L.N. 225 of 2005

VETERINARY SERVICES ACT, 2001
(ACT NO. XXIII OF 2001)

Conditions governing the preparation, placing on the market and use of medicated feedingstuffs Rules, 2005

IN exercise of the powers conferred by article 26 of the Veterinary Services Act, the Minister for Rural Affairs and the Environment has made the following rules:-

Title and scope.

1. (1) The title of these rules is Conditions governing the preparation, placing on the market and use of medicated feedingstuffs Rules, 2005.

(2) These rules lay down, without prejudice to the adoption of the list laid down in Article 3 point 1, second sub-paragraph to European Union Directive 2001/82/EC, the conditions other than those of animal health, governing the preparation, placing on the market and use of medicated feedingstuffs within the territory of Malta.

(3) These rules shall not affect European Community rules applicable to additives used in feedingstuffs, or national rules adopted pursuant to the said rules, and in particular those applicable to the additives referred to in Article 1 second sub-paragraph to European Union Council Directive 90/167/EC

(4) The scope of these rules is to implement the rules found under the European Union Council Directive of the 26th March, 1990 laying down the conditions governing the preparation, placing on the market and use of medicated feedingstuffs in the Community

Definitions.

2. (1) For the purposes of these rules the definitions appearing in Article 1 of European Union Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to veterinary medicinal products and Article 2 of Council Directive 79/373/EEC of 2 April 1979 on the marketing of compound feedingstuffs, as last amended by Directive 2000/16/EC of the European Parliament and the Council of 10 April 2000 shall apply as necessary.

(2) For the purposes of these rules, the following definitions shall also apply:

"authorized medicated pre-mix" means any pre-mix for the manufacture of medicated feedingstuffs as defined in Article 1

point 5 of European Union Directive 2001/82/EC which has been granted an authorization in accordance with Articles 5,6,7,8,9,10,and 11, of that Directive;

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

"placing on the market" means the holding in the territory of the Community for sale or disposal in any other form whatever to third parties, whether or not for consideration, and actual sale or disposal;

"the Commission" means the European Union Commission;

"the Community" means the European Community;

"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.

Medicated feedingstuffs to be manufactured from authorised medicated pre-mixes.

3. (1) The Veterinary Services shall prescribe that, as regards the medicinal component, medicated feedingstuffs may be manufactured from authorized medicated pre-mixes only.

(2) By way of derogation from the first subparagraph, the Veterinary Services may, provided they comply with the requirements of Article 6 of European Union Directive 2001/82/EC:

(a) subject to any specific conditions laid down in authorizations to place authorized medicated pre-mixes on the market, authorize intermediate products which are prepared from such medicated pre-mixes authorized in accordance with Article 6, 7, 8, 9,10, and 11 of Directive European Union Directive 2001/82/EC and from one or more feedingstuffs and which are intended for the subsequent manufacture of medicated feedingstuffs ready for use.

(b) The Veterinary Services shall take all necessary steps to ensure that intermediate products are manufactured only by establishments authorized in accordance with rule 4 and that they are the subject of a declaration to the Veterinary Services, authorize the veterinarian to have manufactured under the conditions laid down in Article 4 (3) of Directive 81/851/EEC, and under his

responsibility and on prescription, medicated feedingstuffs from several authorized medicated pre-mixes, provided that there is no specific authorized therapeutic agent in pre-mix form for the disease to be treated or for the species concerned.

(c) Until the date on which the Veterinary Services has to comply with the new rules laid down in Article 9 of European Union Directive 2001/82/EC, national rules governing the above conditions shall remain applicable, with due regard for the general provisions of the Treaty.

(3) Products authorized pursuant to sub-rule (1) shall be subject to the rules laid down in Articles 44 to 63 of European Union Directive 2001/82/EC.

Conditions for the manufacture of medicated feedingstuffs.

4. (1) The Veterinary Services shall take all necessary measures to ensure that medicated feedingstuffs are manufactured only under the conditions set out below:

(a) the manufacturer shall have premises which have been previously approved by the competent national authority, technical equipment and suitable and adequate storage and inspection facilities;

(b) the medicated feedingstuffs manufacturing plant shall be manned by staff whose knowledge of and qualifications in mixing technology are adequate;

(c) the producer shall be responsible for ensuring that:

(i) only feedingstuffs or combinations thereof which comply with Community provisions on feedingstuffs are used,

(ii) the feedingstuff used produces a homogeneous and stable mix with the authorized medicated pre-mix,

(iii) the authorized medicated pre-mix is used during the manufacturing process in accordance with the conditions laid down when authorization for placing on the market was given and, in particular, that:

(1) there is no possibility of any undesirable interaction between veterinary medicinal products, additives and feedingstuffs;

(2) the medicated feedingstuff will keep for the stipulated period;

(3) the feedingstuff to be used for producing the medicated feedingstuff does not contain the same antibiotic or the same coccidiostat as those used as an active substance in the medicated pre-mix;

(iv) the daily dose of medicinal product is contained in a quantity of feedingstuff corresponding to at least half the daily feed ration of the animals treated or, in the case of ruminants, corresponding to at least half the daily requirement of nonmineral supplementary feedingstuffs;

(d) premises, staff and equipment used and participating in the entire manufacturing process must comply with the manufacturing hygiene rules and principles of the Member State in question; the manufacturing process must conform to the rules of good manufacturing practice;

(e) the medicated feedingstuffs manufactured shall undergo regular checks, including appropriate laboratory tests of homogeneity by the manufacturing establishments, under the supervision and periodic control of the official department, to ensure that the medicated feedingstuff complies with the requirements of these rules, especially in respect of its homogeneity, stability and storability;

(f) manufacturers shall be obliged to keep daily records of the types and quantities of the authorized medicated pre-mixes and feedingstuffs used and of the medicated feedingstuffs manufactured, held or dispatched, together with the names and addresses of the breeders or holders of the animals, and in the case provided for in rule 10 (2), the name and address of the authorized distributor and, where appropriate, the name and address of the prescribing veterinarian. The records, which must meet the requirements of Article 12 and Article 13 (1) of European Union Directive 2001/82/EC, must be kept for at least three years after the date of the last entry and must be made available at any time to the competent authorities in case of checking;

(g) pre-mixes and medicated feedingstuffs shall be stored in suitable separate and secured rooms or hermetic containers which are specially designed for the storage of such products.

(2) The Veterinary Services may, by way of derogation from paragraph 1, subject to any additional guarantees appropriate, authorize the manufacture of medicated feedingstuffs on farms provided that the said paragraph is complied with.

Placing on the market of medicated feedingstuffs.

5. (1) The Veterinary Services shall prescribe that medicated feedingstuffs may be placed on the market only in packages or containers sealed in such a way that, when the package is opened, the closure or seal is damaged and they cannot be re-used.

(2) Where road tankers or similar containers are used to place medicated feedingstuffs on the market, these must be cleaned before any re-use in order to prevent any subsequent undesirable interaction or contamination.

Labelling of medicated feedingstuffs.

6. (1) The Veterinary Services shall take all necessary measures to ensure that medicated feedingstuffs are not put into circulation unless the labelling complies with the European Community provisions in force. Furthermore, the packages or containers referred to in rule 5 (1) shall be clearly marked "Medicated Feedingstuffs".

(2) Where road tankers or similar containers are used to place medicated feedingstuffs on the market, it shall be sufficient for the information referred to in paragraph 1 to be contained in the accompanying documents.

Further requirements.

7. (1) The Veterinary Services shall take all necessary measures to ensure that a medicated feedingstuff cannot be held, placed on the market or used unless it has been manufactured in accordance with these rules.

(2) Subject to the requirements of Article 6 of European Union Directive 2001/82/EC with regard to the tests to be carried out on veterinary medicinal products, the Veterinary Services may, however, for scientific purposes, provide for derogations from these rules, provided there is adequate official control.

Medicated feedingstuff prescriptions.

8. (1) The Veterinary Services shall ensure that medicated feedingstuffs are not supplied to stockfarmers or holders of animals except on presentation of a prescription from a registered veterinarian on the following terms:

(a) the veterinarian's prescription shall be made out on a form shown on the specimen in Schedule I; the original form shall be for the manufacturer or, where appropriate, a distributor

approved by the competent authority of the Member State of destination of the medicated feedingstuffs;

(b) the veterinarian shall fill Part A of the following prescription and copies of prescription shown in Schedule I:

(i) Manufacturer's or authorised distributors original, which shall be retained by the manufacturer or authorised distributor for a period which is not less than three years from date when the prescription was filled by the veterinarian. The veterinarian shall omit the details of the disease for which the treatment is prescribed in Part A of this original. The manufacturer or authorised distributor shall fill Part B of this original. This prescription shall be made available at all times to the Veterinary Services during official inspections;

(ii) Food and Veterinary Regulation Division copy which shall be sent by the manufacturer or authorised distributor to the Veterinary Services within five days of the presentation of the prescription. The veterinarian shall omit the disease for which the treatment is prescribed in Part A of this copy. The manufacturer or authorised distributor shall fill Part B of this copy;

(iii) The veterinarian's copy which shall be retained by the veterinarian for a period of not less than three years from the date the prescription was made by him. The disease to be treated shall only be indicated in Part A of this copy. This prescription copy shall be made available at all times to the Veterinary Services during official inspections.

