Veterinary pharmacovigilance also covers the adverse effects of veterinary medicinal products on humans

Veterinary medicinal products are authorised after an assessment of data on their quality, safety and efficacy has confirmed that the benefits associated with their use outweigh the risks.

The purpose of veterinary pharmacovigilance is to collect and analyse adverse reactions to veterinary medicinal products, in order to ensure that the benefits continue to outweigh the risks. The French Agency for Veterinary Medicinal Products (ANSES-ANMV) is responsible for running this scheme.

The scope of veterinary pharmacovigilance is very broad since it encompasses the reporting of:

- adverse effects in animals after administration of a veterinary medicinal product;
- adverse effects in animals after administration of a medicinal product for human use in the framework of the "cascade" approach[1];
- information about suspicions of lack of efficacy;
- residue problems when the withdrawal period defined in the MA has been complied with;
- environmental problems;

as well as the *reporting of adverse effects in humans after exposure to a veterinary medicinal product*.

These adverse effects in humans can occur through contact with treated animals, through direct contact with a veterinary medicinal product during administration to animals, or following an error of handling or use, such as accidental ingestion by a child, for example.

The risk to the user is assessed as part of the marketing authorisation (MA) procedure for veterinary medicinal products. Any precautions to be taken by the user are mentioned in each medicinal product's summary of product characteristics (SPC) (http://www.ircp.anmv.anses.fr/).

Thanks to feedback via the veterinary pharmacovigilance scheme starting from when the medicinal products are placed on the market, appropriate risk management measures – ranging from the addition of a precaution for use to the withdrawal of the MA – can be taken if necessary.

In France, there are multiple channels for reporting adverse effects in humans (see Figure 1). Most cases requiring a medical response are recorded by the French Poison Control Centres (PCCs) via the toxicology emergency telephone hotline (RTU) after the exposed individual or their doctor has called the PCC for medical advice on the action to be taken.

If there is no emergency, any adverse effects occurring in humans following the use of a veterinary medicinal product can, since March 2017, be notified through the Ministry of Health's **portal for reporting adverse health effects**. These reports are then forwarded to the poison control centre with territorial jurisdiction for analysis.

Since April 2017, all cases recorded by the PCCs have been transmitted to ANSES.

Some reports are sent directly to the o MA holder for the veterinary medicinal product involved. In accordance with the regulation, these cases must be notified to ANSES within 15 days.

As veterinary pharmacovigilance is governed by a European framework, all the cases recorded by ANSES are fed into the European veterinary pharmacovigilance database, which therefore capitalises on all the information from all the countries in the European Union.

2016 review of reports of adverse effects of veterinary medicinal products in humans

Through their emergency telephone hotline activity, the PCCs receive an average of 190,000 calls every year, 40% of which concern cases of symptomatic exposure.

Cases of human exposure to veterinary medicinal products recorded by PCCs are unusual. In 2016, 1,127 calls were related to a veterinary medicinal product, of which 364 cases (32%) were symptomatic. Sixty additional reports concerning humans were also registered directly by ANSES-ANMV.

The main therapeutic categories concerned by these 424 reports (involving 455 veterinary medicinal products) were antiparasitics (40%) followed by vaccines (22%). The remaining reports were divided among the other therapeutic categories.

1. Non-MA use regulated by the French Public Health Code (L.5143-4), which defines under what conditions a veterinary practitioner can in exceptional circumstances use a human medicinal product if no veterinary medicinal products are available on the market to treat a diagnosed disease in a given species.

