REGULATION

respecting veterinarians' authorisations to prescribe drugs

SECTION I

Scope and definitions

Article 1

This Regulation contains special provisions applying to veterinarians' authorisations to prescribe drugs, which in other respects are governed by the Regulation on prescription forms and the prescribing of medicinal products.

Article 2

Veterinary drugs may only be prescribed by veterinarians.

Article 3

As used in this Regulation, the term 'livestock' refers to cattle, pigs, sheep, goats, horses and other ungulates, fur-bearing animals, and all types of poultry, as well as to aquaculture species (all types of aquaculture animals, whether raised in sea or fresh water) and other animals kept for the purpose of food production.

The term 'animal' refers to any animal, including livestock.

The term 'veterinary drug' refers to any drug intended to be used in veterinary medicine.

The terms 'owner' and 'keeper' refer to any natural or legal person having ownership or custody of the animal in question.

SECTION II

Drugs which may not be administered to animals or which may only be used subject to specific limitations

Article 4

Drugs containing any of the following substances may not be administered to animals:

1. […][1]
2. […][2]
3. Arsenic and arsenic compounds
4. Lead and lead compounds
5. Clofenotane
6. Mercury and mercury compounds

Article 5

The following drugs may not be administered to livestock:

1. Nitrofurans
2. Ronidazole
3. Dapsone
4. [Chloramphenicol][3]
5. Furazolidone
6. Dimetridazole
7. [Malachite green][4]
8. [Stilbenes, stilbene derivatives, their salts and esters
9. Drugs with a thyrostatic action

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[1] Regulation No 392/2012.
[2] Regulation No 392/2012.
[3] Regulation No 1069/2008.
[4] Regulation No 14/2008.

10. Estradiol 17β and its ester-like derivatives
11. Chloroform
12. Chlorpromazine
13. Colchicine
14. Metronidazole
15. Birthwort species (*Aristolochia* spp.) and preparations thereof][5]

Article 6

Drugs having a hormonal or hormonal-like action, including somatropin and beta adrenergic agonists, may not be administered to livestock for the purpose of stimulating their growth or increasing yield. The administration of such drugs to livestock for any other purpose is prohibited except with the written permission of [the Icelandic Medicines Agency][6].

Drugs containing sulfadimidine (sulfamethazine) may not be administered to pigs.

Article 7

[Drugs containing anabolic steroids may only be administered to animals when authorised by the Icelandic Medicines Agency.][7]

Article 8

Drugs of the type referred to in Article 7 may only be supplied to veterinarians on presentation of a written authorisation issued by [the Icelandic Medicines Agency][8], and in the quantity indicated therein.

Article 9

The following drugs may only be used for animals when administered by a veterinarian and must therefore only be supplied to a veterinarian or a veterinarian's duly appointed representative, and only against a prescription issued in the name of the veterinarian and for professional use:

1. Injectable analgesics.
2. Inhalable and injectable sedatives, hypnotics and anaesthetics.
3. [Nonsteroidal anti-inflammatory drugs (NSAIDs). Notwithstanding the provision of the first paragraph, a veterinarian who has signed a service contract pursuant to Article 5 of Regulation No 353/2011 on pig health and housing may prescribe such drugs for intramuscular use to the owner of the pig farm concerned by the contract, as follows:
   a. To reduce pain in pigs after castration or tail docking, see Article 12, third paragraph, of Regulation No 353/2011 on pig health and housing and the transitional provision of that Regulation, provided that the livestock owner has obtained the Food and Veterinary Authority's permission for this;
   b. For non-infectious arthritis in pigs; and
   c. As an ancillary anti-inflammatory and antipyretic treatment of pneumonia and MMA (mastitis, metritis, agalactia) in pigs, to complement appropriate antibiotic treatment.

   Additionally, a veterinarian may prescribe such drugs to the livestock owner to treat pain in the udders of mink dams after parturition and during the lactation period.][9]
4. Narcotics, as further provided in the Regulation on narcotics.
5. Injectable selenium-containing drugs, unless intended for newborn lambs.
6. Injectable direct-acting cholinergic agonists.
7. The following hormones and substances with hormone-like activity, in the form of injectable drugs:
   a. Adrenocortical hormones.
   b. Adrenal hormones.

