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# Assessment of compliance of current legislation: Veterinary Products Act

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# Objectives

Veterinary legislation should address the following:

- Avoiding presence of harmful residues in the food chain;
- Ensuring that the use of veterinary products does not give rise to human health risks

Assessment



# General measures

Veterinary legislation should address the following:

- Definition of veterinary products, including any specific exclusions;
- Regulation of the importation, manufacture, distribution and usage of, and commerce in, veterinary products

Assessment



# Raw materials & veterinary products

Veterinary legislation should address:

- Quality standards for raw materials used in the manufacture or composition of veterinary products and arrangements for checking quality;

Assessment



# Raw materials & veterinary products

## Assessment

- Establishment of withdrawal periods and maximum residue limits for veterinary products, as appropriate;
- Requirements for any substances that may interfere with the conduct of veterinary checks



# Authorisation of veterinary products

## Assessment

Veterinary legislation should ensure that only authorised veterinary products may be placed on the market.



# Authorisation of veterinary products

Special provisions should be made for:

- Veterinary products that do not present any risk of residues or interference with the conduct of disease prevention and control programmes;

Assessment



# Authorisation of veterinary products

Special provisions should be made for:

- Medicated feed;
- Products prepared by veterinarians or pharmacists
- Emergencies and temporary situations;

Assessment





# Authorisation of veterinary products

## Assessment

Veterinary legislation should address the technical, administrative, and financial conditions associated with the granting, refusal and withdrawal of authorisations.



# Authorisation of veterinary products

In defining the procedures for seeking and granting authorisations, the legislation should describe the functioning of the competent authority concerned and establish rules providing for the transparency of decisions.

Assessment



# Authorisation of veterinary products

## Assessment

Veterinary legislation may provide for the possibility of recognition of the equivalence of authorisations made by other countries.



# Quality of veterinary products

Veterinary legislation should address the following:

- The conduct of clinical and non-clinical trials to verify all claims made by the manufacturer, including analysis and dosage methods;

Assessment



# Quality of veterinary products

## Assessment

- Conditions for the conduct of trials;
- Qualifications of experts involved in trials
- Surveillance for adverse effects arising from the use of veterinary products.



# Establishments producing, storing and selling veterinary products

Veterinary legislation should address the following:

- Registration or authorisation of all operators importing, storing, processing, selling or otherwise distributing veterinary products or raw materials for use in making veterinary products;

Assessment



# Establishments producing, storing and selling veterinary products

## Assessment

- Definition of responsibility of operators;
- Good manufacturing practices, as appropriate;
- Arrangements for informing the competent authority about traceability of products and adverse effects



# Commerce, distribution, use and traceability of vet. products (1)

Veterinary legislation should address the following:

- Control over the circulation and distribution of veterinary products and arrangements for traceability and condition of use;

Assessment





# Commerce, distribution, use and traceability of vet. products (2)

## Assessment

- Establishment of rules of prescription and provision of veterinary products to the end user;
- Restricting to authorised professionals all commerce in veterinary products that are subject to prescription;



# Commerce, distribution, use and traceability of vet. products (3)

- The supervision by an authorised professional of organisations approved for holding and use of veterinary products;
- The regulation of advertising claims and other marketing and promotional activities.

Assessment

