Director General, Animal Health and Welfare Department

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Prime Minister

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Minister for the for Agriculture, Fisheries and Animal Rights

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L.N. _____ of 2020

VETERINARY SERVICES ACT

(CAP. 437)

Veterinary Medicinal Products (Amendment 4) Regulations, 2020

IN exercise of the powers conferred by articles 30, 38 and 53 of the Veterinary Services Act, the Minister for Agriculture, Fisheries and Animal Rights after consultation with the Head of the National Veterinary Laboratory, has made the following regulations:-

Title and scope

S.L. 437.47

1. (1) The title of these regulations is Veterinary Medicinal Products (Amendment) Regulations, 2020 and these regulations shall be read and construed as one with the Veterinary Medicinal Products Regulations, 2004, hereinafter referred to as "the principal regulations".

(2) The scope of these regulations is to add a number of essential provisions in the 'the principal regulations' in order to provide a more adequate and modern legal framework for the regulation and control of veterinary medicinal products.

Amendment of regulation 2 of the principal regulations.

2. Regulation 2 of the principal regulations shall be amended as follows:

(a) the definition “pharmacist” shall be substituted with the following definition:

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“(26) “Pharmacist means a person who is enlisted in the Register of Pharmacists kept by the Pharmacy Council in terms of Article 17 of the Health Care Professions Act.”

(b) the definition “veterinary prescription” shall be substituted with the following definition:

“(28) "Veterinary Prescription’’ means a document issued by a veterinary surgeon for a veterinary medicinal product or a medicinal product for human use for its use in animals.”

(c) immediately after the definition “package leaflet”, there shall be added the following new definitions:

(37) “Procurement” means the act of acquiring, for profit or not, a Veterinary medicinal product, or part thereof, from a Member State of the European Union.

(38) “Suitably Qualified Persons” means that person who has a qualification in a Veterinary science and included in one of the para-veterinary professions mentioned in the Act.

(39) “Preventive use of an antimicrobial agents” means the administration of antimicrobial agents to healthy animals to prevent infections.

(40) ‘’Metaphylactic’’ means the administration of a medicinal product to a group of animals after a diagnosis of clinical disease in part of the group has been established, with the aim of treating the clinically sick and controlling the spread of the disease to animals in close contact and at risk and which may already be sub clinically infected.

(41) ‘’Prophylactic administration of antimicrobials’’ means the administration of a medicinal product to an animal or group of animal before clinical signs of a disease, in order to prevent the occurrence of disease or infection

(42) “Veterinary surgeon” means a licensed professional whose name is entered in the Register of Veterinary Surgeons referred to in article 42 (1) (b) of The Veterinary Services Act, or that person, coming from any other Member State of the European Union, whose name is entered in the relevant register kept by the relevant body of that Member State which regulates the profession of Veterinary surgeons. In the latter case the provisions of the Mutual Recognition of Qualifications Act and the Services (Internal Market) Act shall apply.

(43) “Psychotropic drugs” means the substances listed in the Third schedule of the Medical and Kindred Professions Ordinance and those substances listed on the Green List prepared by International Narcotics Control Board in accordance with the Convention on Psychotropic Substances of 1971.

(44**)** “Narcotic drugs” means the substances present on the Yellow List prepared by the International Narcotics Control Board in accordance with the Single Convention on Narcotic Drugs, 1961, Protocol of 25 March 1972 amending the Single Convention on Narcotic Drugs, 1961.

(45) “Medicinal products” shall have the same meaning as is assigned to in the Medicines Act, Cap. 458

(46) **"**Veterinary pharmacy" means the premises from where veterinary medicinal products are, dispensed directly to the public except for licenced veterinary establishments.

(47) "Veterinary wholesale dealer" means that person authorised to carry out wholesale distribution of veterinary medicinal products.

(48) "licensed veterinary establishment " has the same meaning as assigned to it in the Private Veterinary Establishments (Licensing) Regulations.

(49) "advertising" means any form of door-to-door information or in the media, canvassing activity or inducement designed to promote the prescription, supply, sale or consumption of veterinary medicinal products.

(50) "Dispensing" means the sale or supply of veterinary medicinal products The products are sold or supplied from a veterinary pharmacy or by a veterinary surgeon in veterinary establishments or during out calls.

(51) "Prescribing" means instructions on paper or electronic media for the dispensing of a veterinary medicinal products or medicinal products and for the preparation of veterinary medicinal products in a veterinary pharmacy in accordance with a veterinary prescription for an individual animal or a small group of animals

(52) "food " shall have the same meaning as assigned to it in the Food Safety Act.

(53) "Placing under official control" means the detaining of any article by the Director for Veterinary Services in order to permit the accomplishment of any of its functions.

(54) "Director for Veterinary Services" means the Director for Veterinary Services as defined in the Veterinary Services Act, and includes, to the extent of the authority given, to any officer authorised by him, in writing, to act on his behalf for any of the purposes mentioned in the Veterinary Services Act. Whenever in the text the words 'Veterinary Services' are used these should be construed as referring to the 'Director for Veterinary Services'

(55) "Source country" means a Member State of the EU or a country in the European Economical Area from where the veterinary medicinal products referred to in Regulation 7 of these Regulations can be procured

(56) " active substance' means any substance or mixture of substances intended to be used in the manufacture of a veterinary medicinal product and that, when used in its production, becomes an active ingredient of that product intended to exert a pharmacological, immunological or metabolic action with a view to restoring, correcting or modifying physiological functions or to make a diagnosis;

(57)"the Agency" means the European Medicines Agency established by Regulation (EC) No 726/2004

(58)"the Commission" means the Commission in accordance with Council Decision 1999/468/EC of 28th June,1999;

(59)"imported veterinary medicinal products " means veterinary medicinal products obtained from a source outside the EU;

(60)‘European Union" means the European Union as referred to in the Treaty;

(61)“the Treaty” shall have the same meaning as is assigned to it in the European Union Act, Cap. 460

(62)‘Member State" means a State which is a member of the European Union

Amendment to regulation 3 of the principal regulations.

3. Sub-regulation (1)(e) of regulation 3 of the principal regulations shall be deleted.

Amendment of regulation 4 of the principal regulations.

4. Immediately after sub-regulation 4(2) of the principal regulations, there shall be added the following new sub-regulations:

(3) In order to be granted the exemption for the veterinary medicinal product referred to in regulation 4(2) applicants shall submit an application with the Veterinary Services.

(4) In order to qualify under the exemption described in sub-regulation 4(2) the product must be manufactured by:

(a) the holder of a manufacturing authorisation if .manufactured in Malta or in another Member State of the European Union;

(b) the holder of a relevant licence conferring authorisation to manufacture veterinary medicinal products if the product is manufactured in a Third country.

(5) The product must not be intended for treatments of pathological processes that require a precise prior diagnosis or the use of which may cause effects that may impede or interfere with subsequent diagnostic or therapeutic measures.

(6) The manufacturer, importer, wholesale dealer or retailer of a veterinary medicinal product shall declare that he will notify the Veterinary Services within fifteen (15) days of learning of any serious adverse reactions in accordance with regulation 68(2) and 68(3) of these regulations. A record of each adverse reaction and serious adverse reaction must be maintained on becoming aware of it. The records shall be kept for 5 years.

(7) The Veterinary Services shall prepare and publish a list of active substances that can be used in veterinary medicinal products authorised under sub-regulation (2) of this regulation, specifying the species of non-food producing animals for which it is approved and may specify how the active substance or a product containing the active substances to be administered.

(8) The Veterinary Services may decide not to apply the provisions of this Regulation to a previously exempted product if any one or more of the following occur:

(i) serious adverse reactions are reported;

(ii) it is demonstrated, at any time after authorisation, that the substance is carcinogenic, genotoxic or that it shows developmental toxicity (including teratogenicity);

(iii) the product contain active substances that are re-classified as narcotic or psychotropic substances;

(iv) the ingredient or ingredients in the product is or are not included anymore in the list mentioned in sub-regulation (3)(d);

(v) it is reported and is verified by the Veterinary Services that the product is not being used on .....the animals mentioned in sub-regulation (2);

(9) The product authorised under sub-regulation (2) of this regulation shall be clearly labelled as being exempt from the requirements of regulations 5, 6, 7 and 8 of the principal regulations in relation to a Marketing Authorisation. The information obtainable from the whole pack must at least show the following details:

I. the name of the veterinary medicinal product;
II. the pharmaceutical dosage form
III. the name and strength of each active substance;
IV. the route of administration;
V. the batch number;
VI. the expiry date;
VII. a sentence to the effect of "For administration on non-food producing animals only". Authorised in accordance to Regulation 4(2) of S.L 437.47;
VIII. the target species;
IX. storage instructions;
X. the shelf-life after the immediate packaging has been opened for the first time;
XI. therapeutic indications;
XII. contra-indications,;
XIII. interaction with other medicines and other forms of interaction;
XIV. dosage instructions.

(10) If there is sufficient room on the label, the information may be present only on it without the need of a package leaflet. The information must be conveyed in a clear and legible manner.

Addition of regulation 4A of the principal regulations.

