Veterinary pharmacovigilance: 2016 review of adverse effects in animals

In November 2017, ANSES published its 2016 report on post-marketing authorisation (MA) surveillance of veterinary medicinal products. This report, prepared by the French Agency for Veterinary Medicinal Products (ANMV), presents the main results and actions concerning market surveillance of French veterinary medicinal products and veterinary pharmacovigilance.

Since 2011, the number of pharmacovigilance reports has increased by 46%. In 2016, the ANMV recorded 4,113 cases of adverse effects in animals in its national database, 51% of which were considered serious.

This increase in the total number of reports has been accompanied by a change in the reporting channels, with in particular the continuing growth of direct transmissions (by mail or electronic submission) to the ANMV. Compared with 2015, the number of reports via this transmission channel increased by 24%, and reporters are increasingly turning to electronic submission (81% of reports sent directly to the ANMV in 2016).

More than 90% of these reports were sent by veterinary practitioners (90.8%). Animal owners and breeders submitted 7.8% of all reports. The remaining reports were sent by veterinary schools (1.1%) and pharmacists (0.3%).

As in previous years, the vast majority of adverse effects reported in 2016 involved domestic carnivores, with around 80% of reports concerning dogs or cats. Cattle represented 9% of all reports and other species accounted for less than 3% per species.

The relative share of the different therapeutic categories involved varied by species. In cats, the primary therapeutic category mentioned was antiparasitics. In dogs and cattle, vaccines were the most frequently mentioned category.

In veterinary pharmacovigilance, reports are classified into four different types: strict adverse effects, suspicions of lack of efficacy, issues of residues in foodstuffs, and environmental problems. Cases of strict adverse effects in animals made up a clear majority (89%). Suspicions of lack of efficacy accounted for just under 11% of all reports, and other cases accounted for less than 0.4%.

The total number of reports of lack of efficacy increased compared with previous years (406 in 2016 compared with 363 in 2015). This increase applied to all the main species. This change could indicate greater awareness among veterinarians and breeders of this component of pharmacovigilance, as a result of the communication and training measures implemented in recent years.

The reports are used to supplement the information available in the summaries of product characteristics (SPCs) of veterinary medicinal products. For example, in 2016, the SPCs of 39 medicinal products were amended following pharmacovigilance reports and due to data from the scientific literature: these amendments mainly concerned the "Adverse events" section (addition of new adverse effects and/or revision of the frequency of occurrence of effects that are already known) but also other sections such as "Special warnings", "Special precautions for use in animals" or "Contraindications".

In addition, following reports of serious adverse effects in certain countries (mainly Denmark), sometimes resulting in the death of dairy cows, the authorisation for the medicinal product VELACTIS® was suspended in Europe in August 2016. This medication containing cabergoline was authorised for inducing a reduction in milk production in cows during dry-off.

As part of the promotion of pharmacovigilance among veterinarians, the ANMV continued its different training and communication initiatives for veterinarians in 2016, in particular with the publication of a note on the "Definition of a serious pharmacovigilance case in an organised production sector", and a complete dossier on nonsteroidal anti-inflammatory drugs for dogs.

To ensure that knowledge on veterinary medicinal products is continually updated, the ANMV reminds you that any adverse effect observed following the use of veterinary medicinal products can be reported via the dedicated website https://pharmacovigilance-anmv.anses.fr/

Sylviane LAURENTIE (Anses-ANMV)

TO FIND OUT MORE, VISIT:

Post-MA surveillance of veterinary medicinal products. Annual Report