L.N. 82 of 2006

VETERINARY SERVICES ACT
(CAP. 437)

Veterinary Medicinal Products (Amendment) Regulations, 2006

IN exercise of the powers conferred by articles 30 and 31 of the Veterinary Services Act, 2001, the Minister for Rural Affairs and the Environment has made the following regulations:-

Title and scope.

1. (1) The title to these regulations is the Veterinary Medicinal Products (Amendment) Regulations, 2006 and they shall be read and construed as one with the Veterinary Medicinal Products Regulations, 2004 hereinafter in these regulations referred to as "the principal regulations".

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(2) The scope of these rules is to implement the rules found under European Union Council Directive 2004/28 EC amending European Council Directive 2001/82/EC on the Community code relating to veterinary medicinal products.

Amends regulation 1 of the principal regulations.

2. For sub-regulation (3) of regulation 1 of the principal regulations, there shall be substituted the following:

"(3) (a) These regulations shall apply to veterinary medicinal products, including pre-mixes for medicated feedingstuffs, intended to be placed on the market in Malta and prepared industrially or by a method involving an industrial process.

(b) In cases of doubt, where, taking into account all its characteristics, a product may fall within the definition of a "veterinary medicinal product" and within the definition of a product covered by other Community legislation, the provisions of these regulations shall apply.

(c) Notwithstanding paragraph (a) hereof, these regulations shall also apply to active substances used as starting materials to the extent set out in regulations 44, 44A, 45 and 72 and additionally to certain substances that may be used as veterinary medicinal products that have anabolic, anti-infectious, anti-parasitic, anti-inflammatory, hormonal or psychotropic properties to the extent set out in regulation 61.".

Amends regulation 2 of the principal regulations.

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

(a) point (1) shall be deleted;

(b) for point (2) there shall be substituted the following:

"(2) "Veterinary medicinal product" means:

(a) any substance or combination of substances presented as having properties for treating or preventing disease in animals; or

(b) any substance or combination of substances which may be used in or administered to animals with a view either to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or to making a medical diagnosis.";

(c) point (3) shall be deleted;

(d) for points (8), (9) and (10) there shall be substituted the following:

"(8) "Homeopathic veterinary medicinal product" means any veterinary medicinal product prepared from substances called homeopathic stocks in accordance with a homeopathic manufacturing procedure described by the European Pharmacopoeia or, in the absence thereof, by the Pharmacopoeias currently used officially in Member States. A homeopathic veterinary medicinal product may contain a number of principles.

(9) "Withdrawal period" means the period necessary between the last administration of the veterinary medicinal product to animals, under normal conditions of use and in accordance with the provisions of these regulations, and the production of foodstuffs from such animals, in order to protect public health by ensuring that such foodstuffs do not contain residues in quantities in excess of the maximum residue limits for active substances laid down pursuant to European Union Regulation (EEC) No 2377/90.

(10) "Adverse reaction" means a reaction to a veterinary medicinal product which is harmful and unintended

and which occurs at doses normally used in animals for the prophylaxis, diagnosis or treatment of disease or to restore, correct or modify a physiological function.";

(e) immediately after point 17 there shall be inserted the following new point:

"(17A) "Representative of the marketing authorisation holder" means the person, commonly known as local representative, designated by the marketing authorisation holder to represent him in Malta.";

(f) for point 18 there shall be substituted the following:

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

(g) for point 19 there shall be substituted the following:

"(19) "Risks relating to use of the product" means:

– any risk relating to the quality, safety and efficacy of the veterinary medicinal products as regards animal or human health;

– any risk of undesirable effects on the environment.";

(h) immediately after point (26) there shall be added the following points:

"(27) "Risk/benefit balance" means an evaluation of the positive therapeutic effects of the veterinary medicinal product in relation to the risks as defined above.

(28) "Veterinary prescription" means any prescription for a veterinary medicinal product issued by a professional person qualified to do so in accordance with applicable national law.

(29) "Name of veterinary medicinal product" means the name, which may be either an invented name not liable to confusion with the common name, or a common or scientific name accompanied by a trademark or the name of the marketing authorisation holder.

(30) "Common name" means the international non-proprietary name recommended by the World Health Organisation, or, if one does not exist, the usual common name.

(31) "Strength" means the content of active substances, expressed quantitatively per dosage unit, per unit of volume or weight according to the dosage form.

(32) "Immediate packaging" means the container or any other form of packaging that is in direct contact with the medicinal product.

(33) "Outer packaging" means the packaging into which is placed the immediate packaging.

(34) "Labelling" means information on the immediate or outer packaging.

(35) "Package leaflet" means the leaflet containing information for the user that accompanies the medicinal product.".

Substitutes regulation 3 of the principal regulations.

4. For regulation 3 of the principal regulations there shall be substituted the following:

"3. (1) These regulations shall not apply to:

(a) medicated feedingstuffs as defined in European Union Council Directive 90/167/EEC laying down the conditions governing the preparation, placing on the market and use of medicated feedingstuffs in the European Community;

(b) inactivated immunological veterinary medicinal products which are manufactured from pathogens and antigens obtained from an animal or animals from a holding and used for the treatment of that animal or the animals of that holding in the same locality;

(c) veterinary medicinal products based on radio-active isotopes;

(d) any additives covered by European Union Council Directive 70/524/EEC concerning additives in feedingstuffs where they are incorporated in animal feedingstuffs and

supplementary animal feedingstuffs in accordance with that Directive; and

(e) without prejudice to regulation 86, medicinal products for veterinary use intended for research and development trials.

However, medicated feedingstuffs referred to in paragraph (a) hereof may be prepared only from pre-mixes that have been authorised under these regulations.

(2) Except for the provisions on the possession, prescription, dispensing and administration of veterinary medicinal products, these regulations shall not apply to:

(a) any medicinal product prepared in a pharmacy in accordance with a veterinary prescription for an individual animal or a small group of animals, commonly known as the magistral formula; and

(b) any medicinal product prepared in a pharmacy in accordance with the prescriptions of a Pharmacopoeia and intended to be supplied directly to the end-user, commonly known as the officinal formula.".

Amends regulation 4 of the principal regulations.

5. For sub-regulation (2) of regulation 4 of the principal regulations there shall be substituted the following:

"(2) In the case of veterinary medicinal products intended solely for aquarium fish, cage birds, homing pigeons, terrarium animals, small rodents, and ferrets and rabbits kept exclusively as pets, Malta may permit exemptions from the provisions in regulations 5 to 8, provided that such products do not contain substances the use of which requires veterinary control and that all possible measures are taken to prevent unauthorised use of the products for other animals.".

Substitutes regulations 5 and 6 of the principal regulations.

6. For regulations 5 and 6 of the principal regulations there shall be substituted the following:

"5. (1) No veterinary medicinal product may be placed on the market of Malta unless a marketing authorisation has been granted by the Veterinary Services in accordance with these regulations or a marketing authorisation has been granted in accordance with European Union Regulation (EC) No 726/2004.

When a veterinary medicinal product has been granted an initial authorisation in accordance with the first paragraph, any additional species, strengths, pharmaceutical forms, administration routes, presentations, as well as any variations and extensions, shall also be granted an authorisation in accordance with the first paragraph or be included in the initial marketing authorisation. All these marketing authorisations shall be considered as belonging to the same global marketing authorisation, in particular for the purpose of the application of regulation 13(1).

(2) The marketing authorisation holder shall be responsible for the marketing of the medicinal product. The designation of a representative shall not relieve the marketing authorisation holder of his legal responsibility.

6. (1) A veterinary medicinal product may not be the subject of a marketing authorisation for the purpose of administering it to one or more food-producing species unless the pharmacologically active substances which it contains appear in Annexes I, II or III to European Regulation (EEC) No 2377/90.

(2) If an amendment to the Annexes to Regulation (EEC) No 2377/90 so warrants, the marketing authorisation holder or, where appropriate, the Veterinary Services shall take all necessary measures to amend or revoke the marketing authorisation within 60 days of the date on which the amendment to the Annexes to that Regulation was published in the Official Journal of the European Union.

(3) By way of derogation from subregulation (1) hereof, a veterinary medicinal product containing pharmacologically active substances not included in Annexes I, II or III to European Regulation (EEC) No 2377/90 may be authorised for particular animals of the equidae family that have been declared, in accordance with European Commission Decision 93/623/EEC establishing the identification document (passport) accompanying registered equidae and European Commission Decision 2000/68/EC amending Decision 93/623/EEC and establishing the identification of equidae for breeding and production, as not being intended for slaughter for human consumption. Such veterinary medicinal products shall neither include active substances that appear in Annex IV to European Regulation (EEC) No 2377/90 nor be intended for use in the treatment of conditions, as detailed in the authorised Summary of Product Characteristics, for which a veterinary medicinal product is authorized for animals of the equidae family.".