5. Immediately after the amended regulation 4 of the principal regulations, there shall be added the following new regulations 4A

"4 (A) (1) A veterinary medicinal product may be obtained from any country and administered to animals for research purposes in accordance with article 53(3) of the principal act.

(2) The Veterinary medicinal products authorised according to regulation 4A may be exempt from the provisions in regulations 5, 6, 7 and 8.

(3) The veterinary medicinal products shall only be used in authorised research facilities which are in conformity with the Animal Welfare Act and the Protection of Animals for Scientific Purposes Regulations.

(4) (a) In order to be allowed to carry out the activity mentioned in sub-regulation (1) a person, herein referred to as the 'applicant for a veterinary medicinal product to be used for research purposes', shall submit an application with the Veterinary Services.

(b) If the application is positively completed a licence for Research Purposes shall be issued. The Veterinary Services shall make, modify, add or remove any terms and conditions pertaining to the licence that it may deem fit in light of scientific advancements or new information that may emerge on particular substances or ingredients contained in the veterinary medicinal products used for research purposes.

(c) The holder of the licence for a veterinary medicinal product to be used for research purposes shall utilise a product or administer it to a test animal only under the terms and conditions set out under Chapter 439..

(d) The holder of the licence for a veterinary medicinal product to be used for research purposes who becomes aware of any serious adverse reactions on the animal or on the person administering it shall report the reaction to the Veterinary Services within fifteen (15) days 'from the day the 'serious adverse reaction' was discovered'

(e) Food for human consumption can be taken from test animals only in accordance with regulation 86 and with the prior approval of the Veterinary Services.

(f) The application submitted by the applicant shall be granted without prejudice to any licence or permit that the applicant may need to obtain from other departments and directorates in order to engage in the indicated research activity.

(g) The applicant for a veterinary medicinal product or holder of the licence is subject to official inspections by the Veterinary Services on the premises and the activities undertaken within the premises.

(h) The Veterinary Services shall set out the criteria for veterinary medicinal product which are procured in accordance with sub-regulation (1) and make them public.

Addition of regulation 4B of the principal regulations.

6. Immediately after the new regulation 4A, there shall be added the following new regulations 4B

4 B **(**1) Veterinary medicinal products may be exempted from the provisions in regulations 5 to 8 if it can be demonstrated that the products are veterinary samples or demonstration packs distributed to veterinary surgeons or pharmacists by veterinary wholesale distributors

(2) The products referred to in sub-regulation (1) may be used under the following conditions:

(a) They are distributed for free to persons authorised to receive them or are exhibited during conferences or similar activities which are held for intended for veterinary surgeons and/or pharmacists;

(b) They bear a label printed "Free sample/Demonstration pack – Not for sale";

(c) The unit pack should not contain more than:

(i) 50 units for capsules/tablets
(ii) 10 units for injections and spot-ons
(iii) 300g for powders
(iv) 3L for liquids
(v) 5 units for intra-mammary tubes
(vi) any other measurement as established by the Veterinary Services for all other Pharmaceutical forms

(d) The information provided with the samples shall not be promotional in nature;

(e) The maximum period of time the authorised veterinary wholesale dealer can procure a product from a Member State of the European Union as a free sample is one (1) year from the first consignment thereof;

(f) If any product authorised in accordance with the provisions of Regulation 4B (1) is administered to a food producing animals, that animal is excluded permanently from the food chain.

Addition of regulation 4C of the principal regulations.

7. Immediately after the new regulation 4B, there shall be added the following new regulations 4C

"4C. Any authorisation issued under regulations 4(2), 4 A and 4B, shall be deemed to be a Marketing Authorisation for the purposes of articles 38, 53 and 57 of the Principal Act.

Addition of regulation 4D of the principal regulations.

8. Immediately after the new regulation 4C, there shall be added the following new regulation 4D:

4D. (1) Veterinary medicinal products may be exempted from the provisions in regulations 5 to 8 when the products are procured from a Member State of the European Union or imported from a Third country under the terms and conditions mentioned in paragraph (2)

(2) The following terms and conditions shall apply:

(a) The products shall not be re-sold for monetary gain;

(b) The products shall not be transferred to other third parties unless such transfer is authorised by the Veterinary Services;

(c) This provision is not applicable to psychotropic drugs, narcotic drugs for all animals and in the case of food producing animals also the substances listed in Group A in Schedule I of Subsidiary Legislation 437.58 and Table II of Regulation (EU) 37/2010

(d) The quantity of products obtained shall be proportional to the dosage regime of the condition it will be used for;

(e) The quantity of products which is allowed entry in Maltese territory shall cover the period indicated as the duration of treatment in the product's specifications or on the veterinary surgeons 's veterinary prescription. However, products intended to be used for recurrent or chronic conditions can be allowed entry in Malta several times a year, provided that cogent evidence that demonstrate the benefits obtained by the regular use of the products can be provided;

(f) Pursuant to the conditions (d) and (e), the person getting the veterinary medicinal product may be asked for a veterinary prescription and/or written clinical evaluation by a veterinary surgeon;

(g) Only products that do not contain animal by-products which are derived from high risk areas where certain diseases may be, or suspected to be, present or prevalent, can be obtained;

(h) Only products that do not contain ingredients that are classified as illegal in Malta and do not have banned indications in Malta can be obtained;

(i) Only appropriately labelled products which give clear indication of the nature of the ingredient/s within can be obtained;

(j) Food producing animals administered with the veterinary medicinal products authorised in accordance with Regulation 4 D can only be consumed by the person getting the veterinary medicinal products, or by consenting members of the same household;

(k) Before a decision on antimicrobial veterinary medicinal products and products that have a hormonal activity is taken, a risk assessment shall be prepared by the Veterinary Services in a timely manner;

(l) The decision by the Veterinary Service is without prejudice to any license or permit that the person getting the veterinary medicinal products may need to obtain under other regulations of the same or of different department;

(3) The veterinary services shall decide on the release, placing under official control or destruction of veterinary medicinal products, or the products presumed to be veterinary medicinal products, if and when these are intercepted at the various entry control points throughout the territory of Malta;

(4) Pursuant to sub-regulation (3) the Veterinary Services shall keep a record of all the opinions or decisions taken. These records shall be kept by the Veterinary services for a period of not less than ten (10) years.

(5) The Veterinary Services shall set out the criteria for veterinary medicinal product which can be obtained in accordance with sub-regulation (1) and make them public.

Provided that the provisions of Regulation 4D shall also apply to veterinary medicinal products that are brought in the territory of Malta as a *bona fide* donation for use on animals kept in the approved sanctuary subject to the donation on condition that the veterinary services is pre-notified of such a request with the name, quantity and nature of the products, and the names and addresses of the donator, the recipient and the animal sanctuary involved.

Amendment of regulation 7 to the principal regulations

9. Regulation 7 of the principal regulations shall be amended as follows:

Immediately after the words 'Member State', there shall be inserted the following phrase:

referred to as 'the source country',

Addition of new regulation 7A to the principal regulations.

10.Immediatley after regulation 7 of the principal regulations, there shall be added the following new regulation 7A:

7A (1) In order to be allowed to market the products under Regulation 7, a person, herein referred to as the 'applicant for the registration if veterinary medicinal product under Regulation 7, shall submit an application to the Veterinary Services.

(2)Upon a reasoned request the Veterinary Services may decide that regulations 60 (10) and 60 (11) on the legal category of Veterinary medicinal products and sub-regulation 51(4) do not apply to registrations granted under regulation 7.

(3) Before granting such a registration the Veterinary Services may:

(a) request the competent authority in the 'source country' to furnish a copy of the Marketing Authorisation in force;

(b) ensure that the entity applying for a registration in accordance with regulation 7 is a legally established company in the European Union or European Economic Area;

(c) request the applicant for a registration in accordance with regulation 7 to furnish an authenticated copy of the Marketing Authorisation in force;

Provided that it is not possible for the applicant to provide an authenticated copy of the Marketing Authorisation he shall be requested to provide other proof of an existing Marketing Authorisation in the country of source.

(d) request from the applicant data on the impact of the product on the environment in Malta;

(e) if the applicant of the registration in accordance with regulation 7 is not the Marketing Authorisation Holder of the product in the source country, notify the Marketing Authorisation Holder of its intention register the Veterinary medicinal product in Malta in accordance with Regulation 7.

(4)The holder of the registration granted in accordance with regulation 7 shall ensure that:

(a) the veterinary medicinal product is in accordance with the current Marketing Authorisation issued in the 'source country',

(b) notify the veterinary services of any variations to the terms of the Marketing Authorisation approved in the country of source

(c) implements without any delay actions relating to issues concerning the veterinary medicinal product which have resulted in adverse drug reaction and/or a product or batch recall

(d) appoint a person or be himself responsible for the requirements in paragraph (c)

(e) when the applicant is not the Market Authorisation Holder of the product in the 'source country' he shall furnish to the Veterinary Services a 'letter of access' issued by the Market Authorisation Holder granting him the use of the Marketing Authorisation for the purpose of Article 7;

Provided that it is not possible for the applicant to receive a 'letter of access' from the Market Authorisation Holder in the country of source the applicant shall be requested to provide proof of a contractual agreement between himself and a duly authorised veterinary wholesale distributor in the country of source.