(c) medicated feedingstuffs may not be used for more than one treatment under the same prescription;

(d) the veterinary prescription shall be valid only for a period determined by the Veterinary Services which shall not exceed three months from the date on which the prescription is made by the veterinarian;

(e) the veterinarian's prescription may be used only for animals treated by him. The veterinarian must first satisfy himself that:

(i) the use of this medication is justified for the species concerned on veterinary grounds;

(ii) administration of the medicinal product is not incompatible with a previous treatment or use and that there is no contra-indication or interaction where several pre-mixes are used;

(f) the veterinarian must:

(i) prescribe the medicated feedingstuffs only in such quantities as, within the maximum limits laid down by the national authorization for placing medicated pre-mixes on the market, are necessary for the purpose of the treatment;

(ii) satisfy himself that the medicated feedingstuff and the feedingstuff currently used to feed treated animals do not contain the same antibiotic or the same coccidiostat as active substances.

(2) However, in the case of anthelmintic medicinal products (vermifuges), the Veterinary Services may, pending the review to be carried out under European Union Directive 2001/82/EC of the risks associated with the use of these groups of substances, derogate for five years after the adoption of these rules from the obligation laid down in sub-rule (1) not to supply medicated feedingstuffs obtained from authorized medicated pre-mixes except on presentation of a veterinary prescription, provided that:

(a) the medicated pre-mixes used do not contain active substances which belong to the chemical groups used, in the territory of Malta, on medical prescription for human medicine,

(b) the medicated feedingstuffs accorded such authorization are used in their territory only prophylactically and in the dosages necessary for the purpose in question.

(3) The Veterinary Services shall inform the European Union Commission and the other Member States within the Standing Veterinary Committee of the application of such a derogation, specifying in particular the nature of the medicinal products and animal species that it covers.

(4) Where medicated feedingstuffs are administered to animals whose meat, flesh, offal or products are intended for human consumption, the stockfarmer or holder of the animals concerned must ensure that treated animals are not slaughtered in order to be offered for consumption before the end of the withdrawal period and that products obtained from a treated animal before the end of such a withdrawal

period are not disposed of with a view to their being offered for human consumption.

Issuing of medicated feedingstuffs to stockfarmers or holder of the animals.

9. (1) The Veterinary Services shall take all necessary measures to ensure that medicated feedingstuffs are issued directly to the stockfarmer or holder of the animals only by the manufacturer or distributor specially approved by the competent authority of the Member State of destination.

(2) Furthermore, medicated feedingstuffs for the treatment of animals whose meat, flesh, offal or products are intended for human consumption may not be issued unless:

(a) they do not exceed the quantities prescribed for the treatment, in accordance with the veterinary prescription where this is provided for,

(b) they are not issued in quantities greater than one month's requirements as established in accordance with the stipulations of the first indent.

(3) However, notwithstanding sub-rule (1), the Veterinary Services may in special cases authorize distributors specifically approved for that purpose to issue, on the basis of a veterinary prescription, medicated feedingstuffs in small quantities, prepacked and ready for use, and prepared, without prejudice to rule 8 (2) in accordance with the requirements of these rules, provided that these distributors:

(a) comply with the same conditions as the manufacturer regarding the keeping of registers and the storage, transport and issue of the products concerned,

(b) are subject to special checking for the purpose, under the supervision of the competent veterinary authority,

(c) may supply only prepacked or prepackaged medicated feedingstuffs ready for use by the holder or stockfarmer that have on the packaging or containers instructions for the use of the said medicated feedingstuffs and, in particular, an indication of the withdrawal period.

(4) The provisions of sub-rule (2) shall not affect national rules on the legal ownership of the medicated feedingstuffs.

Intra-Community Trade of medicated feedingstuffs.