7. For regulation 8 of the principal regulations there shall be substituted the following: Substitutes regulation 8 of the principal regulations.

"8. (1) In the event of serious epizootic diseases, the Veterinary Services may provisionally allow the use of immunological veterinary medicinal products without a marketing authorisation, in the absence of a suitable medicinal product and after informing the European Commission of the detailed conditions of use.

(2) If an animal is being imported from, or exported to, a third country and is thereby subject to specific binding health rules, the Veterinary Services may permit the use, for the animal in question, of an immunological veterinary medicinal product that is not covered by a marketing authorisation in Malta but is authorized under the legislation of the third country. The Veterinary Services shall take all appropriate measures concerning the supervision of the importation and the use of such immunological products.".

8. For regulations 10 to 13 of the principal regulations there shall be substituted the following: Substitutes regulations 10 to 13 of the principal regulations.

"10. (1) The Veterinary Services shall take the necessary measures to ensure that, if there is no authorised veterinary medicinal product in Malta for a condition affecting a non food-producing species, by way of exception, the veterinarian responsible may, under his/her direct personal responsibility and in particular to avoid causing unacceptable suffering, treat the animal concerned with:

(a) a veterinary medicinal product authorised in Malta under these regulations or under European Regulation (EC) No 726/2004 for use with another animal species, or for another condition in the same species; or

(b) if there is no product as referred to in paragraph (a) –

(i) either a medicinal product authorised for human use in Malta in accordance with European Directive 2001/83/EC of the European Parliament and of the European Council or under European Regulation (EC) No 726/2004,

(ii) or, in accordance with specific national measures, a veterinary medicinal product authorised in another Member State in accordance with these regulations for use in the same species or in another species for the condition in question or for another condition; or

(c) if there is no product as referred to in paragraph (b), and within the limits of the law of Malta, a veterinary medicinal product prepared extemporaneously by a person authorized to do so under national legislation in accordance with the terms of a veterinary prescription.

The veterinarian may administer the medicinal product personally or allow another person to do so under the veterinarian's responsibility.

(2) By way of derogation from regulation 11, the provisions of subregulation (1) hereof shall also apply to the treatment by a veterinarian of an animal belonging to the equidae family provided that it has been declared, in accordance with European Commission Decisions 93/623/EEC and 2000/68/EC, as not being intended for slaughter for human consumption.

11. (1) The Veterinary Services shall take the necessary measures to ensure that, if there is no authorised veterinary medicinal product in Malta for a condition affecting a food-producing species, by way of exception, the veterinarian responsible may, under his direct personal responsibility and in particular to avoid causing unacceptable suffering, treat the animals concerned on a particular holding with:

(a) a veterinary medicinal product authorised in Malta under these regulations or under European Regulation (EC) No 726/2004 for use with another animal species, or for another condition in the same species; or

(b) if there is no product as referred to in paragraph (a), either:

(i) a medicinal product for human use authorised in Malta in accordance with European Directive 2001/83/EC or under European Regulation (EC) No 726/2004, or

(ii) a veterinary medicinal product authorised in another Member State in accordance with these regulations for use in the same species or in another food-producing species for the condition in question or for another condition; or

(c) if there is no product as referred to in paragraph (b), and within the limits of the law of Malta, a veterinary medicinal product prepared extemporaneously by a person authorized to do so under national legislation in accordance with the terms of a veterinary prescription.

The veterinarian may administer the medicinal product personally or allow another person to do so under the veterinarian's responsibility.

(2) Subregulation (1) hereof shall apply provided that pharmacologically active substances included in the medicinal product are listed in Annex I, II or III to European Regulation (EEC) No 2377/90, and that the veterinarian specifies an appropriate withdrawal period.

Unless the medicinal product used indicates a withdrawal period for the species concerned, the specified withdrawal period shall not be less than:

– 7 days for eggs,

– 7 days for milk,

– 28 days for meat from poultry and mammals including fat and offal,

– 500 degree-days for fish meat.

(3) With regard to homeopathic veterinary medicinal products in which active principles figure in Annex II to European Regulation (EEC) No 2377/90, the withdrawal period referred to in the second paragraph of subregulation (2) shall be reduced to zero.

(4) When a veterinarian has recourse to the provisions of subregulations (1) and (2) hereof, he shall keep adequate records of the date of examination of the animals, details of the owner, the number of animals treated, the diagnosis, the medicinal products prescribed, the doses administered, the duration of treatment and

the withdrawal periods recommended, and shall make these records available for inspection by the Veterinary Services for a period of at least five years.

(5) Without prejudice to the other provisions of these regulations, Malta shall take all necessary measures concerning the import, distribution, dispensing of and information on the medicinal products which they permit for administration to food-producing animals in accordance with subregulation (1)(b)(ii).

12. (1) For the purposes of obtaining a marketing authorisation in respect of a veterinary medicinal product, otherwise than under the procedure established by European Regulation (EC) No 726/2004, an application shall be lodged with the Veterinary Services.

In the case of veterinary medicinal products which are intended for one or more food-producing species but whose pharmacologically active substances have not yet been included, for the species in question, in Annexes I, II or III to European Regulation (EEC) No 2377/90, a marketing authorisation may not be applied for until after a valid application has been made for the establishment of maximum residue limits in accordance with that Regulation. At least six months shall elapse between a valid application for the establishment of maximum residue limits and an application for a marketing authorisation.

However, in the case of veterinary medicinal products referred to in regulation 6(3), a marketing authorisation may be applied for without a valid application in accordance with European Regulation (EEC) No 2377/90. All the scientific documentation necessary for the demonstration of the quality, safety and efficacy of the veterinary medicinal product, as provided for in subregulation (3) hereof, shall be submitted.

(2) A marketing authorisation may only be granted to an applicant established in the European Community.

(3) The application for marketing authorisation shall include all the administrative information and scientific documentation necessary for demonstrating the quality, safety and efficacy of the veterinary medicinal product in question. The file shall be submitted in accordance with Schedule I and shall contain, in particular, the following information:

(a) name or business name and permanent address or registered place of business of the person responsible for placing the product on the market and, if different, of the manufacturer or manufacturers involved and of the sites of manufacture;

(b) name of veterinary medicinal product;

(c) qualitative and quantitative particulars of all the constituents of the veterinary medicinal product, including its international non-proprietary name (INN) recommended by the WHO, where an INN exists, or its chemical name;

(d) description of the method of manufacture;

(e) therapeutic indications, contra-indications and adverse reactions;

(f) dosage for the various species of animal for which the veterinary medicinal product is intended, its pharmaceutical form, method and route of administration and proposed shelf life;

(g) reasons for any precautionary and safety measures to be taken when storing the veterinary medicinal product, administering it to animals and disposing of waste, together with an indication of potential risks that the veterinary medicinal product might pose to the environment, to human and animal health and to plants;

(h) indication of the withdrawal period in the case of medicinal products intended for food-producing species;

(i) description of the testing methods employed by the manufacturer;

(j) results of:

– pharmaceutical (physico-chemical, biological or microbiological) tests,

– safety tests and residue tests,

– pre-clinical and clinical trials;

– tests assessing the potential risks posed by the medicinal product for the environment. This impact shall be studied and consideration shall be given on a case-by-case basis to specific provisions seeking to limit it.

(k) a detailed description of the pharmacovigilance system and, where appropriate, the risk management system that the applicant will put in place;

(l) a summary in accordance with regulation 14 of the product characteristics, a mock-up of the immediate packaging and the outer packaging of the veterinary medicinal product, together with the package leaflet, in accordance with regulations 53 to 55;

(m) a document showing that the manufacturer is authorized in his own country to produce veterinary medicinal products;

(n) copies of any marketing authorisation obtained in another Member State or in a third country for the relevant veterinary medicinal product, together with a list of those Member States in which an application for authorisation submitted in accordance with these regulations is under examination. Copies of the summary of the product characteristics proposed by the applicant in accordance with regulation 14 or approved by the Veterinary Services in accordance with regulation 25 and copies of the package insert proposed, details of any decision to refuse authorisation, whether in the European Community or a third country and the reasons for that decision. All this information shall be updated on a regular basis;

(o) proof that the applicant has the services of a qualified person responsible for pharmacovigilance and has the necessary means for the notification of any adverse reaction suspected of occurring either in the European Community or in a third country;

(p) in the case of veterinary medicinal products intended for one or more food-producing species and containing one or more pharmacologically active substances not yet included, for the species in question, in Annexes I, II or III to European Regulation (EEC) No 2377/90, a document certifying that a valid application for the establishment of

maximum residue limits has been submitted to the Agency in accordance with the aforementioned Regulation.

