Chapter 3.4.

**Veterinary legislation**

[…]

Article 3.4.5.

**Competent Authorities**

*Competent Authorities* should be legally mandated, have the necessary technical, administrative and infrastructure capacity and be organised to ensure that all necessary actions are taken in a timely, coherent and effective manner to address animal health, *animal welfare* and veterinary public health matters of concern.

*Veterinary legislation* should provide for a chain of command that is effective, as short as possible, and with all responsibilities clearly defined. For this purpose, the responsibilities and powers of *Competent Authorities*, from the central level to those responsible for the implementation of legislation in the field, should be clearly defined. Where more than one *Competent Authority* is involved, for example in relation to environmental, food safety or other public health matters, including biological threats and natural disasters, a reliable system of coordination and cooperation should be in place, including clarifying the role of each *Competent Authority*.

*Competent Authorities* should appoint technically qualified officials to take any actions needed for implementation, review and verification of compliance with the *veterinary legislation*, respecting the principles of independence and impartiality prescribed in Article 3.2.2.

1. Necessary powers of the Competent Authority

The *veterinary legislation* should also ensure that:

a) the *Competent Authority* has all the necessary legal authorities to achieve the purposes of the legislation, including the powers to enforce the legislation;

b) while executing their legal mandate, officials are protected against legal action and physical harm for actions carried out in good faith and in accordance with professional standards;

c) the powers and functions of officials are explicitly listed to protect the rights of stakeholders and the general public against any abuse of authority. This includes respecting confidentiality and transparency, as appropriate; and

d) at least the following powers are available through the primary legislation:

i) access to premises and *vehicles/vessels* for carrying out inspections;

ii) access to documents;

iii) application of specific *~~sanitary measures~~* measures and procedures such as:

‒ taking samples;

‒ retention (setting aside) of *commodities*, pending a decision on final disposition;

‒ seizure of *commodities* and fomites;

‒ destruction of *commodities* and fomites;

‒ suspension of one or more activities of a facility;

‒ temporary, partial or complete closure of facilities;

‒ suspension or withdrawal of authorisations or approvals;

‒ restrictions on the movement of *commodities*, *vehicles/vessels* and, if required, other fomites and people;

‒ listing disease for mandatory reporting; and

‒ ordering of *disinfection*, *disinfestation* or pest control;

iv) establishment of compensation mechanisms.

These essential powers should be clearly identified because they can result in actions that may conflict with individual *rights* ascribed in fundamental laws.

2. Delegation of powers by the Competent Authority

The *veterinary legislation* should provide the possibility for *Competent Authorities* to delegate specific powers and tasks related to official activities. The specific powers and tasks delegated, the competencies required, the bodies or officers to which the powers and tasks are delegated, the conditions of supervision by the *Competent Authority* and the conditions of withdrawals of delegations should be defined.

[…]

Article 3.4.11.

**Veterinary medicinal products**

*Veterinary legislation* should provide a basis for assuring the quality, safety and effectiveness of *veterinary medicinal products* and minimising the *risk* to human, animal and environmental health associated with their use, including the development of antimicrobial resistance, as described in Chapters 6.7. to 6.11.

1. General measures

*Veterinary legislation* should provide a basis for actions to address the following elements:

a) definition of *veterinary medicinal products*, including any specific exclusions; and

b) regulation of the authorisation, importation, manufacture, wholesale, retail, usage of, commerce in, and disposal of ~~safe and effective~~ *veterinary medicinal products*.

2. Raw materials for use in veterinary medicinal products

*Veterinary legislation* should provide a basis for actions to address the following elements:

a) quality standards for raw materials used in the manufacture or composition of *veterinary medicinal* products and arrangements for checking quality; and

b) restrictions on substances in *veterinary medicinal products* that may, through their effects, interfere with the interpretation of veterinary diagnostic test results or the conduct of other veterinary checks.

3. Authorisation of veterinary medicinal products

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

b) Special provisions should be made for:

i) *veterinary medicinal products* incorporated into *feed*;

ii) products prepared by authorised *veterinarians* or authorised pharmacists;

iii) emergencies and temporary situations;

iv) establishment of maximum residue limits for active substances and withdrawal periods for relevant *veterinary medicinal products* containing these substances; and

v) restrictions of use of *veterinary medicinal products* for food-producing animals.

c) *Veterinary legislation* should address the technical, administrative and financial conditions associated with the granting, suspension, renewal, refusal and withdrawal of authorisations.

d) In defining the procedures for seeking and granting, suspending, withdrawing~~,~~ or refusing~~,~~ authorisations, the legislation should:

i) describe the responsibilities of the relevant *Competent Authorities*; and

ii) establish rules providing for transparency in decision-making.

e) *Veterinary legislation* may provide for the possibility of recognition of the equivalence of authorisations.