(f) have a system in place for recording and investigation adverse drug reactions and batch or product defects.

Amendment to Regulation 10 of the principal regulations.

11. Regulation 10 of the principal regulations, shall be amended as follows:

(a) Paragraph (c) of sub-regulation 1of regulation 10, the words ' a person authorized to do so under national legislation' shall be substituted by the words ' a pharmacist or a veterinary surgeon';

(a) Immediately following sub-regulation 10(2) thereof, there shall be added the following new sub-regulations:

"(3) In the case of a veterinary medicinal product traded from another member State, veterinary surgeons shall obtain an authorisation from the Veterinary Services before getting the product for the administration to the animal.

(4) In case the veterinary medicinal products to be traded contain restricted substances resulting from the implementation of the relevant United Nations conventions on narcotic and psychotropic substances, consideration should be given to any special requirement that need to be satisfied before the products could be traded.

(5) A veterinary medicinal product or a medicinal product supplied for administration under sub-regulation (1) (a), (b) and (c), may only be supplied in accordance with a veterinary prescription from a veterinary surgeon, irrespective of the legal category assigned to the veterinary medicinal product during the Marketing Authorisation procedure.

(6) The veterinary prescription issued under the condition referred to in sub-regulation (5) shall be marked as such. A statement similar to, or stating the equivalent meaning of, the following statement: 'This Product has been Prescribed in accordance with the Cascade Principle', shall be included on the veterinary prescription.

(7) Unless the veterinary surgeon who prescribed the veterinary medicinal product or medicinal product both supplies the product and administers it to the animal in person, the person supplying it must label it (or ensure that it is labelled) with at least the following information:

(a) the name of the veterinary surgeon who has prescribed the product;

(b) the identification (including the species) of the animal or group of animals ;

(c) dosage and administration instructions.

(8) When a veterinary surgeon has recourse to the provisions of regulations 10, the veterinary surgeon shall keep adequate records of the treatment given. The records shall at least contain the particulars mentioned in sub-regulation (7) and shall be available for inspection by the Veterinary Services for a period of not less than three (5) years.

(9) When a veterinary surgeon has recourse to the provisions in sub-regulation (1)(a)(b)(c) the activity undertaken by the veterinary surgeon is excluded from the scope of the definition of wholesale distribution under a decision to be laid down by the Veterinary Services.

Addition of new regulation 10A to the principal regulations.

12. Immediately after regulation 10 of the principal regulations, there shall be added the following new regulation 10A.

"10(A). By way of derogation from regulation 10(1), where there is no suitable veterinary medicinal product available either as an authorised product in Malta or under the provisions of regulation 10(1), veterinary surgeons may, under their direct and only personal responsibility, build up a case and expound it to the Veterinary Services. Veterinary surgeon shall provide detailed justifications to their request. The Veterinary Services may where the disease or condition is such that the veterinary medicinal product is likely to be needed as a matter of urgency for the treatment of an animal, allow the importation of a veterinary medicinal product authorised for any non-food producing species from any third country under any conditions it may deem fit. The Veterinary Services shall base its decision on purely scientific grounds and shall take all precautions, in particular for the safety and environmental risks which may be associated with the use of the veterinary medicinal product, before granting the approval for the importation, which importation shall be considered as a once only grant with the possibility for repeated requests, with each request considered as *sui generis*.

The provisions in regulations 10 (3), (4), (5), (7), and (8) shall apply."

Amendment to regulation 11 of the principal regulations.

13. Regulation 11 of the principal regulations shall be amended as follows:

(a) paragraph (c) of sub-regulation (1) of regulation 1, the ' a person authorized to do so under national legislation' shall be substituted by the words ' a pharmacist or a veterinary surgeon'.

(b) Immediately after sub-regulation 11(5) thereof, there shall be added the following new sub-regulations:

"(6) In the case of a veterinary medicinal product traded from another member State, the veterinary surgeons shall obtain an authorisation from the Veterinary Services before procuring the product for the administration to the food producing animal.

(7) In case the veterinary medicinal products to be traded contain restricted substances resulting from the implementation of the relevant United Nations conventions on narcotic and psychotropic substances, consideration shall be given to any special requirement that need to be satisfied before the products could be traded.

(8) A veterinary medicinal product or a medicinal product supplied for administration under the sub-regulations (1) (a)(b)(c), may only be supplied in accordance with a prescription from a veterinary surgeon, irrespective of the legal category assigned to the veterinary medicinal product in accordance with regulation 60.

(9) The prescription issued under the condition referred to in sub-regulation (8) shall be marked as such. A statement similar to, or stating the equivalent meaning of, the following statement: 'This Product has been prescribed in accordance with Cascade Principle', shall be included on the veterinary prescription.

(10) Unless the veterinary surgeon who prescribed the veterinary medicinal product or the medicinal product both supplies the product and administers it to the animal in person, the

person supplying it must label it (or ensure that it is labelled) with at least the following information:

(a) the name of the veterinary surgeon who has prescribed the product;

(b) the name and address of the animal owner;

(c) the identification (including the species) of the animal or group of animals;

(d) the date of supply;

(e) dosage and administration instructions;

(f) the withdrawal period, if relevant;

(12) When a veterinary surgeon has recourse to the provisions in sub-regulation (1) the activity undertaken by the veterinary surgeon is excluded from the scope of the definition of wholesale distribution

Addition of regulation 11A to the principal regulations.

14. Immediately following regulation 11, there shall be added a new regulation 11A as follows:

"11A. By way of derogation from regulation 11 (1) and from Article 16(1) of Regulation (EC) No 470/2009, where there is no suitable veterinary medicinal product available either as an authorised product in the Malta or under the provisions of regulation 11(1), veterinary surgeon may, under their direct and only personal responsibility, build up a case and expound it to the Veterinary Services. Veterinary surgeons shall provide detailed justifications to their request. The Veterinary Services shall and where the disease or condition is such that the veterinary medicinal product is likely to be needed as a matter of urgency for the treatment of an animal, allow the importation of a veterinary medicinal product authorised for any food producing species from any Third country under any conditions it may deem fit, including the assignment of an appropriate withdrawal period, if applicable. The Veterinary Services shall base its decision on purely scientific grounds and shall take all precautions, in particular for the safety and environmental risks which may be associated with the use of the veterinary medicinal product, before granting the approval for the importation, which importation shall be considered as a once only grant with the possibility for repeated requests, with each request considered as *sui generis*.

The provisions in regulations 11 (6), (7), (9), (10), (11) and (12) shall apply."

Amendments to Title 1V

15 Regulations 38 to 50 under Title IV shall be replaced with the following Regulations (Regulation 38 to 50C)

38 **.**(1)The provisions of this Title shall not apply to

(a) *magistral formula*;

(b) *officinal formula*;

(c) veterinary medicinal products intended for research and development trials;

(d) intermediate products intended for further processing by an authorised manufacturer;
(e) any radionuclides in the form of sealed sources;
(f) whole blood , plasma or blood cells of animal origin, except for plasma which is prepared by a method involving an industrial process;

(g) veterinary medicinal products supplied in response to a bona fide unsolicited order, formulated in accordance with the specifications of a veterinary surgeon and for use by an individual animal under his direct personal responsibility.

(2)The provisions of these regulations shall apply also to the manufacture and assembly of homeopathic veterinary medicinal products, veterinary medicinal products derived from animal blood or plasma, radiopharmaceuticals, immunological veterinary medicinal products and herbal veterinary medicinal products.

39. (1)(a) No veterinary medicinal product, biological active substance, or active substance to be used directly as an investigational veterinary medicinal product , may be manufactured in Malta unless there is, in respect of such product or substance, a Manufacturing Authorisation.

This Manufacturing Authorisation licence shall also be required for the processes of sterilisation of active substances

(b) The Manufacturing Authorisation shall also be required for the manufacture of veterinary medicinal products intended for export

2(a) The Manufacturing Authorisation, which shall remain in force for a period to be determined by the Veterinary Services, shall be required for both total and partial manufacture, and for the various processes of dividing up, packaging or presentation.

2(b) A Manufacturing Authorisation shall not be required for preparation , dividing up , changes in packaging or presentation where such processes are carried out solely for retail supply by pharmacists in veterinary pharmacies, or by other persons legally authorised to carry out such processes.

(3) The authorisation referred to in sub-regulation (1) shall also be required for imports from third countries into the territory of Malta;

The territory of Malta shall take all appropriate measures to ensure that veterinary medicinal products brought into the territory from a third country and destined for Member States are accompanied by a copy of the authorisation referred to in sub-regulation (1).

(4) Any application for the grant of a licence to manufacture, assemble or modify a veterinary medicinal product shall be made to the Veterinary Services and shall contain such information, documents, samples and other material as provided by the provisions of these regulations.

(5) A Manufacturing Authorisation shall include a licence to distribute by wholesale the

veterinary medicinal products in respect of which the Manufacturing Authorisation has been issued.

(6) The Veterinary Services shall forward to the Agency a copy of the Authorisation referred to in sub-regulation (1).

(7) The Veterinary Services shall enter the information relating to the Authorisation referred to in sub-regulation (1) in the European Union database referred to in regulation 72(6).