The documents and particulars relating to the results of the tests referred to in point (j) of the first paragraph shall be accompanied by detailed and critical summaries, drawn up as specified in regulation 15.

13. (1) By way of derogation from point (j) of the first subparagraph of regulation 12(3), and without prejudice to the law relating to the protection of industrial and commercial property, the applicant shall not be required to provide the results of the safety and residue tests or of the pre-clinical and clinical trials if he can demonstrate that the medicinal product is a generic of a reference medicinal product which is or has been authorised under regulation 5 for not less than eight years in a Member State or the European Community.

A generic veterinary medicinal product authorized pursuant to this provision shall not be placed on the market until ten years have elapsed from the initial authorisation of the reference product.

The first subregulation shall also apply when the reference medicinal product was not authorised in the Member State in which the application for the generic medicinal product is submitted. In this case, the applicant shall indicate in the application the Member State in which the reference medicinal product is or has been authorised. At the request of the Veterinary Services, the competent authority of the other Member State shall transmit, within a period of one month, confirmation that the reference medicinal product is or has been authorized together with the full composition of the reference product and if necessary other relevant documentation. However, the ten-year period provided for in the second paragraph shall be extended to 13 years in the case of veterinary medicinal products for fish or bees or other species designated in accordance with the procedure referred to in Article 89(2) of European Union Council Directive 2004/28 EC.

(2) For the purposes of this regulation:

(a) "reference medicinal product" shall mean a product authorised within the meaning of regulation 5 in accordance with the provisions of regulation 12;

(b) "generic medicinal product" shall mean a medicinal product which has the same qualitative and quantitative

composition in active substances and the same pharmaceutical form as the reference medicinal product, and whose bioequivalence with the reference medicinal product has been demonstrated by appropriate bioavailability studies. The different salts, esters, ethers, isomers, mixtures of isomers, complexes or derivatives of an active substance shall be considered to be the same active substance, unless they differ significantly in properties with regard to safety and/or efficacy. In such cases, additional information intended to provide proof of the safety and/or efficacy of the various salts, esters or derivatives of an authorised active substance must be supplied by the applicant. The various immediate-release oral pharmaceutical forms shall be considered to be one and the same pharmaceutical form. Bioavailability studies neednot be required of the applicant if he can demonstrate that the generic medicinal product meets the relevant criteria as defined in the appropriate detailed guidelines.

(3) In cases where the veterinary medicinal product does not fall under the definition of a generic medicinal product set out in subregulation 2(b) or where bio-equivalence cannot be demonstrated through bioavailability studies or in the case of changes to the active substance(s), therapeutic indications, strength, pharmaceutical form or route of administration vis-‡-vis the reference medicinal product, the results of the appropriate safety and residue tests and pre-clinical tests or clinical trials shall be provided.

(4) Where a biological veterinary medicinal product which is similar to a reference biological veterinary medicinal product does not meet the conditions in the definition of generic medicinal products, owing to, in particular, differences relating to raw materials or in manufacturing processes of the biological veterinary medicinal product and the reference biological veterinary medicinal product, the results of appropriate pre-clinical tests or clinical trials relating to these conditions must be provided. The type and quantity of supplementary data to be provided must comply with the relevant criteria stated in Schedule I and the related detailed guidelines. The results of other tests and trials from the reference medicinal product's dossier shall not be provided.

(5) In the case of veterinary medicinal products intended for one or more food-producing species and containing a new active substance that has not been authorised in the European Community by 30 April 2004 the ten-year period provided for in the second paragraph of subregulation (1) shall be extended by

one year for each extension of the marketing authorisation to another food-producing species, if it is authorised within the five years following the granting of the initial marketing authorisation.

This period shall not, however, exceed a total of 13 years, for a marketing authorisation for four or more food-producing species.

The extension of the ten-year period to 11, 12, or 13 years for a veterinary medicinal product intended for food-producing species shall be granted only if the marketing authorisation holder also originally applied for determination of the maximum residue limits established for the species covered by the authorisation.

(6) Conducting the necessary studies, tests and trials with a view to the application of sub-regulations (1) to (5) and the consequential practical requirements shall not be regarded as contrary to patent-related rights or to supplementary-protection certificates for medicinal products.".

Adds new regulations 13A to 13D to the principal regulations.

9. Immediately after regulation 13 of the principal regulations there shall be added the following new regulations:

"Derogation.

13A. (1) By way of derogation from point (j) of the first paragraph of regulation 12(3), and without prejudice to the law on the protection of industrial and commercial property, the applicant shall not be required to provide the results of safety and residue tests or of pre-clinical tests or clinical trials if he can demonstrate that the active substances of the veterinary medicinal product have been in well-established veterinary use within the European Community for at least ten years, with recognised efficacy and an acceptable level of safety in terms of the conditions set out in Schedule I. In that event, the applicant shall provide appropriate scientific literature.

(2) The assessment report published by the Agency following the evaluation of an application for the establishment of maximum residue limits in accordance with European Regulation (EEC) No 2377/90 may be used in an appropriate manner as literature, particularly for the safety tests.

(3) If an applicant makes use of scientific literature to obtain authorisation for a food-producing species, and submits, in respect of the same medicinal product and with a view to obtaining authorisation for another

foodproducing species, new residue studies in accordance with European Regulation (EEC) No 2377/90, together with further clinical trials, it shall not be permissible for a third party to use such studies or such trials pursuant to regulation 13, for a period of three years from the grant of the authorization for which they were carried out.

Active substances.

13B. In the case of veterinary medicinal products containing active substances used in the composition of authorized veterinary medicinal products but not hitherto used in combination for therapeutic purposes, the results of safety and residue tests, if necessary, and new pre-clinical tests or new clinical trials relating to that combination shall be provided in accordance with point (j) of the first paragraph of regulation 12(3), but it shall not be necessary to provide scientific references relating to each individual active substance.

Use of Documentation.

13C. After the marketing authorisation has been granted, the marketing authorisation holder may allow use to be made of the pharmaceutical, safety and residues, pre-clinical and clinical documentation contained in the file for the veterinary medicinal product with a view to examining a subsequent application for a veterinary medicinal product having the same qualitative and quantitative composition in active substances and the same pharmaceutical form.

Derogation.

13D. By way of derogation from point (j) of the first paragraph of regulation 12(3), and in exceptional circumstances with respect to immunological veterinary medicinal products, the applicant shall not be required to provide the results of certain field trials on the target species if these trials cannot be carried out for duly substantiated reasons, in particular on account of other European Community provisions.".

Substitutes regulations 14 to 16 of the principal regulations.

10. For regulations 14 to 16 of the principal regulations there shall be substituted the following:

"14. The summary of the product characteristics shall contain, in the order indicated below, the following information:

(1) name of the veterinary medicinal product followed by the strength and the pharmaceutical form;

(2) qualitative and quantitative composition in terms of the active substances and constituents of the excipient, knowledge of which is essential for proper administration of the medicinal product. The usual common name or chemical description shall be used;

(3) pharmaceutical form;

(4) clinical particulars:

(i) target species,

(ii) indications for use, specifying the target species,

(iii) contra-indications,

(iv) special warnings for each target species,

(v) special precautions for use, including special precautions to be taken by the person administering the medicinal product to the animals,

(vi) adverse reactions (frequency and seriousness),

(vii) use during pregnancy, lactation or lay,

(viii) interaction with other medicinal products and other forms of interaction,

(ix) amounts to be administered and administration route,

(x) overdose (symptoms, emergency procedures, antidotes), if necessary,

(xi) withdrawal periods for the various foodstuffs, including those for which the withdrawal period is zero;

(5) pharmacological properties:

(i) pharmacodynamic properties,

(ii) pharmacokinetic particulars;

(6) pharmaceutical particulars:

(i) list of excipients,

(ii) major incompatibilities,

(iii) shelf life, when necessary after reconstitution of the medicinal product or when the immediate packaging is opened for the first time,

(iv) special precautions for storage,

(v) nature and composition of immediate packaging,

(vi) special precautions for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products, if appropriate;

(7) marketing authorisation holder;

(8) marketing authorisation number(s);

(9) date of the first authorisation or date of renewal of the authorisation;

(10) date of revision of the text.