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[5] Regulation No 392/2012.
[6] Regulation No 14/2008.
[7] Regulation No 392/2012.
[8] Regulation No 14/2008.
[9] Regulation No 931/2012.

c. Oxytocin and substances/compounds having a similar action, unless intended to assist in emptying cows' udders.
d. Progesterone and its derivatives.
e. Prostaglandin and substances/compounds having a similar action.
f. Testosterone and its derivatives.
g. 17-β-estradiol and its derivatives.
h. Gestagen compounds and gonadotropin-releasing hormone.

8. Injectable local anaesthetics.
9. Vaccines for animals other than livestock.
10. Vaccines for livestock, with the exception of inactivated vaccines for herd treatment, including sheep, poultry and aquaculture species. However, the vaccination of poultry and aquaculture species must always take place under the supervision and control of a veterinarian.
11. Injectable drugs belonging to ATCvet category QP54AA (avermectins).
12. [Intra-vaginal drugs for the regulation of the oestrous cycle. Notwithstanding the provision of the first paragraph, the Icelandic Medicines Agency may grant an exemption from the rule preventing non-veterinarians from administering the Veramix vet. vaginal drug, on a request from a veterinarian and after consulting with the Food and Veterinary Authority. An exemption may only be granted when it is not possible to obtain the services of a veterinarian to administer the drug. Furthermore, an exemption may only be granted after the veterinarian has confirmed that the livestock owner in question has received adequate instruction in how to administer, use and dispose of the drug.][10]
13. [Paratuberculosis vaccine. District Veterinary Officers may supply this vaccine to persons in their respective districts who have been appointed as vaccination officials in accordance with Regulation No 638/1997 on the vaccination of sheep and goats against paratuberculosis, provided that they have performed such duties before, received relevant instruction from a veterinarian, and executed their tasks in an irreproachable manner.][11]
14. Euthanasia drugs.

Notwithstanding the provision of the first paragraph, Point 4, a veterinarian may prescribe narcotic drugs for oral administration, provided that the drug in question is not intended for administration to livestock.

Article 10

The injection of drugs intravenously or abdominally, or into joints, entheses or bone marrow, may only be carried out by veterinarians. Moreover, only veterinarians may administer intra-uterine drugs. However, the provisions of this Article do not apply to the vaccination of aquaculture species by abdominal injection, provided that it takes place under the supervision and control of a veterinarian.

SECTION III

Drugs which veterinarians may prescribe to the owners or keepers of animals

Article 11

Notwithstanding the restricting provisions of this Regulation, and subject to the obtention of the written permission of the Chief Veterinary Officer, veterinarians may prescribe the following drugs to the owners or keepers of animals for use in emergency medical boxes on longer trips where the services of a veterinarian can reasonably be expected to be difficult or impossible to obtain.

1. Antibiotics.
2. Horse colic medication.
3. Analgesics, with the exception of controlled drugs.
4. Topical local anaesthetics.
5. Drugs for oral administration belonging to ATCvet category QN05AA.

[10] Regulation No 392/2012.
[11] Regulation No 912/2000.

Article 12

Veterinarians may prescribe to the owners or keepers of animals veterinary drugs for which a marketing authorisation has been issued in Iceland, provided that the drug in question is used for therapeutic indications and for a species of animal referred to in the marketing authorisation.