40**.** The Veterinary Services, shall only grant or renew an Authorisation, if the applicant:

(a) specifies the veterinary medicinal products and pharmaceutical forms which are to be manufactured or imported and the place where they are to be manufactured and, or controlled;

(b) has at his disposal, for the manufacture or import of veterinary medicinal products, suitable and sufficient premises, technical equipment and control facilities complying with requirements set by the Veterinary Services;

(c)has at his disposal the services of at least one qualified person within the meaning of regulation 46; and

(d) provides all necessary documentation in support of his application

41. (1) (a) The Veterinary Services shall issue the Authorisation after verifying the contents of the application but in any case not later than ninety (90) days from receipt of the application.

(b) This time period shall be suspended when the Veterinary Services requests additional information from the applicant.

(c) The Veterinary Services shall, before determining an application, inspect the premises indicated in the application and shall not issue an Authorisation until it is satisfied that such premises conform with the requirements established by the provisions of these regulations;

(d) The Veterinary Services may grant a conditional licence subject to the carrying out of certain obligations imposed on the applicant.

(2) The Authorisation shall apply only to the premises, veterinary medicinal products and pharmaceutical forms specified in the application.

(3) Where the Veterinary Services considers that circumstances may exist which would render necessary the consideration of whether the Authorisation should be varied, suspended or revoked, the Veterinary Services may serve on the holder of a manufacturer's Authorisation a notice requiring him, within such time as may be specified in the notice, to furnish it with any information specified in the notice.

42. (1) When the holder of the Authorisation requests a change in the particulars specified in regulation 4(a) and 4(b), he shall apply in writing to the Veterinary Services.

The process of verification of such information shall not exceed thirty (30) days. However, in exceptional cases, this period of time may be extended to ninety (90) days.

(2) The veterinary services may upon such an application made by the holder of Authorisation in request thereof, vary the condition of the licence if it is satisfied that such variation will not adversely affect standard of good practice in manufacture as may be prescribed

(3) Where the Veterinary Services considers that circumstances may exist which would render necessary the consideration of whether the Authorisation should be varied, suspended or revoked, the Veterinary Services may serve on the holder of a manufacturing Authorisation a notice requiring him, within such time as may be specified in the notice, to furnish it with any information specified in the notice.

43**.** (1) The Veterinary Services may suspend a manufacturer's Authorisation for such period as it may determine, or may refuse, revoke, or vary the provisions of, any such Authorisation.

(2) The powers vested in sub-regulation (1) shall only be exercisable in any of the following circumstances, where:

(a) the matters stated in the application on which the Authorisation was granted were false or incomplete in an essential manner;

(b) a material change of circumstances has occurred in relation to any of those matters;

(c) any of the conditions of the Authorisation has been contravened;

(d) the requirements in relation to the licences as established by these regulations have not been complied with;

(e) the processes of manufacture or assembly of a veterinary medicinal product are carried out in a manner that is not in compliance with the provisions of the marketing authorisation of that veterinary medicinal product;

(f) the conditions for good manufacturing practice are not being complied with;

(g) there is sale and processing of active substance and veterinary medicinal products under unsanitary conditions or leading to adulteration ; and

(h) in any other circumstance as is established under these regulations.

(3) The Veterinary Services shall carry out regular inspections to ensure that the requirements established by these regulations in relation to the manufacture, assembly or modification of a veterinary medicinal product or active substance are complied with.

(4) With respect to the manufacture of veterinary medicinal products or active substance the Veterinary Services or any authorised person carrying out an inspection shall:

(a) inspect the manufacturing establishment and any other location and at any reasonable time the Director may deem necessary

(b) examine any relevant documents;

(c) take any samples the Director may deem necessary and if necessary submit them to designated laboratories for testing;

(d) Open or/and examine or/and seize any article believed to be in violation of these regulations or for obtaining evidence;

(e) draw up a report of the findings and communicate the contents of such report to the Manufacturing Authorisation holder or the applicant for a Manufacturing Authorisation and to the qualified person in relation to such inspection

(f) carry out any other activity the Director may deem appropriate for the proper execution of his duties and responsibilities as provided by these regulations

(g) produce, upon request by the inspected part, the designated document containing information on the legal basis and scope of the inspection and the identification of the inspector/s.

(h) at the time of the inspection draw up a list of deficiencies that may have been identified and shall sign this list, and such list shall be countersigned by the holder of the Authorisation or his legal representative.

(i) shall draw up a report of the inspection within thirty (30) working days of the inspection and shall forward a copy of such report to the holder of the Authorisation.

(5) Except in urgent cases an inspection shall be carried out in the presence of a qualified person or his representative, .

(6) Subject to the provisions of these regulations, every licence shall, unless previously renewed or revoked, continue to be valid until such time as it is renewed by the Veterinary Services following an inspection.

(7) The Veterinary Services shall establish the period of validity of any licence

(8) Following the inspection mentioned in sub-article (1), the Veterinary Services:

(a) may renew the licence, with or without modifications, for such a further period as specified; or

(b) if, having regard to the provisions of these regulations, it considers it necessary

or expedient to do so, may refuse to renew the licence.

44. (1) The holder of the Authorisation or the manufacturer of active substance shall

(a) comply with the EU principles and guidelines of good manufacturing practice and any annexes thereof for veterinary medicinal products and use only active substances which have been manufactured in accordance with the EU guidelines on good manufacturing practice for active substances and distributed in accordance with good distribution practices for active substances . To this end, the holder of the manufacturing authorisation shall verify compliance by the manufacturer and distributors of active substances with good manufacturing practice and good distribution practices by conducting audits at the manufacturing and distribution sites of the manufacturer and distributors of active substances. The holder of the manufacturing authorisation shall verify such compliance either by himself or, without prejudice to his responsibility as provided for in these regulations and in the Act , through an entity acting on his behalf under a contract;

(b) inform the competent authority and the marketing authorisation holder immediately if he obtains information that veterinary medicinal products which come under the scope of his manufacturing authorisation or the active substance are, or are suspected of being, falsified irrespective of whether those veterinary medicinal products were distributed within the legal supply chain or by illegal means, including illegal sale at a distance by means of information society services;

(c) verify that the manufacturers, importers or distributors from whom he obtains active substances are registered with the competent authority of the Member State in which they are established;

(d) verify the authenticity and quality of the active substances and the excipients.

(e) have at his disposal the services of staff complying with the legal requirements set by the Veterinary Services as regards both manufacture and controls

(f) dispose of the veterinary medicinal products only in accordance with the legislation of the territory of Malta;

(g) give prior notice to the Veterinary Services of any changes which he may wish to make to any of the particulars supplied pursuant to regulation 40 or other significant changes or of conditions which may affect the quality, safety or efficacy of the veterinary medicinal product.

The Veterinary Services shall, in any event, be immediately informed if the qualified person referred to in regulation 46(1) is replaced ;

(h) enable the qualified person referred to in regulation 46(1) to carry out his duties, particularly by placing at his disposal all the necessary facilities;

(i) keep detailed records of all veterinary medicinal products supplied by him, including samples, in accordance with the laws of the countries of destination.

i. Date
ii. Name of the veterinary medicinal product
iii. Quantity supplied
iv. Name and address of the recipient
v. Batch number

These records shall be available for inspection by the Veterinary Services for a period of at least three years.

(j) The following information at least shall be recorded in respect of each transaction, whether or not it is made for payment

(k) record all suspected serious adverse reactions and human adverse reactions relating to the use of veterinary medicinal products that are brought to his attention and report them promptly to the Veterinary Services in no later than fifteen days following receipt of the information.

(l) implement a system for recording and reviewing complaints together with an effective system for recalling promptly and at any time the veterinary medicinal products or the active substance in the distribution network.

(m) record and investigate any complaint concerning quality defects

(n) other responsibilities as may be established by the Veterinary Services from time to time

(2) For the purposes of this regulation, manufacture of active substances used as starting materials shall include both total and partial manufacture or import of an active substance used as a starting material as defined in the Schedule Part 2. Section C of these regulations, and the various processes of dividing up, packaging or presentation prior to its incorporation into a veterinary medicinal product, including repackaging or re-labelling, such as are carried out by a distributor of starting materials.

(3) Manufacturing Authorisation holders shall be regarded as producers and therefore held liable for damages in the cases and under the conditions set forth in the Consumers Affairs Act.

(4) It shall be the duty of the importer to ensure that:

(a) in the case of veterinary medicinal products and investigational veterinary medicinal products imported from third countries, these have been manufactured in accordance with standards which are at least equivalent to the good manufacturing practice standards laid down in Subsidiary Legislation 437.108

(b) in the case of veterinary medicinal products, such products have been manufactured by manufacturers duly authorised for the purpose; and

(c) in the case of investigational veterinary medicinal products, such products have been manufactured by a manufacturer notified to the competent authorities and accepted by them for that purpose

45. The Veterinary Services may require from the applicant further information concerning both the particulars supplied pursuant to regulation 40 and the qualified person referred to in regulation 46(1). Where the Veterinary Services exercise this right, application of the time limits referred to in regulations 41 and 42(1) shall be suspended until the additional data required have been supplied.

46**.** (1) The holder of the Authorisation shall have permanently and continuously at his disposal the services of at least one qualified person, in accordance with the conditions laid down in regulation 47, responsible in particular for carrying out the duties specified in regulation 49.