For authorisation under regulation 13, those parts of the summary of product characteristics of the reference medicinal product referring to indications or dosage forms which were still covered by patent law at the time when a generic medicine was marketed need not be included.

15. (1) Applicants shall ensure that the detailed and critical summaries referred to in the second paragraph of regulation 12(3) are drafted and signed by persons with the requisite technical or professional qualifications, set out in a brief curriculum vitae, before being submitted to the Veterinary Services

(2) Persons with the technical or professional qualifications referred to in subregulation (1) hereof shall justify any use made of the scientific literature referred to in regulation 13A(1) in accordance with the conditions set out in Schedule I.

(3) A brief curriculum vitae of the persons referred to in subregulation (1) shall be appended to the detailed critical summaries.

16. (1) The Veterinary Services shall ensure that homeopathic veterinary medicinal products manufactured and placed on the market within the European Community are registered or authorised in accordance with regulations 17, 18 and 19, except where such veterinary medicinal products are covered by a registration or authorisation granted in accordance with national legislation on or before 31 December 1993. In the case of homeopathic medicinal products registered in accordance with regulation 17, regulation 32 and regulation 33(1) to (3) shall apply.

(2) The Veterinary Services shall establish a simplified registration procedure for the homeopathic veterinary medicinal products referred to in regulation 17.

(3) By way of derogation from regulation 10, homeopathic veterinary medicinal products may be administered to non-food producing animals under the responsibility of a veterinarian.

(4) By way of derogation from regulation 11(1) and (2), Malta shall permit the administration of homeopathic veterinary medicinal products intended for food-producing species the active constituents of which appear in Annex II to European Regulation (EEC) No 2377/90 under the responsibility of a veterinarian. The Veterinary Services shall take appropriate measures to control the use of veterinary homeopathic medicinal products registered or authorised in another Member State in accordance with these regulations for use in the same species.".

11. Regulation 17 of the principal regulations shall be amended as follows:- Amends regulation 17 of the principal regulations.

(a) for subregulation (1) thereof, there shall be substituted the following:

"(1) Without prejudice to the provisions of European Regulation (EEC) No 2377/90 on the establishment of maximum residue limits of pharmacologically active substances intended for food-producing animals, only homeopathic veterinary medicinal products which satisfy all

of the following conditions may be subject to a special, simplified registration procedure:

(a) they are administered by a route described in the European Pharmacopoeia or, in the absence thereof, by the Pharmacopoeias currently used officially in Malta;

(b) no specific therapeutic indication appears on the labelling of the veterinary medicinal product or in any information relating thereto;

(c) there is a sufficient degree of dilution to guarantee the safety of the medicinal product. In particular, the medicinal product shall not contain more than one part per 10 000 of the mother tincture."; and

(b) subregulation (3) thereof shall be deleted.

Amends regulation 18 of the principal regulations.

12. Regulation 18 of the principal regulations shall be amended as follows:

(a) for paragraph (c) thereof, there shall be substituted the following:

"(c) manufacturing and control file for each pharmaceutical form and a description of the method of dilution and potentisation,";

(b) for paragraph (f) thereof, there shall substituted the following:

"(f) one or more mock-ups of the outer packaging and immediate packaging of the medicinal products to be registered,"; and

(c) immediately after paragraph (g) thereof there shall be added the following new paragraph:

"(g) proposed withdrawal period together with all requisite justification.".

Substitutes regulation 19 of the principal regulation

13. For regulation 19 of the principal regulations there shall be substituted the following:

"19. (1) Homeopathic veterinary medicinal products other than those referred to in regulation 17(1) shall be authorized in accordance with regulations 12, 13A, 13B, 13C, 13D and 14.

(2) Malta may introduce or retain on its territory specific rules for the safety tests and pre-clinical and clinical trials of homeopathic veterinary medicinal products intended for pet species and non-food-producing exotic species other than those referred to in regulation 17(1), in accordance with the principles and characteristics of homeopathy as practised in Malta. In this case, the Veterinary Services shall notify the European Commission of the specific rules in force.".

Substitutes regulations 21 to 23 of the principal regulations.

14. For regulations 21, 22 and 23 of the principal regulations shall be substituted the following:

"21. (1) The Veterinary Services shall take all appropriate measures to ensure that the procedure for granting a marketing authorisation for a veterinary medicinal product is completed within a maximum of 210 days after the submission of a valid application.

Applications for marketing authorisations for the same veterinary medicinal product in two or more Member States, shall be submitted in accordance with regulations 31 to 43.

(2) Where Malta notes that another marketing authorisation application for the same medicinal product is being examined in another Member State, Malta shall decline to assess the application and shall advise the applicant that regulations 31 to 43 apply.

22. Where the Veterinary Services is informed, in accordance with paragraph (n) of regulation 12(3), that another Member State has authorised a veterinary medicinal product which is the subject of an application for authorisation in Malta, the Veterinary Services shall reject the application unless it was submitted in compliance with regulations 31 to 43.

23. In order to examine the application submitted pursuant to regulations 12 to 13D, the Veterinary Services:

(1) shall check that the documentation submitted in support of the application complies with regulations 12 to 13D and ascertain whether the conditions for the issue of the marketing authorisation have been fulfilled;

(2) may submit the medicinal product, its starting materials and if necessary intermediate products or other constituent materials for testing by an Official Medicines Control Laboratory or a laboratory that has designated for that purpose by the Veterinary Services, in order to ensure that the testing methods employed by the manufacturer and described in the application documents, in accordance with point (i) of the first paragraph of regulation 12(3), are satisfactory;

(3) may similarly check, in particular through consultation of a national or European Community reference laboratory, that the analytical method used for detecting residues presented by the applicant for the purposes of regulation 12(3)(j), second indent is satisfactory;

(4) may, where appropriate, require the applicant to provide further information as regards the items listed in regulations 12, 13a, 13b, 13c and 13d. Where the Veterinary Services take this course of action, the time-limits specified in regulation 21 shall be suspended until the further data required have been provided. Similarly, these time-limits shall be suspended for any period which the applicant may be given to provide oral or written explanations.".

Substitutes regulation 25 of the principal regulations.

15. For regulation 25 of the principal regulations there shall be substituted the following:

"25. (1) When granting a marketing authorisation, the Veterinary Services shall inform the holder of the summary of product characteristics that it has approved.

(2) The Veterinary Services shall take all necessary measures to ensure that information concerning the veterinary medicinal product, and in particular the labelling and package leaflet, is in conformity with the summary of product characteristics approved when the marketing authorisation was granted or subsequently.

(3) The Veterinary Services shall make the marketing authorisation publicly available without delay, together with the summary of product characteristics for each veterinary medicinal product that it has authorised.

(4) The Veterinary Services shall draw up an assessment report and comments on the file as regards the results

of the pharmaceutical, safety and residue tests and the pre-clinical and clinical trials of the veterinary medicinal product concerned. The assessment report shall be updated whenever new information becomes available which is of importance for the evaluation of the quality, safety or efficacy of the veterinary medicinal product concerned.

The Veterinary Services shall make the assessment report and its reasons for the opinion publicly available without delay, after deleting any information of a commercially confidential nature.".

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

Amends regulation 26 of the principal regulations.

(a) for subregulation (1) thereof, there shall be substituted the following:

"(1) The marketing authorisation may require the holder to indicate on the immediate packaging and, or the outer wrapping and the package leaflet, where the latter is required, other particulars essential for safety or health protection, including any special precautions relating to use and any other warnings resulting from the clinical and pharmacological trials prescribed in regulation 12(3)(j) and in regulations 13 to 13D or from experience gained during the use of the veterinary medicinal product once it has been marketed.";

(b) subregulation (2) thereof shall be deleted; and

(c) subregulation (3) shall be renumbered as subregulation (2) thereof and it shall be substituted as follows:

"(2) In exceptional circumstances, and following consultation with the applicant, the authorization may be granted subject to a requirement for the applicant to introduce specific procedures, in particular concerning the safety of the veterinary medicinal product, notification to the competent authorities of any incident relating to its use, and action to be taken. Such authorisations may be granted only for objective, verifiable reasons. Continuation of the authorization shall be linked to the annual reassessment of such conditions.".

17. Regulation 27 shall be amended as follows:

Amends regulation 27 of the principal regulations.

