L.N. 96 of 2005

VETERINARY SERVICES ACT, 2001
(CAP. 437)

Prohibition on the Use in Stock-Farming of Substances having a Hormonal or Thyrostatic Action and of Betaagonists Rules, 2005

IN exercise of the powers conferred under article 13(a) of the Veterinary Services Act, the Minister for Rural Affairs and the Environment has made the following rules:-

Title and scope and applicability.

1. (1) The title of these rules is Prohibition on the Use in Stock-Farming of Substances having a Hormonal or Thyrostatic Action and of Betaagonists Rules, 2005.

(2) The scope of these regulations is to implement the rules found under European Union Council Directive 96/22/EEC on the Prohibition on the Use in Stock-Farming of Certain Substances having a Hormonal or Thyrostatic Action and of Betaagonists.

Definitions.

2. For the purpose of these rules, and unless the context otherwise requires –

"the Commission" means the European Commission;

"the Community" means the European Community as established under the Treaty establishing the European Community;

"Competent authority" means the Veterinary Services within the territory of Malta as provided under article 2 of the Veterinary Services Act;

"farm animals" shall mean domestic animals of the bovine, porcine, ovine and caprine species, domestic solipeds, poultry and rabbits, as well as wild animals of those species and wild ruminants which have been raised on a holding;

"illegal treatment" shall mean the use of unauthorised substances or products or the use of substances or products authorised under national legislation for purposes or under conditions other than those laid down in national legislation;

"Member State" means a State which is a Member within the European Community;

"therapeutic treatment" shall mean the administering under rule 4 of these rules to an individual farm animal of an authorised substance to treat, after examination by a veterinarian, a fertility problem including the termination of unwanted gestation and, in the case of betaagonists, to induce tocolysis in cows when calving and to treat respiratory problems and to induce tocolysis in equidae raised for purposes other than meat production;

"Third country" means a State which is not a Member within the European Community.

"Veterinary Services" means the competent authority within the territory of Malta as established under article 2 of the Veterinary Services Act.

"zootechnical treatment" shall mean the administering:

(a) to an individual farm animal of any substance authorised under rule 6 of these rules for synchronising oestrus and preparing donors and recipients for the implantation of embryos, after examination of the animal by a veterinarian or, in accordance with the second paragraph of rule 6, under his responsibility;

(b) in the case of aquaculture animals, to a group of breeding animals for sex inversion, on a veterinarian's prescription and under his responsibility.

Prohibitions within Malta.

3. In the territory of Malta, the following shall be prohibited -

(i) the placing on the market of stilbenes, stilbene derivatives, their salts and esters and thyrostatic substances for administering to animals of all species;

(ii) the placing on the market of betaagonists for administering to animals the flesh and products of which are intended for human consumption for purposes other than those provided for in sub-paragraph (ii) of rule 5.

Further prohibitions within Malta.

4. In Malta, the following shall also be prohibited -

(i) the administering to a farm or aquaculture animal, by any means whatsoever, of substances having a thyrostatic, oestrogenic, androgenic or gestagenic action and of betaagonists;

(ii) the holding, except under official control, of animals referred to in paragraph (i) on a farm, the placing on the market or slaughter for human consumption of farm animals or of aquaculture animals which contain the substances referred to in paragraph (i) or in which the presence of such substances has been established, unless proof can be given that the animals in question have been treated in accordance with rules 5 or 6;

(iii) the placing on the market for human consumption of aquaculture animals to which substances referred to in paragraph (i) have been administered and of processed products derived from such animals;

(iv) the placing on the market of meat of the animals referred to in paragraph (ii) ;

(v) the processing of the meat referred to in paragraph (iv).

5. Notwithstanding rules 3 and 4, in Malta, the following is authorised: Exemptions to prohibitions.

(i) the administering to farm animals, for therapeutic purposes, of floestradiol 17, testosterone and progesterone and derivatives which readily yield the parent compound on hydrolysis after absorption at the site of application.

Veterinary medicinal products used for therapeutic treatment must comply with the requirements for placing on the market laid down in Order (81/851) and be administered only by a veterinarian, by injection or for the treatment of ovarian dysfunction in the form of vaginal spirals, but not by implant, to farm animals which have been clearly identified. Treatment of identified animals must be registered by the veterinarian responsible. The latter must record at least the following details in a register, which may be the one provided for in Directive 81/851/EEC –

(a) type of treatment;

(b) the type of products authorised;

(c) the date of treatment;

(d) the identity of the animals treated.