Provided that when more than one qualified person is nominated, the application will clearly delineate the specific responsibilities of each person;

Provided that the qualified persons may nominate another person similarly qualified to act as his representative.

(2) When the qualified person has nominated a representative as aforesaid he shall immediately inform the Veterinary Services of such nomination.

(3) If the manufacturing Authorisation holder personally has the qualifications laid down in regulation 47, then he may himself assume the responsibility of a qualified person.

47. For a person to be designated as qualified person, he must possess the following qualifications:

(1) The qualified person shall be in possession of a diploma, certificate or other evidence of formal qualifications awarded on completion of a university course of study, or a course recognised as equivalent by the territory of Malta, extending over a period of at least four years of theoretical and practical study in one of the following scientific disciplines - pharmacy, medicine, veterinary science, chemistry, pharmaceutical chemistry and technology, biology.

However, the minimum duration of the university course may be three and a half years where the course is followed by a period of theoretical and practical training of at least one year and includes a training period of at least six months in a pharmacy open to the public, corroborated by an examination at university level.

The course shall include theoretical and practical tuition bearing upon at least the following basic subjects:

(a) experimental physics,
(b) general and inorganic chemistry,
(c) organic chemistry,
(d) analytical chemistry,
(e) pharmaceutical chemistry, including analysis of medicinal products,
(f) general and applied biochemistry (medical),
(g) physiology,
(h) microbiology,
(i) pharmacology,
(j) pharmaceutical technology,
(k) toxicology,
(l) pharmacognosy (study of the composition and effects of the active principles of natural substances of plant and animal origin).

Tuition in these subjects should be so balanced as to enable the person concerned to fulfil the obligations specified in regulation 49.

Where certain diplomas, certificates or other evidence of formal qualifications mentioned in this sub-regulation do not fulfil the criteria laid down above, the Veterinary Services shall ensure that the person concerned provides evidence that he has, in the subjects involved, the knowledge required for the manufacture and control of veterinary medicinal products.

(2) The qualified person shall have acquired practical experience over at least two (2) years, in one or more undertakings which are authorised manufacturers, in the activities of qualitative analysis of medicinal products, of quantitative analysis of active substances and of the testing and checking necessary to ensure the quality of veterinary medicinal products.

The duration of practical experience may be reduced by one year where a university course lasts for at least five years and by a year and a half where the course lasts for at least six (6) years

48. (1) A person engaging, in Malta, in the activities of the person referred to in regulation 46(1) on the date on which these regulations become applicable, without complying with the provisions of regulation 47, shall be eligible to continue to engage in those activities within the EU.

(2) The holder of a diploma, certificate or other evidence of formal qualifications awarded on completion of a university course or a course recognised as equivalent by the territory of Malta in a scientific discipline allowing him to engage in the activities of the person referred to in regulation 46(1) in accordance with the laws of the territory of Malta, may, if he began his course prior to the date on which these regulations became applicable, be considered as qualified to carry out in the territory of Malta the duties of the person referred to in regulation 46(1), provided that he has previously engaged in the following activities for at least two (2) years before the date on which these regulations became applicable in

one or more undertakings with a manufacturing authorisation, production supervision and, or qualitative and quantitative analysis of active substances, and the necessary testing and checking under the direct authority of a person as referred to in regulation 46(1) to ensure the quality of veterinary medicinal products.

If the person concerned has acquired the practical experience referred to in sub-regulation (1) before the date on which these regulations became applicable, a further one year's practical experience in accordance with the conditions referred to in sub-regulation (1) shall be completed by him immediately before he engages in such activities.

49. (1) The qualified person, without prejudice to his relationship with the holder of the Authorisation, shall be responsible to ensure that:

(a) each batch of veterinary medicinal products manufactured in Malta has been manufactured and checked in terms of the laws in force and is in accordance with the requirements of the marketing authorisation;

(b) in the case of veterinary medicinal products coming from third countries, irrespective of whether the product has been manufactured in the EU, each production batch has undergone in a Member State a full qualitative analysis, a quantitative analysis of at least all the active substances and all the other tests or checks necessary to ensure the quality of the veterinary medicinal product in accordance with the requirements of the marketing authorisation :

Provided that when the batches of medicinal products have already undergone the controls above mentioned in a Member State, they shall be exempt from further controls if they are accompanied by the control reports signed by the qualified person, and are marketed within the EU.

(c) standards of good practice in manufacturing are complied with at all times;

(2) The qualified person need not carry out the controls above mentioned in the case of imported veterinary medicinal products, where arrangements have been made by the EU with the exporting country to ensure that the manufacturer of the veterinary medicinal products applies standards of good manufacturing practice at least equivalent to those laid down by the EU, and to ensure that the controls referred to above have been carried out in the exporting country.

(3) The Veterinary Services, may if it has reasonable suspicion to believe that any qualified person is acting in contravention of any of the provisions of these regulations, suspend the activity of such qualified person by notice in writing specifying the reasons for such suspension until such person has complied with any requirement of the Veterinary Services to remedy the non- compliance.

50. (1) It shall be the duty of the qualified person to keep a register to document and certify that each production batch satisfies provisions of these regulations.

(2) The said register shall be kept up to date as operations are carried out and must be made available for inspection by the Veterinary Services for at least five (5) years.

50 (A) The obligations of qualified persons referred to in regulation 46(1) shall be fulfilled either by means of appropriate administrative measures or by making such persons subject to a professional code of conduct.

The Veterinary Services may provide for the temporary suspension of such a person upon the commencement of administrative or disciplinary proceedings against him for failure to fulfil his obligations.

50(B). (1) Importers, exporters, distributors and manufacturers of active substances who are established in Malta shall register their activity with the Veterinary Services .

(2) The registration form shall include, at least, the following information

(a) name or corporate name and permanent address;

(b) the active substances which are to be imported, exported, distributed or manufactured

(c) particulars regarding the premises and the technical equipment for their activity:

Provided that the persons referred to in sub-regulation (1) shall submit the registration form to the Veterinary Services at least sixty(60) days prior to the intended commencement of their activity.

(3) The Veterinary Services may, based on a risk assessment, decide to carry out an inspection. If the Veterinary Services notifies the applicant within sixty (60) days of the receipt of the registration form that an inspection will be carried out, the activity shall not begin before the Veterinary Services has notified the applicant that he may commence the activity. If within sixty (60) days of the receipt of the registration form the Licensing Authority has not notified the applicant that an inspection will be carried out, the applicant may commence the activity.

(4) The persons referred to in sub-regulation (1) shall communicate annually to the Veterinary Services an inventory of the changes which have taken place as regards the information provided in the registration form. Any changes that may have an impact on the quality or safety of the active substances that are manufactured, exported, distributed or imported shall be notified immediately.

(5) The Veterinary Services, shall only grant or renew an Authorisation, if the applicant:

(a) specifies the veterinary medicinal products and pharmaceutical forms which are to be manufactured or imported and the place where they are to be manufactured and, or controlled ;

(b) has at his disposal, for the manufacture or import of veterinary medicinal products, suitable and sufficient premises, technical equipment and control facilities complying with requirements set by the Veterinary Services;
(c) has at his disposal the services of at least one qualified person within the meaning of regulation 46(1); and
(d) provides all necessary documentation in support of his application.

(6) The Veterinary Services shall issue the Authorisation after verifying the contents of the application but in any case not later than ninety (90) days from receipt of the application.

(7) The time period mentioned in sub-regulation 6 shall be suspended when the Veterinary Services requests additional information from the applicant.

"50(C). (1) When veterinary medicinal products are brought from a third country into Malta for the sole purpose of re-export, and without placing them on the market in Malta, the provisions of regulation 38 still apply even though the product remains intact and no manufacturing activities are carried out.

(2) The only exclusion in respect of the requirement in regulation 38 , is when the operations of import for the sole purpose of re-export are effected within a freeport, free trade zone or customs warehouse. However, in such instances a veterinary wholesale dealer's licence is still required by the company engaging in the process.

(3) In those cases involving a manufacturing activity in relation to imported products that are destined for re-export only, a manufacturing authorisation is required, even if the operations are effected within the freeport, free trade zone or customs (e.g. bonded warehouse). Operations of re-labelling and/or affixing of labels to the outer pack also fall within this category.

(4) The Veterinary Services shall establish procedures to ensure that the requirements of sub-regulations (2) and (3) are complied with.

(5) The Veterinary medicinal products imported for the sole purpose of re-export may be exempted from obtaining a Marketing Authorisation from the Veterinary Services.

(6) The authorisation to engage in such an activity is only given to persons in possession of a veterinary wholesale dealer licence and without prejudice to other authorisations that the persons may have to obtain, particularly with respect to the requirements of the Import Control Regulations.

Amendment to regulation 58 of the principal regulations.

16. Sub-regulation 58 (1) of the principal regulations shall be amended as follows:

Immediately after the second paragraph thereof there shall be added the following new paragraph:

"When the market situation in Malta is such that it gives rise to a temporary supply issues for an authorised veterinary medicinal product, the purchase, importation, sale, procurement and trade of small quantities of the same authorised veterinary medicinal product, or an essentially similar veterinary medicinal product, by a veterinary surgeon is permitted and is excluded from the scope of the definition of wholesale distribution under a decision to be laid down by the Veterinary Services."