(a) for subregulations (2) and (3) thereof, there shall be substituted the following:

"(2) The Veterinary Services may require the applicant or the marketing authorisation holder to provide sufficient quantities of the substances to enable controls to be made on the identification of the presence of residues of the veterinary medicinal products in question.

At the Veterinary Services' request, the marketing authorisation holder shall provide his technical expertise to facilitate the implementation of the analytical method for detecting residues of the veterinary medicinal products in the national reference laboratory designated under European Union Council Directive 96/23/EC on measures to monitor certain substances and residues thereof in live animals and animal products.

(3) The authorisation holder shall immediately supply the Veterinary Services with any new information that might entail the amendment of the particulars or documents referred to in regulations 12(3), 13, 13A, 13B and 14 or Schedule I.

In particular, he shall immediately inform the Veterinary Services of any prohibition or restriction imposed by the competent authorities of any country in which the veterinary medicinal product is placed on the market and of any other new information which might influence the assessment of the benefits and risks of the veterinary medicinal product concerned.

In order to permit continuous assessment of the risk-benefit balance, the Veterinary Services may at any time ask the marketing authorisation holder to forward data demonstrating that the risk-benefit balance remains favourable.";

(b) subregulation (4) thereof shall be deleted;

(c) for subregulation (5) there shall be substituted the following:

"(5) The marketing authorisation holder shall immediately inform the Veterinary Services, with a view to authorisation, of any alteration which he proposes to make to

the particulars or documents referred to in regulations 12 to 13D.".

18. Immediately after regulation 27 of the principal regulations, there shall be added the following new regulation: Adds new regulation 27A to the principal regulations.

"Holder to inform the Veterinary Services.

27A. After a marketing authorisation has been granted, the holder of the authorisation shall inform the Veterinary Services of the date of the actual placing on the market of the veterinary medicinal product in Malta, taking into account the various presentations authorised.

The holder shall also notify the Veterinary Services if the product ceases to be placed on the market of Malta, either temporarily or permanently. Such notification shall, otherwise than in exceptional circumstances, be made no less than two months before the interruption in the placing on the market of the product.

Upon request by the Veterinary Services, particularly in the context of pharmacovigilance, the marketing authorization holder shall provide the Veterinary Services with all data relating to the volume of sales of the veterinary medicinal product, and any data in his possession relating to the volume of prescriptions.".

19. For regulation 28 of the principal regulations there shall be substituted the following: Substitutes regulation 28 of the principal regulations.

"28. (1) Without prejudice to subregulations (4) and (5), a marketing authorisation shall be valid for five years.

(2) The authorisation may be renewed after five years on the basis of a re-evaluation of the risk-benefit balance.

To this end, the marketing authorisation holder shall submit a consolidated list of all documents submitted in respect of quality, safety and efficacy, including all variations introduced since the marketing authorization was granted, at least six months before the marketing authorisation ceases to be valid in accordance with subregulatioon (1) hereof. The Veterinary Services may require the applicant to submit the listed documents at any time.

(3) Once renewed, the marketing authorisation shall be valid for an unlimited period, unless the Veterinary Services decides, on justified grounds relating to pharmacovigilance, to

proceed with one additional five-year renewal in accordance with subregulation (2).

(4) Any authorisation that is not followed within three years of its granting by the actual placing on the market of the authorised veterinary medicinal product in Malta, shall cease to be valid.

(5) When an authorised veterinary medicinal product previously placed on the market in Malta is no longer actually present on Malta for a period of three consecutive years, the authorisation granted for that veterinary medicinal product shall cease to be valid.

(6) The Veterinary Services may, in exceptional circumstances, and on human or animal health grounds, grant exemptions from subregulations (4) and (5). Such exemptions shall be duly justified.".

Substitutes regulation 30 of the principal regulations.

20. For regulation 30 of the principal regulations, there shall be substituted the following:

"30. The marketing authorisation shall be refused if the file submitted to the Veterinary Services does not comply with regulations 12 to 13D and regulation 15.

The authorisation shall also be refused if, after examination of the documents and particulars listed in regulations 12 and 13(1), it is clear that:

(a) the risk-benefit balance of the veterinary medicinal product is, under the authorised conditions of use, unfavourable; when the application concerns a veterinary medicinal product for zootechnical use, particular regard shall be had to the benefits for animal health and welfare and to consumer safety; or

(b) the product has no therapeutic effect or the applicant has not provided sufficient proof of such effect as regards the species of animal which is to be treated; or

(c) its qualitative or quantitative composition is not as stated; or

(d) the withdrawal period recommended by the applicant is not long enough to ensure that foodstuffs obtained

from the treated animal do not contain residues which might constitute a health hazard to the consumer, or is insufficiently substantiated; or

(e) the labelling or the package leaflet proposed by the applicant does not comply with these regulations; or

(f) the veterinary medicinal product is offered for sale for a use prohibited under other European Union Community provisions.

However, when a European Union Community legislative framework is in the course of being adopted, the Veterinary Services may refuse authorisation for a veterinary medicinal product where such action is necessary for the protection of public health, consumer or animal health.

The applicant or marketing authorisation holder shall be responsible for the accuracy of documents and data submitted.".

21. The heading of Chapter 4 of the principal regulations shall be substituted as follows:

Substitutes heading of Chapter 4 of the principal regulations.

"CHAPTER 4

Mutual recognition procedure and decentralized procedure".

22. For regulations 31 to 34 of the principal regulations there shall be substituted the following:

Substitutes regulations 31 to 34 of the principal regulations.

"31. (1) With a view to the granting of a marketing authorization for a veterinary medicinal product in more than one Member State, the applicant shall submit an application based on an identical dossier in those Member States. The dossier shall contain all the administrative information and scientific and technical documentation described in regulations 12 to 14. The documents submitted shall include a list of Member States concerned by the application.

The applicant shall request one Member State to act as reference Member State and to prepare an assessment report in respect of the veterinary medicinal product in accordance with subregulation (2) or (3).

Where appropriate, the assessment report shall contain an evaluation for the purposes of regulation 13(5) or regulation 13A(3).

(2) If the veterinary medicinal product has already received a marketing authorisation at the time of application, the concerned Member States shall recognize the marketing authorisation granted by the reference Member State. To this end, the marketing authorization holder shall request the reference Member State either to prepare an assessment report in respect of the veterinary medicinal product or, if necessary, to update any existing assessment report. The reference Member State shall prepare or update the assessment report within 90 days of receipt of a valid application. The assessment report together with the approved summary of product characteristics, labelling and package leaflet shall be forwarded to the concerned Member States and the applicant.

(3) If the veterinary medicinal product has not received authorisation by the time of application, the applicant shall request the reference Member State to prepare a draft assessment report and drafts of the summary of product characteristics, labelling and package leaflet. The reference Member State shall prepare these drafts within 120 days of the receipt of a valid application and shall send them to the concerned Member States and the applicant.

(4) Within 90 days after receipt of the documents referred to in sub-regulations (2) and (3), the Member States concerned shall approve the assessment report, the summary of product characteristics, the labelling and the package leaflet and inform the reference Member State accordingly. The reference Member State shall record the agreement of all parties, close the procedure and inform the applicant accordingly.

(5) Each Member State in which an application following paragraph 1 has been submitted shall adopt a decision in conformity with the approved assessment report, summary of product characteristics, labelling and package leaflet within 30 days after acknowledgement of the agreement.

32. (1) If Malta cannot, within the period allowed in regulation 31(4), agree with the assessment report, summary of product characteristics, labelling and package leaflet on grounds of a potential serious risk to human or animal health or to the environment, a detailed statement of the reasons shall be provided to the reference Member State, the other Member States concerned

and the applicant. The points of disagreement shall be referred without delay to the coordination group.

If a Member State to which an application has been submitted invokes the reasons referred to in regulation 64(1), it shall no longer be regarded as a Member State concerned by this Chapter.

(2) Within the coordination group, all Member States referred to in subregulation (1) shall use their best endeavours to reach agreement on the action to be taken. They shall provide the applicant with the opportunity to make his point of view known orally or in writing. If, within 60 days of the communication of the reasons for disagreement to the coordination group the Member States reach an agreement, the reference Member State shall record the agreement, close the procedure and inform the applicant accordingly. Regulation 31(5) shall apply in such cases.

(3) If within the period of 60 days the Member States fail to reach an agreement, the Agency shall be immediately informed with a view to application of the procedure laid down in Articles 36, 37 and 38 of European Union Council Directive 2004/28/EC. The Agency shall be provided with a detailed description of the matters on which agreement could not be reached and the reasons for the disagreement. The applicant shall be provided with a copy of such information.

