

Definitions

The following definitions are adapted from the WHO definitions of substandard, falsified, and unregistered/unlicensed medical products to be applicable for veterinary products. Examples are provided to illustrate the definitions and make them clearer, but these are not the only situations to which these definitions could apply.

- *Substandard veterinary products:* Authorised veterinary products that fail to meet either their quality standards, or their specifications, or both.
For example: An antibiotic that was produced by an authorised manufacturer, but for some reason (poor storage conditions, production error) contains only 80% of the active ingredient listed on its label. This could be discovered by a veterinarian or livestock owner through treatment failure, or be picked up by the manufacturer in routine testing of their own products.
- *Falsified veterinary products:* Veterinary products that deliberately/fraudulently misrepresent their identity, composition, or source.
For example: A vaccine vial that was intentionally filled with water, or tablets that were intentionally filled with paracetamol (a painkiller) rather than the ingredient listed on the tablet's box. This could be discovered through errors in the packaging (unusually long or short expiry dates, spelling errors, non-existent manufacturers, etc.) by veterinarians or livestock owners, and confirmed with the manufacturers. It could also be discovered through treatment failure, or, in the case of contamination with another product, poisonings or even death.
- *Unregistered/unlicensed veterinary products:* Veterinary products that have not undergone evaluation and/or approval by the national or regional regulatory authority for the market in which they are marketed/distributed or used, subject to permitted conditions under national or regional regulation and legislation.
For example: An antibiotic taken by one individual from a country where it is registered, to be sold or distributed in a neighbouring country where it is not authorised for use. The product is still of good quality, it is just not legally allowed to be used. This could be detected through verification of the product against the list of VMPs authorised for use in the country.

This definition is sourced from the “How to set up a pharmacovigilance system for veterinary medicinal products” (page 3) prepared by HealthforAnimals in support of the OIE 6th cycle Focal Points Seminar alignment with VICH Guidance and international standards.

- *Pharmacovigilance:* Pharmacovigilance is a process by which information is collected to detect and prevent unexpected or unwanted adverse effects following the use of (veterinary) medicinal products. The scope of veterinary pharmacovigilance is mainly the safety and efficacy in animals and safety in people, and may include other events associated with the use of the product, such as lack of expected efficacy, residues exceeding the established safe limit, environmental issues and suspected transmission of infectious agents (for vaccines).