The register must be made available to the Veterinary Services at its request;

(ii) the administering for therapeutic purposes of authorised veterinary medicinal products containing:

(a) allyl trenbolone, administered orally, or betaagonists to equidae and pets, provided they are used in accordance with the manufacturer's instructions;

(b) betaagonists, in the form of an injection to induce tocolysis in cows when calving.

Such substances must be administered by a veterinarian or, in the case of the veterinary medicinal products referred to in paragraph (a) hereof, under his direct responsibility; treatment must be registered by the veterinarian responsible, who shall record at least the details referred to in point (i).

Farmers shall be prohibited from holding veterinary medicinal products containing betaagonists which may be used for induction purposes in the treatment of tocolysis.

However, without prejudice to the first subparagraph of point ii (b), therapeutic treatment of production animals, including breeding animals at the end of their reproductive life, shall be prohibited.

Certain treatments permitted within the Maltese territory.

6. (1) Notwithstanding rule 4 (i) and without prejudice to rule 3, in Malta the administering to farm animals is authorised, for the purpose of zootechnical treatment, of veterinary medicinal products having an oestrogenic, androgenic or gestagenic action which are authorised in accordance with Orders (81/851) and (81/852). Such veterinary medicinal products must be administered by a veterinarian to clearly identified animals; the treatment must be recorded by the veterinarian responsible in accordance with rule 5 (i):

Provided that Veterinary Services may allow the synchronisation of oestrus and the preparation of donors and recipients for the implantation of embryos to be effected not by the veterinarian direct, but under his responsibility.

(2) With regard to aquaculture animals, young fish may be treated for the first three months for the purpose of sex inversion with veterinary medicinal products that have an androgenous action and are authorised in accordance with Directives 81/851/EEC and 81/852/EEC.

(3) In the cases provided for in this rule, the veterinarian shall make out a non-renewable prescription, specifying the treatment

in question and the quantity of the product required and shall record the products prescribed:

Provided that zootechnical treatment of production animals, including during the fattening period for breeding animals at the end of their reproductive life, shall be prohibited.

Authorisation of administration of hormonal products and Betaagonists.

7. (1) Hormonal products and Betaagonists the administration of which to farm animals is authorised in accordance with rules 5 and 6 must meet the requirements of Directives 81/851/EEC and 81/852/EEC.

(2) The following are not, however, authorised in accordance with sub-rule (1)

(a) the following hormonal products:

(i) products acting as a deposit;

(ii) products with a withdrawal period of more than 15 days after the end of treatment;

(iii) products:

(1) which were authorised under rules that preceded the national legislation laying down procedures in conformity with international agreement for the authorisation and supervision of medicinal products for human and veterinary use,

(2) whose conditions of use are not known,

(3) or which no reagents or equipment exist for use in the analytical techniques for detecting the presence of residues in excess of the permitted limits,

(b) veterinary medicinal products containing betaagonists which have a withdrawal period of more than 28 days after the end of treatment.

Trade, breeding and relative health marks.

8. (1) For the purpose of trade, it is permitted in Malta, the placing on the market of animals for breeding and breeding animals at the end of their reproductive life which, during the latter period, have undergone a treatment referred to in rules 5 and 6 and may authorise the affixing of the health mark of Annex I, Chapter XI, (50) of Directive 64/433/EEC to meat from such animals where the conditions laid down in rules 5 and 6 and the minimum withdrawal periods laid down in rule

7 (2), under paragraph (a) (ii) or (b) respectively or the withdrawal periods provided for in the authorisation to place on the market are complied with.

However, trade in highvalue horses, and in particular racehorses, competition horses, circus horses or horses intended for stud purposes or for exhibitions, including registered equidae to which veterinary medicinal products containing allyl trenbolone or betaagonists have been administered for the purposes referred to in rule 5, may take place before the end of the withdrawal period, provided that the conditions governing administration are fulfilled and that the type and date of treatment are entered on the certificate or passport accompanying these animals.

(2) Meat or products from animals to which substances having an oestrogenic, androgenic or gestagenic action or betaagonists have been administered in accordance with the dispensatory provisions of these regulations may not be placed on the market for human consumption unless the animals in question have been treated with veterinary medicinal products complying with the requirements of rule 7 and in so far as the withdrawal period laid down was observed before the animals were slaughtered.