(4) As soon as the applicant has been informed that the matter has been referred to the Agency, he shall forthwith forward to the Agency a copy of the information and documents referred to in the first subparagraph of regulation 31(1).

(5) In the case referred to in subregulation (3), the Member States that have approved the assessment report, summary of product characteristics, labelling and package leaflet of the reference Member State may, on request by the applicant, grant a marketing authorisation for the veterinary medicinal product without waiting for the outcome of the procedure laid down in Article 36 of European Union Council Directive 2004/28/EC. In that case, the authorisation granted shall be without prejudice to the outcome of that procedure.

33. (1) If two or more applications submitted in accordance with regulations 12 to 14 have been made for marketing authorisation for a particular veterinary medicinal product and Member States have adopted divergent decisions concerning the authorisation of that veterinary medicinal product, or suspension

or revocation of authorisation, a Member State, or the European Commission, or the marketing-authorisation holder may refer the matter to the Committee for Medicinal Products for Veterinary Use, hereinafter referred to as "the Committee", for the application of the procedure laid down in Articles 36, 37 and 38 of European Union Council Directive 2004/28/EC.

34. (1) Malta or the European Commission or the applicant or marketing authorisation holder shall, in specific cases where the interests of the European Community are involved, refer the matter to the Committee for the application of the procedure laid down in Articles 36, 37 and 38 of European Union Council Directive 2004/28/EC before a decision is reached on a request for a marketing authorization or on the suspension or withdrawal of an authorisation, or on any other variations to the terms of a marketing authorisation which appear necessary, so as to take account in particular of the information collected in accordance with Title VII.

Malta or the European Commission shall clearly identify the question which is referred to the Committee for consideration and shall inform the applicant or the marketing authorisation holder.

Malta and the applicant or the marketing authorisation holder shall forward to the Committee all available information relating to the matter in question.".

Substitutes regulation 37 of the principal regulations.

23. For regulation 37 of the principal regulations there shall be substituted the following:

"37. Regulations 32(3), (4) and (5) and 33 to 34 shall not apply to the homeopathic veterinary medicinal products referred to in regulation 17.

Regulations 31 to 34 shall not apply to the homeopathic veterinary medicinal products referred to in regulation 19(2).".

Amends regulation 38 of the principal regulations.

24. Immediately after subregulation (3) of regulation 38 of the principal regulations there shall be added the following subregulation:

"(4) Malta shall forward to the Agency a copy of the manufacturing authorisations referred to in subregulation (1). The Agency shall enter that information in the Community database referred to in Article 80(6) of European Union Council Directive 2004/28/EC.".

25. Paragraph (f) in regulation 44 of the principal regulations shall be substituted as follows:

Amends regulation 44 of the principal regulations.

"(f) comply with the principles and the guidelines on good manufacturing practice for medicinal products and use as starting materials only active substances which have been manufactured in accordance with the detailed guidelines on good manufacturing practice for starting materials;".

26. Immediately after regulation 44 of the principal regulations there shall be added the following new regulation:

Adds new regulation 44A to the principal regulations.

"*Starting materials.*

44A. (1) For the purposes of these regulations, manufacturing active substances for use as starting materials shall include the complete or partial manufacture or the import of an active substance used as a starting material, as defined in Part 2, Section C of Schedule I, and the various processes of dividing up, packaging or presentation prior to its incorporation in a veterinary medicinal product, including repackaging or re-labelling, such as carried out by a starting material distributor.".

27. Subregulation (1) of regulation 46 of the principal regulations shall be substituted as follows:

Amends regulation 46 of the principal regulations.

"(1) Malta shall ensure that the qualified person referred to in regulation 45 fulfils the conditions of qualification referred to in subregulations (2) and (3).".

28. Subregulation (1) of regulation 47 of the principal regulations shall be substituted as follows:

Amends regulation 47 of the principal regulations.

"(1) A person engaging, in Malta, in the activities of the person referred to in regulation 45(1) on the date on which these regulations became applicable, without complying with the provisions of regulation 46, shall be eligible to continue to engage in those activities within the Community.".

29. In regulation 48 of the principal regulations, for paragraph (b) of subregulation (1) thereof, there shall be substituted the following:

Amends regulation 48 of the principal regulations.

"(b) in the case of veterinary medicinal products coming from third countries, even if manufactured in the Community, each production batch imported has undergone in Malta a full qualitative analysis, a quantitative analysis of at least all the active substances, and all the other tests or controls necessary to ensure the quality of

veterinary medicinal products in accordance with the requirements of the marketing authorisation.".

Amends regulation 51 of the principal regulations.

30. Regulation 51 of the principal regulations shall be amended as follows:

(a) subregulation (1) shall be amended as follows:

(i) For the words from "(1) The following" to the words "of medicinal products –" there shall be substituted the following:

"Except in the case of the medicinal products referred to in regulation 17(1), the Veterinary Services shall approve the immediate packaging and outer packaging of veterinary medicinal products. Packaging shall bear the following information, which shall conform with the particulars and documents provided pursuant to regulations 12 to 13d and the summary of product characteristics, and shall appear in legible characters:";

(ii) for paragraphs (a) and (b) there shall be substituted the following:

"(a) the name of the medicinal product, followed by its strength and pharmaceutical form. The common name shall appear if the medicinal product contains only one active substance and its name is an invented name;

(b) a statement of the active substances expressed qualitatively and quantitatively per unit or according to the form of administration for a particular volume or weight, using the common names;";

(iii) for paragraph (e) there shall be substituted the following:

"(e) name or corporate name and permanent address or registered place of business of the marketing authorisation holder and, where appropriate, of the representative designated by the marketing authorization holder;";

(iv) for paragraph (f) there shall be substituted the following:

"(f) the species of animal for which the veterinary medicinal product is intended; the method and, if necessary, the route of administration. Space shall be provided for the prescribed dose to be indicated;";

(v) for paragraph (g) there shall be substituted the following:

"(g) the withdrawal period for veterinary medicinal products to be administered to food-producing species, for all the species concerned and for the various foodstuffs concerned (meat and offal, eggs, milk, honey), including those for which the withdrawal period is zero;";

(vi) for paragraph (j) shall be substituted the following:

"(j) specific precautions relating to the disposal of unused medicinal products or waste derived from veterinary medicinal products, where appropriate, as well as a reference to any appropriate collection system in place;";

(vii) for paragraph (l) shall be substituted the following:

"(l) the words "*For animal treatment only*" or, in the case of the medicinal products referred to in regulation 60, the words "*For animal treatment only — to be supplied only on veterinary prescription*."";

(b) immediately after subregulation (4) there shall be added the following subregulation:

"(5) In the case of medicinal products that have been granted a marketing authorisation under European Regulation (EC) No 726/2004, Malta may permit or require that the outer packaging bear additional information concerning distribution, possession, sale or any necessary precautions, provided that such information is not in infringement of Community law or the terms of the marketing authorisation, and is not promotional.

This additional information shall appear in a box with a blue border to separate it clearly from the information referred to in subregulation (1).".

Amends regulation 52 of the principal regulations.

31. Regulation 52 of the principal regulations shall be amended as follows:

(a) for the words from "(1)As regards" to "be necessary –" in subregulation (1) thereof, there shall be substituted the words:

"(1) As regards ampoules, the particulars listed in the first paragraph of regulation 51(1) shall be given on the outer package. On the immediate packaging, however, only the following particulars shall be necessary:"; and

(b) for subregulations (2) and (3) thereof, there shall be substituted the following:

"(2) As regards small immediate packaging containing a single dose, other than ampoules, on which it is impossible to give the particulars mentioned in subregulation (1), the requirements of regulation 51(1), (2) and (3) shall apply only to the outer package.

(3) The particulars mentioned in paragraphs (c) and (f) of subregulation (1) shall appear on the outer package and on the immediate packaging of the medicinal products in the language or languages of the country in which they are placed on the market.".

Substitutes regulation 53 of the principal regulations.

32. For regulation 53 of the principal regulations there shall be replaced by the following:

"53. Where there is no outer package, all the particulars which should feature on such a package pursuant to regulations 51 and 52 shall be shown on the immediate packaging.".

Amends regulation 54 of the principal regulations.

33. Regulation 54 of the principal regulations shall be amended as follows:

(a) for subregulation (1) thereof, there shall be substituted the following:

"(1) The inclusion of a package leaflet in the packaging of veterinary medicinal products shall be obligatory unless all the information required by this regulation can be conveyed on the immediate packaging and the outer packaging. Malta shall take all appropriate measures to ensure that the package leaflet relates solely to the veterinary medicinal product with which it is included. The package leaflet shall be written in

terms that are comprehensible to the general public and in the official language or languages of Malta.