10. (1) The Veterinary Services shall ensure that, without prejudice to animal-health rules, there are no prohibitions, limitations or obstacles in respect of intra-Community trade:

(a) in medicated feedingstuffs which have been manufactured in accordance with the requirements of these regulations, and in particular rule 4 thereof, with authorized pre-mixes which have the same active substances as pre-mixes authorized by the Member State of destination, in accordance with the criteria of European Union Directive 2001/82/EC, and a quantitative and qualitative composition similar thereto,

(b) subject to the specific provisions of European Union Council Directive 96/23/EC of 29 April 1996 on measures to monitor certain substances and residues thereof in live animals and animal products and repealing Directives 85/358/EEC and 86/469/EEC and Decisions 89/187/EEC and 91/664/EEC and Council Directive 96/22/EC of 29 April 1996 concerning the prohibition on the use in stockfarming of certain substances having a hormonal or thyrostatic action and of b-agonists, and repealing Directives 81/602/EEC, 88/146/EEC and 88/299/EEC as referred to in Article 7 (1) of Council Directive 96/22/EC, in animals to which those medicated feedingstuffs except those produced pursuant to rule 3 (2), have been administered, or in meat, flesh, offal or their products from such animals.

(2) Where the application of sub-rule (1) gives rise to dispute, in particular as concerns recognition of the similar nature of the pre-mix, the Member States concerned or the Commission may submit the dispute to assessment by an expert appearing on a list of Community experts to be drawn up by the Commission on a proposal from the Member States. If the two Member States so agree beforehand, the parties shall abide by the opinion of the expert, in compliance with Community legislation.

(3) The Member State of destination may require that each consignment of a medicated feedingstuff be accompanied by a certificate issued by the competent authority, corresponding to the specimen form in Schedule II.

Safeguard Measures.

11. (1) The safeguard measures laid down by European Union Council Directive 89/662/EEC shall apply to trade in authorized medicated pre-mixes or medicated feedingstuffs.

(2) The rules laid down concerning veterinary control and, in particular, the requirements laid down in Article 5 (2) and Article 20

of European Union Council Directive 89/662/EEC shall apply to trade in authorized pre-mixes or medicated feedingstuffs to the extent that they are subject to veterinary control.

Control by sampling checks.

12. The Veterinary Services shall take all necessary measures to ensure compliance to these rules:

(a) by making sampling checks at all stages of the production and marketing of the products referred to by these rules, to ensure that the provisions of these rules are complied with;

(b) in particular, by making sampling checks on farms and slaughterhouses, to ensure that medicated feedingstuffs are used in compliance with the conditions of use, and that withdrawal periods have been complied with.

Medicated feedingstuffs from Third Countries.

13. Pending the implementation of Community measures relating to imports of medicated feedingstuffs from third countries, the Veterinary Services shall apply to those imports measures which are at least equivalent to those of these rules.

Schedule I

No:

MINISTERU GHALL-AFFARIJIET RURALI U L-AMBJENT

Taqsima ta' l-Ikel u Attivita' Veterinarja

MALTA

MINISTRY FOR RURAL AFFAIRS AND THE ENVIRONMENT

Food and Veterinary Regulation Division

PART A: TO BE COMPLETED BY THE PRESCRIBING VETERINARIAN			
Surname and forename of veterinarian			
Name of house or clinic		Street	
Village		Postal Code	
Name or business name and address of manufacturer or supplier of the medicated feedingstuff			
Street		Village	
Postal code			
Name and address of stockfarmer or holder of animals / churn no. /stamp / stable no.			
Street		Village	
Postal Code			

Identification and number of animals					
Number	Species	Stamp / Tag Tattoo / Microchip	Breed	Sex	Category
1.					
2.					
3.					

Disease to be treated [4]	
Designation of authorised medicated pre-mixes	
Quantity of medicated feedingstuff in kilograms	
Special instructions for the stockfarmer or holder of the animals	

Percentage of medicated feedingstuff in the daily ration	Frequency of treatment	Duration of treatment in days	Withdrawal time in days		
			Eggs	Meat	Milk
1.					
2.					
3.					

Date when prescription was filled			Personal signature of veterinarian	Registration Number	Stamp
Day	Month	Year			

PART B: TO BE COMPLETED BY THE MANUFACTURER OR AUTHORISED DISTRIBUTOR						
Date of delivery	Day		Month		Year	
To be used before	Day		Month		Year	

Date when prescription was presented			Signature of manufacturer or supplier	Stamp of manufacturer or supplier
Day	Month	Year		

[1] To be filled in accordance with sub-rule 8 (1) (b).
[2] This prescription is valid for a period not exceeding 3 months and shall be used only once.
[3] This prescription shall be kept for a period of not less than three years from the date from which the prescription is filled by the veterinarian.
[4] Disease to be treated shall be entered only on Veterinarian's copy.