Possession and use of substances by authorised persons.

9. Within the territory of Malta -

(i) at the time of the import, manufacture, storage, distribution, sale and use of the substances referred to in rules 3 and 4 (i), their possession is restricted to the persons authorised by national legislation in accordance with Article 1 (5) of Order (81/851);

(ii) in addition to the checks provided for in the Orders governing the placing on the market of the various products in question, the official checks provided for in Article 11 of Directive 96/23/EEC are carried out by the competent national authorities without prior notice, with a view to ascertaining:

(a) the possession or presence of substances or products prohibited under rule 3, intended to be administered to animals for the purpose of fattening;

(b) the illegal treatment of animals;

(c) failure to observe the withdrawal periods provided for in regulation 7;

(d) failure to observe the restrictions on the use of certain substances or products laid down in rules 5 and 6;

(iii) the tests for the presence of:

(a) the substances referred to in point (i) in animals, in the drinking water of animals and in all places where animals are bred or kept;

(b) residues of the aforementioned substances in live animals, their excrement and body fluids and in animal tissues and products, are carried out in accordance with Annexes III and IV to Directive 96/23/EEC;

(iv) where the checks provided for in points (ii) and (iii) reveal:

(a) the presence of substances or products the use or possession of which is prohibited, or the presence of residues of substances the administering of which comes under the heading of illegal treatment, such substances or products are confiscated, while any animals treated or the meat therefrom is placed under official supervision until the requisite penalties have been applied;

(b) failure to comply with the requirements of points (ii) (b) and (c), the Veterinary Services takes appropriate measures consistent with the gravity of the infringement.

Keeping of registers of substances.

10. (1) Without prejudice to Directive 81/851/EEC, undertakings buying or producing substances having a thyrostatic, oestrogenic, androgenic or gestagenic action and betaagonists, undertakings authorised in any capacity to market such substances and undertakings buying or producing pharmaceutical and veterinary medicinal products from such substances shall be required to keep registers detailing, in chronological order, quantities produced or acquired and those sold or used for the production of pharmaceutical and veterinary medicinal products and the names of the persons to whom such quantities were sold or from whom they were purchased.

(2) The information in sub-rule (1) hereof shall be made available to the Veterinary Services at its request and, in the case of computerised records, in the form of a print-out.

Failure to comply with the requirements of these rules.

11. Where the results of checks carried out in the territory of Malta show failure to comply with the requirements of these regulations in the country of origin of the animals or products, the Veterinary Services shall have recourse to provisions taken according to the procedure laid down in Article RE1 of the Veterinary Framework Act on mutual assistance between the administrative authorities of Malta and of the Member States to ensure the correct application of legislation on veterinary and zootechnical matters.

Limitation of importation.

12. (1) Third countries whose legislation authorizes the placing on the market and administration of stilbenes, stilbene derivatives, their salts and esters, or of thyrostatic substances for administering to animals of all species may not appear on any of the lists of countries provided for under veterinary legislation from which Malta authorizes to import farm or aquaculture animals or meat or products obtained from such animals.

(2) In Malta, it is prohibited to import from third countries on any of the lists referred to in sub-rule (1) of:

(a) farm or aquaculture animals

(i) to which products or substances referred to in point (i) of rule 3 have been administered by any means whatsoever;

(ii) to which substances or products referred to in point (i) of rule 4 have been administered, unless those substances or products were administered in compliance with the provisions and requirements laid down in rules 5, 6 and 8 and the withdrawal periods allowed in international recommendations have been observed;

(b) meat or products obtained from animals the importation of which is prohibited under point (a).

(3) However, animals intended for breeding, breeding animals at the end of their reproductive life, or meat there from, from third countries may be imported subject to their affording guarantees at least equivalent to those laid down in these regulations or which have been established for the implementation and enforcement of Chapter V of Directive 96/23/EEC on measures to be taken in the event of infringement.

(4) Checks on imports from third countries shall be carried out in accordance with Article 17 (2) and (3) of the Veterinary Framework Act.

Ippubblikat mid-Dipartiment ta' l-Informazzjoni (doi.gov.mt) — Valletta — *Published by the Department of Information (doi.gov.mt) — Valletta*
Mitbugh fl-Istamperija tal-Gvern — *Printed at the Government Printing Press*
Prezz 32c – *Price 32c*