Subregulation (1) shall not prevent the package leaflet from being written in several languages, provided that the information given is identical in all the languages.

The Veterinary Services may exempt labels and package leaflets for specific veterinary medicinal products from the obligation for certain particulars to appear and for the leaflet to be in the official language or languages of Malta, when the product is intended to be administered only by a veterinarian.";

(b) subregulation (2) shall be amended as follows:

(i) for the words from "(2) The package insert" to the words "by the Veterinary Services –" there shall be substituted the following:

"(2) The Veterinary Services shall approve package leaflets. Leaflets shall contain at least the following information, in the order indicated, which shall conform to the particulars and documents provided pursuant to regulations 12 to 13D and the approved summary of product characteristics:"; and

(ii) for paragraphs (a) and (b) there shall be substituted the following:

"(a) name or corporate name and permanent address or registered place of business of the marketing authorisation holder and of the manufacturer and, where appropriate, of the representative of the marketing authorization holder;

(b) name of the veterinary medicinal product followed by its strength and pharmaceutical form. The common name shall appear if the product contains only one active substance and its name is an invented name. Where the medicinal product is authorised according to the procedure provided for in regulations Articles 31 to 43 of European Union Council Directive 2004/28/EC under different names in Malta, a list of the names authorised in Malta;"; and

(c) subregulation (3) thereof shall be deleted.

Substitutes regulation 55 of the principal regulations.

34. For regulation 55 of the principal regulations there shall be substituted the following:

"55. Where the provisions of this Title are not observed and a formal notice addressed to the person concerned has been ineffectual, the Veterinary Services may suspend or revoke the marketing authorisation.".

Amends regulation 57 of the principal regulations.

35. Subregulation (2) of regulation 57 of the principal regulations shall be amended as follows:

(a) for the words from "(2) In addition to" to the words "no other information –" there shall be substituted the following:

"(2) In addition to the clear mention of the words "homeopathic veterinary medicinal product without approved therapeutic indications", the labelling and, where appropriate, package leaflet for the homeopathic veterinary medicinal products referred to in regulation 17(1) shall bear the following information and no other information:'; and

(b) for paragraph (a) thereof, there shall be substituted the following:

"(a) the scientific name of the stock or stocks followed by the degree of dilution, using the symbols of the Pharmacopoeia used in accordance with paragraph (8) of regulation 2. If the homeopathic veterinary medicinal product is composed of more than one stock, the labelling may mention an invented name in addition to the scientific names of the stocks,".

Substitutes heading of Title VI of the principal regulations.

36. For Title VI of the principal regulations, there shall be substituted the following:

"TITLE VI

POSSESSION, DISTRIBUTION AND DISPENSING OF VETERINARY MEDICINAL PRODUCTS".

Amends regulation 58 of the principal regulations.

37. Regulation 58 of the principal regulations shall be amended as follows:

(a) immediately after subregulation (3) there shall be inserted the following new subregulation:

"3A. The holder of a distribution authorisation shall have an emergency plan guaranteeing the effective implementation of any recall operation ordered by the competent authorities or undertaken in cooperation with the manufacturer of the medicinal product in question or the holder of the marketing authorisation.";

(b) immediately after subregulation (4) there shall be inserted the following new subregulation:

"(5) Any distributor, not being the marketing authorization holder, who imports a product from another Member State shall notify the marketing authorization holder and the Veterinary Services to which the product will be imported of his intention to import it. In the case of products which have not been granted an authorisation pursuant to European Regulation (EC) No 726/2004, the notification to the Veterinary Services shall be without prejudice to additional procedures provided for in the legislation of Malta.".

Amends regulation 59 of the principal regulations.

38. Regulation 59 of the principal regulations shall be amended as follows:

(a) subregulation (2) shall be amended as follows:

(i) for the words from "(2) Any person permitted" to the words "or outgoing transaction –" there shall be substituted the following:

"(2) Any person permitted under subregulation (1) to supply veterinary medicinal products shall be required to keep detailed records for veterinary medicinal products that may be supplied only on prescription, the following information being recorded in respect of each incoming or outgoing transaction:"; and

(ii) in the third paragraph thereof, for the words "for a period of the years" there shall be substituted the words:

"for a period of five years";

(b) for subregulation (3) there shall be substituted the following:

"(3) The Veterinary Services may permit the supply in Malta of veterinary medicinal products for foodproducing

animals for which a veterinary prescription is required by or under the supervision of a person registered for this purpose who provides guarantees with respect to qualifications, record-keeping and reporting in accordance with national law. The Veterinary Services shall notify the European Commission of relevant provisions of national law. This provision shall not apply to the supply of veterinary medicinal products for the oral or parenteral treatment of bacterial infections."; and

(c) subregulation (4) thereof shall be deleted.

Amends regulation 60 of the principal regulations.

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

(a) for the words from "Without prejudice" to the words "medicinal products –" there shall be substituted by the following:

"Without prejudice to stricter European Community or national rules relating to dispensing veterinary medicinal products and serving to protect human and animal health, a veterinary prescription shall be required for dispensing to the public the following veterinary medicinal products:";

(b) immediately after paragraph (a) thereof there shall be inserted the following new paragraph:

"(aa) veterinary medicinal products for foodproducing animals.

However, Malta may grant exemptions from this requirement according to criteria established in accordance with the procedure referred to in Article 89(2) of European Union Council Directive 2004/28/EC;";

(c) subparagraph (iii) of paragraph (b) shall be deleted and subparagraph (iv) shall be renumbered as subparagraph (iii) thereof;

(d) for subparagraph (d) there shall be substituted the following:

"(d) official formula, within the meaning of Article 3(2)(b) of European Union Council Directive 2004/28/EC, intended for food-producing animals."; and

(e) for the words from "In addition," to the words "sub-regulation (1) apply." there shall be substituted the following:

"Malta shall take all necessary measures to ensure that, in the case of medicinal products supplied only on prescription, the quantity prescribed and supplied shall be restricted to the minimum amount required for the treatment or therapy concerned.

In addition, a prescription shall be required for new veterinary medicinal products containing an active substance that has been authorised for use in a veterinary medicinal product for fewer than five years.".

Amends regulation 62 of the principal regulations.

40. In regulation 62 of the principal regulations, for the words "In the territory of Malta," to the words "in regulation 61." there shall be substituted the following:

"Malta shall ensure that the owners or keepers of food-producing animals can provide proof of purchase, possession and administration of veterinary medicinal products to such animals for five years after their administration, including when the animal is slaughtered during the five-year period.".

Amends regulation 63 of the principal regulations.

41. In regulation 63 of the principal regulations, for the words from "Notwithstanding regulations 9 and 60," to the words "are satisfied –" there shall be substituted the following:

"By way of derogation from regulation 9 and without prejudice to regulation 60, Malta shall ensure that veterinarians providing services in another Member State can take with them and administer to animals small quantities of veterinary medicinal products not exceeding daily requirements other than immunological veterinary medicinal products which are not authorised for use in the Member State in which the services are provided, provided that the following conditions are satisfied:".

Amends regulation 64 of the principal regulations.

42. Immediately at the end of subregulation (1) of regulation 64 of the principal regulations, there shall be added the following paragraph:-

"Malta may also invoke the provisions of the first paragraph in order to withhold marketing authorisation in accordance with a decentralised procedure as provided for in Articles 31 to 43 of European Union Council Directive 2004/28/EC.".

Amends regulation 65 of the principal regulations.

43. For subregulation (2) of regulation 65 of the principal regulations, there shall be substituted the following:

"(2) Malta may impose specific requirements on veterinary practitioners and other health-care professionals in respect of the reporting of suspected serious or unexpected adverse reactions and human adverse reactions.".

Amends regulation 66 of the principal regulations.

44. Regulation 66 of the principal regulations shall be amended as follows:

(a) for the words from "In order to ensure" to the words "such information scientifically." there shall be substituted the following:

"In order to ensure the adoption of appropriate and harmonised regulatory decisions concerning the veterinary medicinal products authorised within the European Community, having regard to information obtained about suspected adverse reactions to veterinary medicinal products under normal conditions of use, Malta shall administer a veterinary pharmacovigilance system. This system shall be used to collect information useful in the surveillance of veterinary medicinal products, with particular reference to adverse reactions in animals and in human beings relating to the use of veterinary medicinal products, and to evaluate such information scientifically."; and

(b) immediately after the second paragraph ending with the words "medicinal products." there shall be inserted the following new paragraph:

"Malta shall ensure that suitable information collected within this system is communicated to other Member States and the Agency. This information shall be recorded in the database referred to in point (k) of the second subparagraph of Article 57(1) of European Regulation (EC) No 726/2004 and shall be permanently accessible to all Member States and without delay to the public.".

