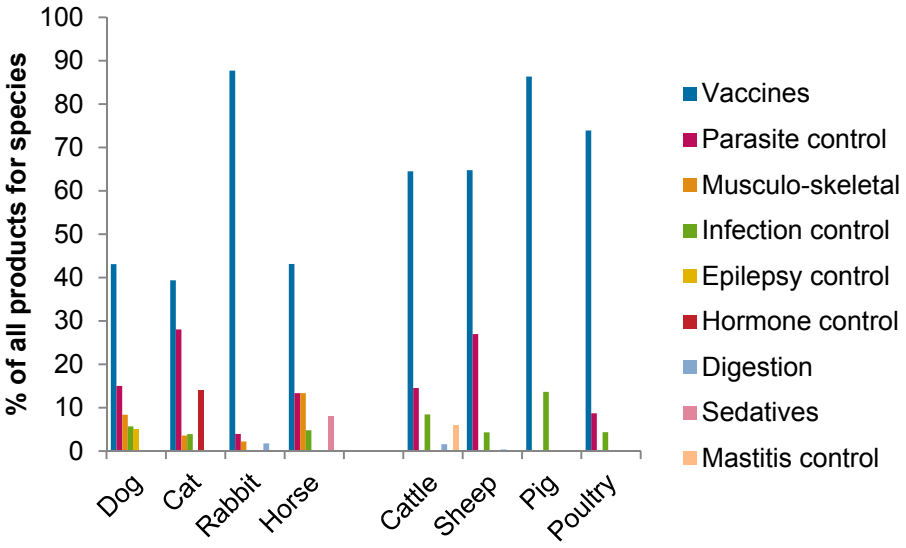

Figure 4 Therapeutic groups of medicines reported in cases involving specific species

Issues of concern

Needle stick injuries to people administering medicines to both small and large animals continue to feature in adverse reaction reports. Of particular concern are those that involve vaccines with a mineral oil adjuvant. Often, reports involving these products fail to show that the injured party has received prompt and correct treatment, either because they are themselves unaware of the necessity for swift intervention, or because they do not take the product package information leaflet with them when seeking medical treatment. The Summary of Product Characteristics (SPC), which contains the same information as the package leaflet, of every authorised product can be accessed at www.vmd.defra.gov.uk/ProductInformationDatabase/

Similarly, incidents involving injectable tilmicosin seem to be often dismissed as just a scratch. If you use these products, you should make sure you are fully aware of the warnings contained in the product leaflets.

Many of the adverse events involving horses reported the use of euthanasia products that did not perform as expected. It is important that an alternative means of euthanasia is always available, for the welfare of the animal involved, and for the safety of people in the vicinity.

Dog owners are warned that they should make sure their animals do not ingest anything found on the ground close to where large animals are kept and treated. Several dogs died during 2015, after chewing regurgitated monensin cattle boli. Several others were affected after eating horse dung that may have contained the residues of parasiticide medication, or chewing discarded dosing syringes.

Conclusion

No effective medicine is risk-free, and all veterinary medicines have the potential to cause side effects. However, it is important to note that most animals treated with veterinary medicines suffer no serious effects. The VMD is grateful to the all reporters in the UK for its assistance in minimising the risks and maximising the benefits of veterinary medicines through its continuing commitment to adverse event reporting.