4. Facilities producing, storing and wholesaling veterinary medicinal products

*Veterinary legislation* should provide a basis for actions to address the following elements:

a) registration or authorisation of all operators manufacturing importing, exporting, storing, processing, wholesaling or otherwise distributing *veterinary medicinal products* or raw materials for use in making [*veterinary medicinal products*](http://127.0.0.1:54914/content/1ysvQbGhPPvTidTpAAAB/chYObID/OYuPCl4/9pTCHad/YrndtbT/pfZlRuR/Eu21EA8/Dtp3eq8/en_glossaire.htm#terme_medicament_veterinaire);

b) definition of the responsibilities of operators;

c) good manufacturing practices and good distribution practices as appropriate;

d) reporting on adverse effects to the [Competent Authority](http://127.0.0.1:54914/content/1ysvQbGhPPvTidTpAAAB/chYObID/OYuPCl4/9pTCHad/YrndtbT/pfZlRuR/Eu21EA8/Dtp3eq8/en_glossaire.htm#terme_autorite_competente); and

e) mechanisms for traceability and recall.

5. Retailing, use and traceability of veterinary medicinal products

*Veterinary legislation* should provide a basis for actions to address the following elements:

a) control over the distribution of *veterinary medicinal products* and arrangements for traceability, recall and conditions of use;

b) establishment of rules for the prescription and provision of [veterinary medicinal products](http://127.0.0.1:54914/content/1ysvQbGhPPvTidTpAAAB/chYObID/OYuPCl4/9pTCHad/YrndtbT/pfZlRuR/Eu21EA8/Dtp3eq8/en_glossaire.htm#terme_medicament_veterinaire) to end users, including appropriate labelling;

c) restriction to *veterinarians* or other authorised professionals and, as appropriate, authorised *veterinary paraprofessionals*, of commerce in *veterinary medicinal products* that are subject to prescription;

d) obligation of [*veterinarians*](http://127.0.0.1:54914/content/1ysvQbGhPPvTidTpAAAB/chYObID/OYuPCl4/9pTCHad/YrndtbT/pfZlRuR/Eu21EA8/Dtp3eq8/en_glossaire.htm#terme_veterinaire), other authorised professionals or authorised [*veterinary paraprofessionals*](http://127.0.0.1:54914/content/1ysvQbGhPPvTidTpAAAB/chYObID/OYuPCl4/9pTCHad/YrndtbT/pfZlRuR/Eu21EA8/Dtp3eq8/en_glossaire.htm#terme_paraprofessionnel_veterinaire) to inform end users of the withdrawal periods of relevant [*veterinary medicinal products*](http://127.0.0.1:54914/content/1ysvQbGhPPvTidTpAAAB/chYObID/OYuPCl4/9pTCHad/YrndtbT/pfZlRuR/Eu21EA8/Dtp3eq8/en_glossaire.htm#terme_medicament_veterinaire) and the obligation of end users to observe those withdrawal periods when using those products;

e) the supervision, by an authorised professional, of organisations approved for the holding and use of [*veterinary medicinal products*](http://127.0.0.1:54914/content/1ysvQbGhPPvTidTpAAAB/chYObID/OYuPCl4/9pTCHad/YrndtbT/pfZlRuR/Eu21EA8/Dtp3eq8/en_glossaire.htm#terme_medicament_veterinaire);

f) the regulation of advertising claims and other marketing and promotional activities;

g) a system of [*surveillance*](http://127.0.0.1:54914/content/1ysvQbGhPPvTidTpAAAB/chYObID/OYuPCl4/9pTCHad/YrndtbT/pfZlRuR/Eu21EA8/Dtp3eq8/en_glossaire.htm#terme_surveillance) of the quality of [*veterinary medicinal products*](http://127.0.0.1:54914/content/1ysvQbGhPPvTidTpAAAB/chYObID/OYuPCl4/9pTCHad/YrndtbT/pfZlRuR/Eu21EA8/Dtp3eq8/en_glossaire.htm#terme_medicament_veterinaire) marketed in the country, including a system of [*surveillance*](http://127.0.0.1:54914/content/1ysvQbGhPPvTidTpAAAB/chYObID/OYuPCl4/9pTCHad/YrndtbT/pfZlRuR/Eu21EA8/Dtp3eq8/en_glossaire.htm#terme_surveillance) for falsification; and

h) a system for the reporting on adverse effects to the *Competent Authority*.

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