Change in scope of Title VII.

17. Immediately after regulation 58 of the principal regulations there shall be added a new Title as follows:

"TITLE VII

RETAIL SUPPLY OF VETERINARY MEDICINAL PRODUCTS"

Addition of new regulation 58A to the principal regulations.

18. Immediately after the new Title VII, there shall be added the new Regulation 58A to the principal regulations as follows:

"58(A). In the territory of Malta, the retail supply of veterinary medicinal products shall be conducted only from veterinary pharmacies, licensed veterinary establishments, other establishments mentioned in 60(4)(d) and by veterinary surgeons during out call visits."

Change in scope of Title VIII

19. Following the new regulation 58A to the principal regulations there shall be added the following new Title:

"TITLE VIII
DISPENSING REGULATIONS FOR VETERINARIAN"

Substitution of regulation 59 to the principal regulations.

20. Regulation 59 of the principal regulations shall be substituted by the following:

"59. (1) In the territory of Malta, only pharmacists and veterinary surgeons can dispense and supply veterinary medicinal products to the owners of animals.

(2) Veterinary surgeons shall dispense veterinary medicinal products during an in-call by the animal owner in the licensed veterinary establishments and during out-call visits to the animals under their care.

(3) Veterinary surgeons shall dispense a veterinary medicinal product in such quantities as would be required for the treatment of the condition, where delay in the administration of the product may adversely affect the health of the animal.

Provided that the veterinary surgeon shall supply the quantities of veterinary medicinal product for treatments or conditions only to animals under his care. If the type of the packaging is such that the veterinary surgeon cannot supply lesser quantities thereof, the veterinary surgeon may supply the animal owner with the quantities needed for the full treatment of the condition.

Provided further that the above may not apply for veterinary medicinal product that are regulated by specific instruments.

(4) Veterinary surgeons shall be required to keep detailed records for veterinary medicinal products or treatments that may be supplied only on prescription, the following information being recorded in respect of each incoming or outgoing transaction:

(a) date;

(b) identity of the product/s used for treatment ;

(c) quantity received or dispensed;

(e) name and address of the supplier and recipient of the products used for treatment ;

(f) copy of the veterinary prescription.

At least once a year a detailed audit shall be carried out, and incoming and outgoing veterinary medicinal products and other products issued on a veterinary prescription shall be reconciled with products currently held in stock, any discrepancies being recorded in an appropriate register. These records shall be available for inspection by the Veterinary Services for a period of not less than five (5) years.

(5) When dispensing a veterinary medicinal product veterinary surgeons must be satisfied that the person who will use the product is competent to do so safely, and intends to use it for a purpose for which it is authorised.

(6) When dispensing veterinary medicinal product, veterinary surgeons shall advise the receiver of the product on the safe administration of the product and on any warnings or contra-indications on the label or package leaflet.

(7) If veterinary surgeons dispense an amount of veterinary medicinal product that is less than the unit dose of a package, the veterinary surgeons may break open any package containing a product for the purposes of supply, other than the immediate packaging of an injectable product.

(8) If a veterinary medicinal product is supplied in a container other than that specified in the marketing authorisation, the veterinary surgeon dispensing the product must ensure that the container is suitably labelled and shall supply sufficient written information to enable the product to be used safely.

(9) the veterinary surgeon referred to in regulation 79 (2) shall be responsible for the cabinet where veterinary medicinal products are kept In particular , storage conditions, traceability issues and record keeping requirements shall be strictly adhered to. .

(10) A veterinary surgeon dispensing a veterinary medicinal product must be present when the product is handed over unless the veterinary surgeon:

(a) authorises each transaction individually before the product is supplied;

(b) is satisfied that the person handing it over is competent to do so.

(11) Veterinary surgeons shall dispense only veterinary medicinal product that have not passed their expiry date.

Change in scope of Title IX

21. Following the amended regulation 59 to the principal regulations there shall be added the following new Title:

TITLE IX
DISPENSING REGULATIONS FOR PHARMACIST

Addition of new regulation 59A to the principal regulations.

22. Immediately after the new Title IX, there shall be added a new Regulation 59A to the principal regulations as follows:

59(A). In the territory of Malta pharmacists can only dispense veterinary medicinal products in accordance with the provisions of this regulation.

(1) Pharmacists shall dispense veterinary medicinal product only from veterinary pharmacies

(2) When dispensing a veterinary medicinal product the pharmacists must be satisfied that the person who will use the product is competent to do so safely, and intends to use it for a purpose for which it is authorised or indicated by the veterinary surgeon.

(3) When dispensing an antimicrobial agent the pharmacists must be satisfied that all necessary precautions have been taken to minimise the risks of antimicrobial resistance and that the prudent use of the antimicrobial agent have been taken in consideration, in particular to the use critically important antimicrobials.

(4) When dispensing a veterinary medicinal product pharmacists must advise the receiver of the product on the safe administration of the product and on any warnings or contra-indications on the label or package leaflet.

(5) Pharmacist may prepare and supply an extemporaneous veterinary medicinal product prepared in the veterinary pharmacy in accordance with a veterinary prescription or in accordance with the pharmacopoeia.

(6) If pharmacists dispense an amount of veterinary medicinal product that is less than the unit dose of a package, the pharmacists may break open any package containing a medicinal product for the purposes of supply, other than the immediate packaging of an injectable product.

(7) Pharmacists shall be required to keep detailed records for veterinary medicinal product or other treatments that may be supplied only on prescription, the following information being recorded in respect of each incoming or outgoing transaction:

(a) date;

(b) precise identity of the product/s used for treatment;;

(c) quantity received or supplied;

(d) name and address of the supplier and recipient;

(e) name and address of the prescribing veterinary surgeon and a copy of the veterinary prescription

At least once a year a detailed audit shall be carried out, and incoming and outgoing veterinary medicinal product or product used for treatment on a veterinary prescription shall be reconciled with products currently held in stock, any discrepancies being recorded in an appropriate register. These records shall be available for inspection by the Veterinary Services for a period of five (5) years.

(8) If a veterinary medicinal product is supplied in a container other than that specified in the marketing authorisation, the pharmacist supplying the veterinary medicinal product must ensure that the container is suitably labelled and shall supply sufficient written information to enable the product to be used safely.

(9) Pharmacists shall use their professional knowledge to check that the prescription concurs with their own understanding of the veterinary medicinal product.. If they have concerns about the content of the veterinary prescription they shall resolve them with the prescribing veterinary surgeon before dispensing the product.

(10) Pharmacists shall dispense only veterinary medicinal product that have not passed their expiry date.

Change in scope of Title X

23. Following the regulation 59(A) to the principal regulations there shall be added the following new Title:

TITLE X
PRESCRIBING REGULATIONS

Addition of new regulation 58(B) to the principal regulations.

24.Immediately after the Title X, there shall be added a new Regulation 59(B) to the principal regulations as follows:

59(B). In the territory of Malta veterinary surgeons can only prescribe veterinary medicinal products in accordance with the provisions of this regulation.

(1) In the territory of Malta, the prescribing of veterinary medicinal product or medicinal product to animals shall be conducted only by Veterinary surgeons.

(2) The prescribing of veterinary medicinal product or medicinal product for animals shall be made only on the veterinary prescriptions.

(3) Veterinary surgeons may only prescribe a veterinary medicinal product or medicinal product for animals which they have examined themselves and shall accept clinical responsibility for the treatment of the animal under their care.

(4) Veterinary medicinal product or medicinal product may not be used for more than one treatment under the same prescription.

(5) Before prescribing a veterinary medicinal product or medicinal product which requires a prescription, veterinary surgeons shall carry out a clinical assessment of the animal under their care.

(6) The clinical assessment by the veterinary surgeons shall be carried out recently enough for the veterinary surgeons to have personal knowledge of the condition of the animal or current health status of the herd or flock to make a reliable diagnosis or start empirical treatment.

(7) Before prescribing a veterinary medicinal product or medicinal product the veterinary surgeons must first satisfy themselves that:

(a) the use of the veterinary medicinal product or medicinal product is justified for the species concerned on veterinary grounds;
(b) the administration of the veterinary medicinal product or 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;
(c) the veterinary medicinal product or medicinal product are prescribed only in such quantities as are necessary for the purpose of the treatment;
(d) that treatment with an antimicrobial agent does not increase the selection for resistant bacteria;

(8) When prescribing a veterinary medicinal product or medicinal product veterinary surgeons must be satisfied that the person who will use the product is competent to do so safely, and intends to use it for a purpose for which it is authorised.

(9) When prescribing antimicrobial agents veterinary surgeons shall consider the latest guidelines issued by the Veterinary Services, and other relevant national, European and International organisations with regard to critically important antimicrobials.

(10) When preparing a veterinary prescription the prescribing veterinary surgeon shall advise the receiver of the prescription on the safe administration of the product and on any warnings or contra-indications associated with the product.

(11) When the full treatment course with a veterinary medicinal product is dispensed by the veterinary surgeon for a non-food producing animal, the veterinary surgeon may opt not to prepare a veterinary prescription unless the animal owner wishes to have a veterinary prescription that covers that specific treatment course.