Manufacturer's or Authorised Distributor's Original

No:

MINISTERU GHALL-AFFARIJIET RURALI U L-AMBJENT

Taqsima ta' l-Ikel u Attivita' Veterinarja

MALTA

MINISTRY FOR RURAL AFFAIRS AND THE ENVIRONMENT

Food and Veterinary Regulation Division

PART A: TO BE COMPLETED BY THE PRESCRIBING VETERINARIAN			
Surname and forename of veterinarian			
Name of house or clinic		Street	
Village		Postal Code	
Name or business name and address of manufacturer and supplier of the medicated feedingstuff			
Street		Village	
Postal code			
Name and address of stockfarmer or holder of animals / churn no. /stamp / stable no.			
Street		Village	
Postal Code			

Identification and number of animals					
Number	Species	Stamp / Tag Tattoo / Microchip	Breed	Sex	Category
1.					
2.					
3.					

Disease to be treated (3)	
Designation of authorised medicated pre-mixes	
Quantity of medicated feedingstuff in kilograms	
Special instructions for the stockfarmer or holder of the animals	

Percentage of medicated feedingstuff in the daily ration	Frequency of treatment	Duration of treatment in days	Withdrawal time in days		
			Eggs	Meat	Milk
1.					
2.					
3.					

Date when prescription was filled			Personal signature of veterinarian	Registration Number	Stamp
Day	Month	Year			

PART B: TO BE COMPLETED BY THE MANUFACTURER OR AUTHORISED DISTRIBUTOR						
Date of delivery	Day		Month		Year	
To be used before	Day		Month		Year	

Date when prescription was presented			Signature of manufacturer or supplier	Stamp of manufacturer or supplier
Day	Month	Year		

(1) To be filled in accordance with sub-rule 8 (1) (b).
(2) This prescription shall be sent by manufacturer or authorised distributor to the Food and Veterinary Regulation Division within 5 days of presentation of this prescription.
(3) Disease to be treated shall be entered only on Veterinarian's copy.

Food and Veterinary Regulation Division Copy

No:

MINISTERU GHALL-AFFARIJIET RURALI U L-AMBJENT

Taqsima ta' l-Ikel u Attivita' Veterinarja

MALTA

MINISTRY FOR RURAL AFFAIRS AND THE ENVIRONMENT

Food and Veterinary Regulation Division

PART A: TO BE COMPLETED BY THE PRESCRIBING VETERINARIAN			
Surname and forename of veterinarian			
Name of house or clinic		Street	
Village		Postal Code	
Name or business name and address of manufacturer or supplier of the medicated feedingstuff			
Street		Village	
Postal code			
Name and address of stockfarmer or holder of animals / churn no. / stamp / stable no.			
Street		Village	
Postal Code			

Identification and number of animals					
Number	Species	Stamp / Tag Tattoo / Microchip	Breed	Sex	Category
1.					
2.					
3.					

Disease to be treated [3]	
Designation of authorised medicated pre-mixes	
Quantity of medicated feedingstuff in kilograms	
Special instructions for the stockfarmer or holder of the animals	

Percentage of medicated feedingstuff in the daily ration	Frequency of treatment	Duration of treatment in days	Withdrawal time in days		
			Eggs	Meat	Milk
1.					
2.					
3.					

Date when prescription was filled			Personal signature of veterinarian	Registration Number	Stamp
Day	Month	Year			

PART B: TO BE COMPLETED BY THE MANUFACTURER OR AUTHORISED DISTRIBUTOR						
Date of delivery	Day		Month		Year	
To be used before	Day		Month		Year	

Date when prescription was presented			Signature of manufacturer or supplier	Stamp of manufacturer or supplier
Day	Month	Year		

[1] To be filled in accordance with sub-rule 8 (1) (b).
[2] This prescription shall be kept for a period of not less than three years from the date when the prescription is filled by the veterinarian.
[3] Disease to be treated shall be entered only on Veterinarian's copy.

Veterinarian's Copy

Schedule II

ACCOMPANYING CERTIFICATE IN RESPECT OF MEDICATED FEEDINGSTUFFS FOR ANIMALS INTENDED FOR TRADE

Name and address of the manufacturer or approved distributor: ……..
……
.....
.....

Name of the medicated feedingstuff: .....
.....

Type of animal for which the medicated feedingstuff is intended: .....

Name and composition of the authorised medicated pre-mix: .....
.....

Dosage of the medicated pre-mix authorised in the medicated feedingstuff: .....
.....

Quantity of medicated feedingstuff: .....

Name and address of the recipient: .....
.....
.....

It is hereby certified that the medicated feedingstuff as described above has been manufactured by an authorised person in accordance with Directive 90/167/EEC.

Done at ....., **on** .....
(place) ***(date)***

.....
(Signature)
(Name and position)

Stamp of the veterinary authority or other competent authority

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