Article 13

[Where no marketing authorisation has been issued in Iceland for drugs to treat a specific disease in a species of animal the products of which are not used for human consumption, veterinarians may decide, on their own responsibility, to administer or supervise personally the administration to the animal of:

1. a veterinary drug for which an Icelandic marketing authorisation has been issued for use in a different species of animal, or for the treatment of a different disease in the same species; or,
2. where no drug as referred to in Point 1 exists, a drug for which a marketing authorisation has been issued in another EEA state for use in the same species of animal, or a different one, and for the treatment of the disease in question or a different disease; or,
3. where no drug as referred to in Point 2 exists, a drug for which an Icelandic marketing authorisation has been issued for human use; or,
4. where no drug as referred to in Point 3 exists, a drug prepared in a pharmacy to the veterinarian's specifications.][12]

[Article 13a

Where no marketing authorisation has been issued in Iceland for drugs to treat a specific disease in a species of animal the products of which are used for human consumption, veterinarians may decide, on their own responsibility, to administer or supervise personally the administration to animals at a specific location of:

1. a veterinary drug for which an Icelandic marketing authorisation has been issued for use in a different species of animal, or for the treatment of a different disease in the same species; or,
2. where no drug as referred to in Point 1 exists, a drug for which a marketing authorisation has been issued in another EEA state for use in the same species of animal, or in a different species the products of which are used for human consumption, and for the treatment of the disease in question or a different disease; or,
3. where no drug as referred to in Point 2 exists, a drug for which an Icelandic marketing authorisation has been issued for human use; or,
4. where no drug as referred to in Point 3 exists, a drug prepared in a pharmacy to the veterinarian's specifications.][13]

Article 14

When a drug as referred to in [Article 13a][14] is prescribed for administration to livestock and no waiting period is indicated, the minimum waiting period is as follows:

Waiting period	Products
7 days	Eggs
7 days	Milk
28 days	Meat from poultry or mammals, including fat and offal
500 degree-days	Fish

[No drugs may be administered to animals the products of which are used for human consumption unless the pharmacologically active ingredients are listed in Table 1 of the Annex to Commission Regulation (EU) No 37/2010.][15]

[12] Regulation No 661/2015.
[13] Regulation No 661/2015.
[14] Regulation No 661/2015.

SECTION IV

Drugs administered to aquaculture species

Article 15

The use of vaccines, antibiotics and colouring agents in aquaculture is prohibited except with the approval of the Committee for Fish Pathology. The Committee's approval does not eliminate the need to obtain other authorisations required by this Regulation or to the meet any of the conditions laid down herein.

SECTION V

Miscellaneous provisions

Article 16

On issuing a marketing authorisation for a veterinary drug, the Icelandic Medicines Agency decides whether it is to be sold as a prescription drug, see Section VII of Regulation No 141/2011 on marketing authorisations for proprietary medicinal products, their labelling and package leaflets.

Article 17

[Animals may only be treated with antibiotics following diagnosis by a veterinarian, who must also personally initiate the treatment when the animals in question are livestock. Nevertheless, following a veterinarian's diagnosis, the oral or topical administration of antibiotics and the use of feed and drinking water supplemented with antibiotics may be initiated without the intervention of a veterinarian.][16]

Notwithstanding the provision of the first paragraph, first sentence, the Chief Veterinary Officer may exempt a veterinarian from the requirement to personally initiate the treatment of livestock with antibiotics in those cases where the veterinarian is prevented from doing so by geographical conditions, weather or other external factors.

SECTION VI

Monitoring, penalties and entry into force

Article 18

Monitoring

The Icelandic Medicines Agency monitors the implementation of this Regulation. Those concerned must provide the Agency with any document or information which it considers necessary for its work.

Article 19

Penalties

Infringements of this Regulation are subject to the penalties laid down in Article 43 of the Medicinal Products Act, No 93/1994, as amended.

Disputes arising from infringement of this Regulation are subject to the rules relating to criminal procedure.

Article 20

Entry into force

This Regulation is issued on the basis of Article 12 of the Medicinal Products Act, No 93/1994, read in conjunction with Article 44 of that Act, and enters into force on 1 August 2000. On the same date, Articles 22 to 28, inclusive, of Regulation No 421/1988 concerning prescription forms and the prescribing of medicinal products, their dispensing and labelling are repealed.

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[15] Regulation No 661/2015.
[16] Regulation No 912/2000.

[This Regulation is issued having regard to Council Directives 81/851/EEC and 96/22/EC.][17]

Ministry for Health and Social Security, 17 July 2000.

Ingibjörg Pálmadóttir.

Davíð Á. Gunnarsson.

[17] Regulation No 392/2012.