(12) The veterinary surgeons shall prepare a veterinary prescription if the animal owner wishes to obtain the veterinary medicinal product from a supplier other than the prescribing veterinary surgeon.

Amendment to regulation 60 of the principal regulations.

25. Regulation 60 of the principal regulations shall be amended as follows:

(a) Immediately following point (ii) of paragraph (a) of sub-regulation (1) of regulation 60, there shall be added the following point (iii) as follows:

"(iii) Veterinary medicinal products that do not fall within the classification of 60 (1) (a) (i), (b) and (c) but nonetheless are deemed to require a veterinary prescription for a temporary period."

(b) Immediately after paragraph (h) of sub-regulation (2) of regulation (60) there shall be added paragraph (i) as follows:
1

"(i) Veterinary medicinal product classified as prescription only medicines may be exempted from being prescribed and dispensed by a prescription if entirely administered by the veterinary surgeon responsible for the non-food producing animal, who himself provides the veterinary medicinal product , and if the animal owner does not explicitly request a prescription."

(c) Immediately after sub-regulation 60 (2), there shall be added the following new sub-regulations:

"(3) Pursuant to sub-regulation (1) there shall be the following four (4) distribution categories of veterinary medicinal product:

(a) Prescription-Only-Medicine, Veterinary surgeon and Pharmacist- abbreviated to **POM-VP.**

(b) Prescription-Only-Medicine, Veterinary surgeon- abbreviated to **POM-V.**

(c) Over- the- Counter –Medicine, abbreviated to **OTC**

(d) General Sales , abbreviated to **GS**

(4) The supply of veterinary medicinal products for each distribution category shall be made as follows**:**

(a) POM-VP, shall only be prescribed and/or dispensed by a veterinary surgeon or dispensed by a pharmacist according the terms of a veterinary prescription. Premises from where the

products can be supplied are veterinary pharmacies, licensed veterinary establishments, and by the veterinary surgeon during an outcall.

(b) POM-V shall only be prescribed, dispensed and administered by a veterinary surgeon. Premises from where the products can be supplied are veterinary clinics or hospitals, and by the veterinary surgeon during an outcall.

(c) OTC, may be dispensed without a veterinary prescription. The persons who can dispense this category of veterinary medicinal products are veterinary surgeons, pharmacists and suitably qualified persons under the direction of a pharmacist or a veterinary surgeon. Premises from where the products can be supplied are veterinary pharmacies, establishments , and by the veterinary surgeon during an outcall.

(d) GS, may be dispensed without a veterinary prescription. The persons who can dispense this category of veterinary medicinal products are veterinary surgeons, pharmacists and suitably qualified persons. Products that fall under this category can be supplied from veterinary pharmacies, veterinary establishments, registered pet shops, registered aquarium fish product retailers and approved feed traders where animal medicated feeds are produced, sold or traded.

Provided, that the veterinary services may make requirements to allow products classified in this category to be supplied from premises other those listed above to alleviate supply shortages and facilitate accessibility to treatment that otherwise could be detrimental to animal welfare. Such premises shall not be general retail outlets and must be under the responsibility of a person with an experience of not less than 2 years in the handling of this category of veterinary medicinal products.

(5) The Veterinary Services shall categorise the distribution category of the veterinary medicinal product when authorising veterinary medicinal products.

(6) When deciding the distribution category of a veterinary medicinal product the Veterinary Services may seek the advice from suitable expert committees and may take in consideration the guidelines of other National, European and International relevant bodies, as may be decided by the Veterinary Services.

(7) Notwithstanding what had been decided during the initial Marketing Authorisation procedure, the Veterinary Services may change the distribution category of a veterinary medicinal product either at the request of the Marketing Authorisation Holder or due to a compulsory variation.

(8) The Veterinary Services shall set out the criteria for the categorisation of a Veterinary Medicinal product and make them public.

(9) Different pack sizes of the same Marketing Authorisation may be assigned a different distribution category.

(10) When the distribution category of the veterinary medicinal product is POM-V or POM-VP this shall be indicated on the immediate and/or outer packaging of the product in legible, undeletable characters.

(11) The legible, undeletable characters citing the distribution category of the veterinary medicinal product may be printed on the immediate and/or outer packaging or made noticeable through an appropriate label.

(12) Both the abbreviated form and the full description of the distribution category of the veterinary medicinal product present on the immediate and/or outer packaging shall be acceptable."

Amendment to regulation 62 of the principal regulations.

26. Regulation 62 of the principal regulations shall be amended as follows:

(a) In the first paragraph thereof, immediately after the words "keepers of food-producing animals" there shall be added the words "or keeper of animals that are confined within enclosures, displayed to the public, or kept for breeding".
(b) In the first paragraph thereof, immediately after the words "including when the animal is slaughtered", there shall be added the words "or culled".
(c) Immediately following the "The territory of Malta may extend the scope of this obligation to other veterinary medicinal products," there shall be added the following new paragraphs:

"The records shall be kept electronically or printed hard copies. Hard copies shall be kept as hard bound records or in paper binders. Official hard copies or electronic templates may be provided by the Veterinary Services. The records shall be kept in a suitable place in the farm and available immediately for inspection by the Veterinary Services for a period of not less than three (5) years.

Proof of purchase refers in particular to the invoices and/or to the receipts or any document existing as hard copy or in electronic format that provides documentary evidence of how, when and from whom the veterinary medicinal product or medicinal product were acquired.

(d) Immediately following paragraph (e) thereof, there shall be added the following paragraph: "(f) scenario under which the medicine was prescribed, which could be either one of three possible scenario, treatment, prophylactic or metaphlactic."

(e) Immediately following the new paragraph (e), there shall be added the following:

Scientific justification as to why antimicrobial agents were recommended by the veterinary surgeon in the case of metaphylactic and/or prophylactic use.veterinary surgeon

Amendment to regulation 64 of the principal regulations.

27. Sub-regulation (1) of regulation 64 thereof, the words "in accordance with its national legislation" shall be deleted.

Amendment to regulation 72 (1) of the principal regulations.

28. Regulation 72 of the principal regulations shall be amended as follows:

(a)In sub-regulation (1), in the second paragraph immediately after the words 'carry out' of there shall be added the following word 'at any reasonable time'

(b) In sub-regulation (1), immediately after the words veterinary medicinal products there shall be added the following sentences: in any place where active substances and veterinary medicinal products are manufactured, distributed, imported, exported or used.

(c) In sub-regulation (1), immediately after the words Council Directive 2004/28/EC there shall be added the following sentence: or any provisions of these Regulations.

(d) Immediately after sub-regulation (7) there shall be added the following new sub-regulation

(8) the persons responsible for the premises mentioned in this regulation shall allow entry to the authorised representatives of the veterinary services to carry out their duties

Addition of new regulation 77 A to the principal regulations.

29. Immediately after regulation 77 of the principal regulations, there shall be added the following new regulation:

"77A (1) The Veterinary Services shall permit the advertising of veterinary medicinal products that in accordance with regulation 60, are available on veterinary prescription to:

(a) Veterinary surgeons and pharmacists

(b) Professional keepers of animals, provided that the veterinary medicinal products are preventive immunological products or anti-helmintic therapies.

(2) The Veterinary Services shall permit the advertising of veterinary medicinal products to the general public which, by virtue of their composition and purpose, are intended and designed for use with the advice of the pharmacist, if necessary, but without the intervention of a veterinary surgeon for diagnostic purposes or for the prescription or monitoring of treatment.

(3) No person may advertise medicinal product for administration to animals. Scientific informative material can be sent on request to the veterinary surgeon when the provisions of regulation 10 and 11 are to be applied. The information must not be promotional in nature and must not include a price list.

(4) (a) It shall not be permissible for persons allowed to supply veterinary medicinal products to veterinary surgeons or pharmacy owners to induce them to prescribe or supply veterinary medicinal products by the gift, offer or promise of any benefit or bonus, whether in money or in kind.

(b) It shall not be permissible for persons allowed to supply veterinary medicinal products to make any form of contractual agreement with animal keepers that benefits the sale of their products.

(c) It shall not be permissible for persons allowed to supply veterinary medicinal products to solicit or accept any inducement prohibited under sub-regulations 4(a) and 4(b). Provided that existing measures or trade practices relating to prices, profit margins and discounts shall not be affected.