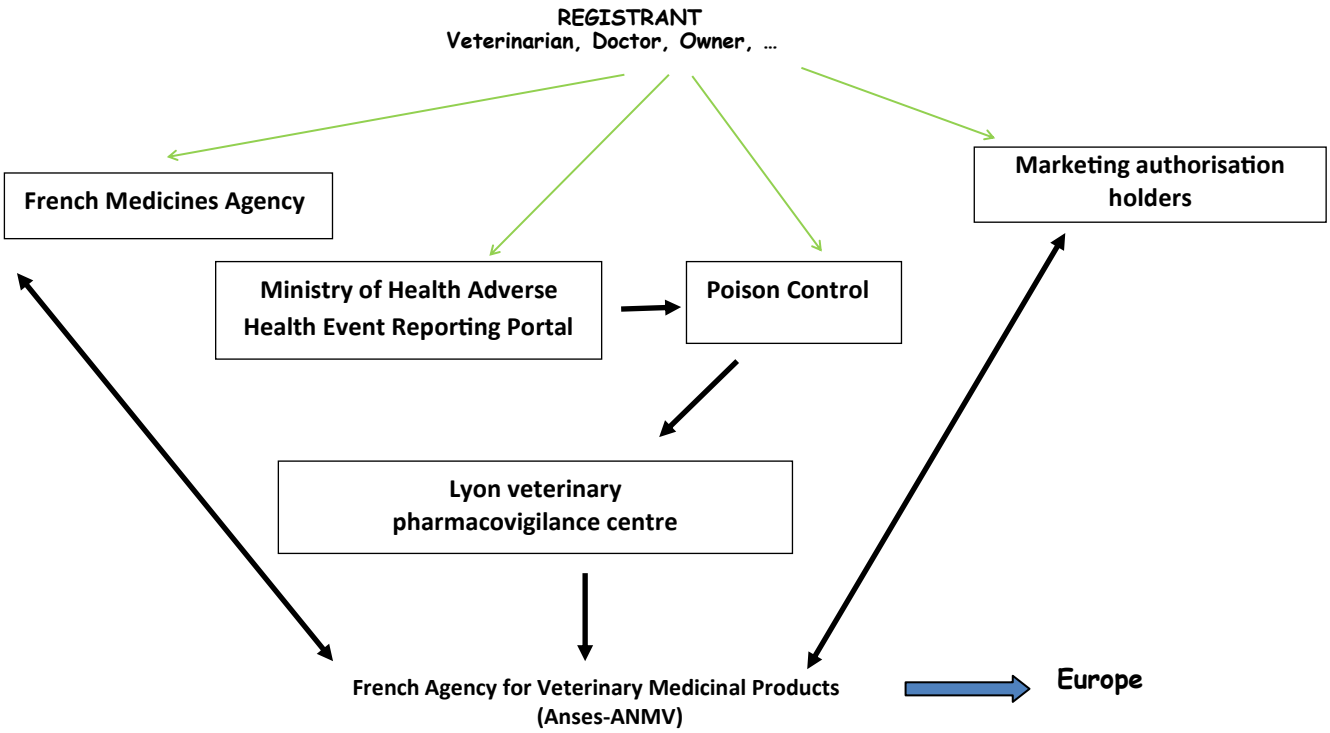

Figure 1: Reporting channel for adverse effects of veterinary medicinal products in humans

This breakdown reflects the sales of these products:

- Antiparasitics proved to be the most frequently implicated veterinary medicinal products. They are widely used in routine treatment for the animal population as a whole (not just sick animals) and are frequently administered by the owners themselves.
- Vaccines were in second place, essentially due to accidental injections. Although this is a category of products whose use potentially concerns all animals (due to it being preventive and not curative), 95% of the 86 reports that stated the name of the vaccine were due to the use of vaccines in production livestock (mainly swine and poultry). This finding is unsurprising insofar as mass vaccination in industrial sectors is more likely to lead to accidents than individual vaccination.

The symptoms described were mainly transient and relatively benign irritations: essentially dermal, eye and/or respiratory signs with ectoparasiticides, or inflammatory reactions in the case of accidental injections. In this framework, a national prospective study (2016-2018) on the risk of complications from accidental needle-sticks involving veterinary vaccines is being conducted by the Poison Control Centres and ANSES.

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TO FIND OUT MORE, VISIT:

https://www.anses.fr/fr/content/la-pharmacovigilance-vétérinaire