(5) The advertising of a veterinary medicinal product shall:

(*a*) encourage the rational use of the veterinary medicinal product, by presenting it objectively and without exaggerating its properties;
(*b*) comply with the particulars listed in the summary of product characteristics;
(*c*) not be misleading;
(d) be set out in such a way that it is clear that the message is an advertisement and that the product is clearly identified as a veterinary medicinal product;
(*e*) not give the impression that a veterinary surgeon is unnecessary, in particular by offering a diagnosis or by suggesting treatment by mail, internet or any other means;
(*f*) not suggests that the effects of administering the veterinary medicinal product are guaranteed, are not accompanied by adverse reactions or are better than, or equivalent to, those of another treatment or veterinary medicinal product;
(*g*) not suggests that the health of the animal can be enhanced by taking the veterinary medicinal product;
(*h*) not suggests that the health of the animal could be affected by not taking the veterinary medicinal product provided that this shall not apply to the vaccination campaigns;
(*i*) not suggests that the veterinary medicinal product is a foodstuff, cosmetic or other consumer product;
(*j*) not suggests that the safety or efficacy of the veterinary medicinal product is due to the fact that it is natural;

(6) (a) Any advertising of a veterinary medicinal product to persons qualified to prescribe or supply such products shall include:

(i) the trade name;
(ii) a list of active ingredients;
(iii) the pharmaceutical form;
(iv) major indications for use;
(v) the dosage and method of use;
(vi) side effects, warnings, precautions and contraindications;
(vii) the name and address of the marketing authorization holder;
(viii) any research and/or publications on the use of the active substance

(b) All the information contained in the documentation referred to in sub-regulation (6) (a) shall be accurate, up-to-date, verifiable and sufficiently complete to enable the recipient to form his or her own opinion of the therapeutic value of the veterinary medicinal product concerned.

(c) Quotations as well as tables and other illustrative matter taken from scientific works for use in the documentation referred to in sub-regulation (9)(a) shall be faithfully reproduced.

(7) (a) Free samples shall be provided on an exceptional basis only to persons qualified to prescribe them and on the following conditions:

(*i*) each sample shall be no larger than the smallest presentation on the market;
(*ii*) each sample shall be marked "free sample - not for sale";
(*iii*) each sample shall be accompanied by a copy of the summary of product characteristics;
(*iv*) veterinary medicinal products containing psychotropic or narcotic substances as defined under the First Schedule to the Dangerous Drugs Ordinance and the Third Schedule to the Medical and Kindred Professions Ordinance cannot be distributed as samples;

(b) Starter packs shall not be regarded as samples and shall not be labelled as such.

(c) During visits by sales representatives the persons visited should be given information about the use of the veterinary medicinal products, with particular reference to any adverse reactions.

(8**).** The person who advertises the veterinary medicinal products shall:

(*a*) keep available for, or communicate to, the Veterinary Services, a sample of all advertisements emanating from his undertaking together with a statement indicating the persons to whom it is addressed, the method of dissemination and the date of first dissemination;

(*b*) supply the Veterinary Services with the information and assistance it requires to carry out its responsibilities;

(*c*) ensure that the decisions taken and conditions imposed by the Veterinary Services are immediately and fully complied with.

(9). It is not permissible to advertise veterinary medicinal products which are not registered with the Veterinary Services.

Amendment to Regulation 79 of the principal regulations.

22. 1Regulation 79 of the principal regulations shall be amended as follows:

30. Sub-regulation 2 of regulation 79 shall be substituted by the following:

"For the purposes of these regulations every registered farm or licensed place where animals are kept for display to the public or for breeding purposes in the territory of Malta shall have an appropriate animal health control programme designed and implemented under the responsibility of a veterinary surgeon. .

Provided that a register of the veterinary surgeon for the animal health control programme by the owner of the registered farm, licensed place where animals are kept for display to the public or for breeding purposes shall be kept by the Veterinary Services.

Provided that the Veterinary Services may from time to time publish requirements related to animal health control programmes.

Addition of a new Title to the principal Regulations.

31. Immediately after regulation 79 of the principal regulations, there shall be added a new title and a new regulation 79A as follows:

"TITLE XI

ADMINISTRATION OF MEDICINES

Addition of a new regulation 79A to the principal Regulations.

32. Immediately after the new Title XI of the principal regulations, there shall be added a new regulation 79A as follows:

79 A (1) In extreme and/or urgent situation to alleviate suffering of the animal or impending spread of disease any person can administer a veterinary medicinal product or medicinal product which requires a veterinary prescription without the veterinary prescription or the instructions to administer the product by the veterinary surgeon.

(2) No person can administer a veterinary medicinal product or medicinal product to animals in order to gain profit, monetary or in any other form, unless authorised to do so by,. the Veterinary Services.

(3) No person can administer, or supply for administration, a veterinary medicinal product to animals unless the product obtains an authorisation from the Veterinary Services.

(4) Products whose therapeutic effectiveness is merely anecdotal should be used with caution in all animals. The administration of these products to food producing species is subject to the approval of the veterinary services. The veterinary services may ask the animal keeper to provide chemical data, clinical documentation and studies about the possible environmental impact before granting its approval.

(5) The keeper of animal must keep proof of purchase of all products administered or intended to be administered to the animals for the treatment or prevention of disease or, if he did not buy them, documentary evidence of how he acquired them. .

(6) metaphlaxis or prophlaxis Metaphylactic or prophylactic antimicrobial treatment may be allowed with conditions.

(7) Except in emergency situations, before prescribing an antimicrobial agent that is critically important to human health or that is reserved for treating infections in animals for which no effective alternative treatments exist, the prescribing veterinary surgeon shall take into account the results of the diagnostic laboratory information (pathogen isolation, identification and antibiogram)

(8) No person shall administer a veterinary medicinal product or a medicinal product to a food producing species and place the animal for slaughter to be consumed unless the relevant withdrawal period has been observed.

(9) Stockpiling of antimicrobial products in a farm to be administered at a later stage is not permitted.

(10) Use of combination of antimicrobials should be scientifically supported. Combinations of antimicrobials may be used for their synergistic effect to increase therapeutic efficacy or to broaden the spectrum of activity.

Amendment of regulation 82 of the principal regulation.

33. Regulation 82 of the principal regulations shall be amended as follows:

Sub-regulation 2 of Regulation 82 shall be re-numbered as sub-regulation (2)(a) and immediately following it there shall be added the new paragraphs as follows:

(b) The marketing authorisation holder shall implement a system for recording and reviewing complaints together with an effective system for recalling promptly and at any time the veterinary medicinal products in the distribution network.

(c) record and investigate any complaint concerning a quality defect.

(d) The Veterinary Services shall be informed by the Marketing Authorisation holder of any quality defect that could result in a recall or abnormal restriction on the supply. In so far as possible, the countries where the products are marketed shall also be indicated.

Substitution of regulation 87 of the principal regulations.

34. Regulation 87 of the principal regulations shall be substituted as follows:

"87(1) Any person who in the course of his activity generates veterinary medicinal products waste, shall inform himself of the current procedures regarding the safe disposal of unused, unsuitable or expired medicinal products from the entity responsible for waste management in Malta and shall follow the guidelines issued by the veterinary services.

(2) Companies, large establishments and professional bodies shall describe the procedure they follow for the safe disposal of unused, unsuitable or expired veterinary medicinal products in writing, and keep it updated according to the requirements that may change over-time.

(3) The Veterinary Services shall ensure that veterinary medicinal product waste producers have appropriate procedures set in place for the disposal of unused, unsuitable or expired veterinary medicinal products in accordance with the law of Malta and any particular instructions described in the summary of product characteristics of the product."

Addition of regulation 88 to the principal regulations.

35. Immediately after regulation 87 of the principal regulations, there shall be added the following new regulation:

" Offences and Penalties.

88. Any person who contravenes regulations 5(1), 27(A), 39(1)(a)(b), 39(2)(a), 39(3), 46(1), 50(B), 50(C),58(1), 59(1), 59(2), 59(A)(1), 62 and 77A(4) shall be guilty of an offence against Article 38 of the Act and shall be liable, on conviction, to a fine (multa) of not more than fifteen thousand euro (15,000).".

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Addition of regulation 89 to the principal regulations.

36. Immediately after regulation 88 of the principal regulations, there shall be added the following new regulation

89. Any person who contravenes regulation 72(8) shall be guilty of an offence against Article 35 of the Act and shall be liable, on conviction, to a fine (multa) of not more than fifteen thousand euro (15,000).".

Addition of regulation 90 to the principal regulations.

37 Immediately after the new regulation 89 of the principal regulations, there shall be added the following new regulation:

" Other offences''

90. Any person who contravenes any regulation other than those mentioned in regulation 88 shall be guilty of an offence and shall be liable, on conviction, to a fine (multa) of not more than twelve thousand euro (12,000).".

Renumbering of Title VII of the principal regulations

38. Title V11 of the principal regulation shall be renumbered XI

Renumbering of Title VIII of the principal regulations

39. Title V111 of the principal regulation shall be renumbered XII

Renumbering of Title IX of the principal regulations

40. Title IX of the principal regulation shall be renumbered XIII

Renumbering of Title X of the principal regulations

41. Title X of the principal regulation shall be renumbered XIV

42. The principal regulations shall be amended as follows:

(a) for the word "veterinarian", wherever it occurs, there shall be substituted the words "veterinary surgeon"; and

(b) for the word "veterinarians", wherever it occurs, there shall be substituted the words "veterinarian surgeons".

43. In the principal regulations, for the words "territory of Malta", wherever they occur with the exception of the same words used in the meaning of the term "Veterinary Services" in Article 2 and in Regulation 51, there shall be substituted the word "Director".

44. In the principal regulations, for the word “Community”, wherever it occurs with the exception of the same word used in Regulation 1 subregulation (2) and Regulation 30, there shall be substituted the word “Union”.

45. In Regulation 30 of the principal regulations, the word “Community” shall be deleted wherever it occurs.