Adds new regulation 66A to the principal regulations.

45. Immediately after regulation 66 of the principal regulations there shall be added the following new regulation:

"Management of Funds.

66A. The management of funds intended for activities connected with pharmacovigilance, the operation of communication networks and market surveillance shall be under the permanent control of the Veterinary Services in order to guarantee their independence.".

46. For the words "The qualified person shall be responsible for the following -" in regulation 67 of the principal regulations, there shall be substituted the following: Amends regulation 67 of the principal regulations.

"That qualified person shall reside in the European Community and shall be responsible for the following:".

47. For regulation 68 of the principal regulations there shall be substituted the following: Substitutes regulation 68 of the principal regulations.

"68. (1) The marketing authorisation holder shall maintain detailed records of all suspected adverse reactions occurring within the European Community or in a third country.

Save in exceptional circumstances, these reactions shall be communicated electronically in the form of a report in accordance with the guidelines referred to in regulation 70(1).

(2) The marketing authorisation holder shall 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, and no later than 15 days following receipt of the information.

The marketing authorisation holder shall also record all suspected serious adverse reactions and human adverse reactions related to the use of veterinary medicinal products of which he can reasonably be expected to have knowledge, and report them promptly to the Veterinary Services, and no later than 15 days following receipt of the information.

(3) The marketing authorisation holder shall ensure that all suspected serious unexpected adverse reactions, human adverse reactions and any suspected transmission via a veterinary medicinal product of any infectious agent occurring on the territory of a third country are reported promptly in accordance with the guidelines referred to in regulation 70(1), so that they are available to the Agency and the competent authorities of the Member States in which the veterinary medicinal product is authorised, and no later than 15 days following the receipt of the information.

(4) By way of derogation from subregulations (2) and (3), in the case of veterinary medicinal products which are covered by European Directive 87/22/EEC, have benefited from the authorisation procedures under Articles 31 and 32 of European

Union Council Directive 2004/28/EC or have been the subject of the procedures provided for in Articles 36, 37 and 38 of European Union Council Directive 2004/28/EC, the marketing authorisation holder shall additionally ensure that all suspected serious adverse reactions and human adverse reactions occurring in the Community are reported in such a way so as to be accessible to the reference Member State or a competent authority designated as reference Member State. The reference Member State shall assume responsibility for the analysis and follow-up of any such adverse reactions.

(5) Unless other requirements have been laid down as a condition for the granting of the marketing authorisation or subsequently as indicated in the guidelines referred to in regulation 70(1), reports of all adverse reactions shall be submitted to the Veterinary Services in the form of a periodic safety update report, immediately upon request or at least every six months after authorisation until the placing on the market. Periodic safety update reports shall also be submitted immediately upon request or at least every six months during the first two years following the initial placing on the market, and once a year for the following two years. Thereafter, the reports shall be submitted at three-yearly intervals, or immediately upon request.

The periodic safety update reports shall include a scientific evaluation of the risk-benefit balance of the veterinary medicinal product.

(6) Following the granting of a marketing authorisation, the holder of such authorisation may request the amendment of the periods referred to in subregulation (5) hereof in accordance with the procedure laid down by European Commission Regulation (EC) No 1084/2003.

(7) The holder of a marketing authorisation may not communicate information relating to pharmacovigilance concerns to the general public in relation to its authorized veterinary medicinal product without giving prior or simultaneous notification to the Veterinary Services.

In any case, the marketing authorisation holder shall ensure that such information is presented objectively and is not misleading.

Malta shall take the necessary measures to ensure that a marketing authorisation holder who fails to discharge these

obligations is subject to effective, proportionate and dissuasive penalties.".

48. For subregulation (2) of regulation 71 of the principal regulations there shall be substituted the following: Amends regulation 71 of the principal regulations.

"(2) If urgent action is necessary for protecting human or animal health, Malta may suspend the marketing authorisation of a veterinary medicinal product, provided that the Agency, the Commission and the other Member States are informed on the following working day at the latest.".

49. Regulation 72 of the principal regulations shall be amended as follows: Amends regulation 72 of the principal regulations.

(a) For subregulation (1) thereof, there shall be substituted the following:

"(1) The Veterinary Services shall ensure, by means of repeated inspections and, if necessary, unannounced inspections, and where appropriate, by asking an Official Medicines Control Laboratory or a laboratory designated for that purpose to conduct tests on samples, that the legal requirements relating to veterinary medicinal products are complied with.

The Veterinary Services may also carry out unannounced inspections at the premises of manufacturers of active substances used as starting materials for veterinary medicinal products, and of the premises of the marketing authorisation holder whenever it considers that there are grounds for suspecting non-compliance with the provisions of regulation Article 51 of European Union Council Directive 2004/28/EC. Such inspections may also be carried out at the request of another Member State, the Commission or the Agency.

In order to verify whether the data submitted in order to obtain a conformity certificate comply with the monographs of the European Pharmacopoeia, the standardization body for nomenclatures and quality norms within the meaning of the Convention relating to the elaboration of a European Pharmacopoeia (European Directorate for the Quality of Medicines) may ask the Commission or the Agency to request such an inspection when the starting material concerned is the subject of a European Pharmacopoeia monograph.

The Veterinary Services may carry out inspections of starting material manufacturers at the manufacturer's own request.

Such inspections shall be carried out by authorized representatives of the Veterinary Services who shall be empowered to:

(a) inspect manufacturing or trading establishments and any laboratories entrusted by the holder of the manufacturing authorisation with the task of carrying out control tests pursuant to regulation 24;

(b) take samples including with a view to an independent analysis by an Official Medicines Control Laboratory or by a laboratory designated for that purpose by Malta;

(c) examine any documents relating to the object of the inspection, subject to the provisions in force in Malta placing restrictions on these powers with regard to the description of the manufacturing method;

(d) inspect the premises, records and documents of marketing authorisation holders or any firms performing the activities described in Title VII, and in particular regulations 67 and 68 thereof, on behalf of a marketing authorisation holder.";

(b) subregulation (3) thereof shall be substituted by the following:

"(3) The authorised representatives of the Veterinary Services shall report after each of the inspections mentioned in subregulation (1) on whether the principles and guidelines on good manufacturing practice referred to in Article 51 of European Union Council Directive 2004/28/EC or, where appropriate, the requirements set out in Title VII, are being complied with. The inspected manufacturer or market authorization holder shall be informed of the content of such reports."; and

(c) immediately at the end of subregulation (3) thereof, there shall be added the following new subregulations:

"(4) Without prejudice to any arrangements which may have been concluded between the European Community and a third country, Malta, the European Commission or the Agency may require a manufacturer established in a third country to undergo an inspection as referred to in subregulation (1).

(5) Within 90 days after an inspection as referred to in subregulation (1), a certificate of good manufacturing practice shall be issued to the manufacturer if the inspection established that the manufacturer in question is complying with the principles and guidelines on good manufacturing practice as provided for by Community law.

In the event of an inspection carried out at the request of the European Pharmacopoeia, a certificate of compliance with the monograph shall be issued, if appropriate.

(6) Malta shall enter the certificates of good manufacturing practice which they issue in a Community database managed by the Agency on behalf of the Community.

(7) If the outcome of the inspection as referred to in subregulation (1) is that the manufacturer does not comply with the principles and guidelines of good manufacturing practice as provided for by Community legislation, the information shall be entered in the Community database as referred to in subregulation (6).".

Substitutes regulation 74 of the principal regulations.

50. Regulation 74 of the principal regulations shall be substituted as follows:

"74. (1) Where it considers it necessary for reasons of human or animal health, the Veterinary Services may require the marketing authorisation holder for an immunological veterinary medicinal product to submit samples of batches of the bulk product and, or veterinary medicinal product, for control by an Official Medicines Control Laboratory before the product is put into circulation.

(2) On request by the Veterinary Services, the marketing authorisation holder shall promptly supply the samples referred to in subregulation (1), together with the reports of the control referred to in regulation 73(2).

The Veterinary Services shall inform all the other Member States in which the veterinary medicinal product is authorised as well as the European Directorate for the Quality of Medicines of its intention to control batches or the batch in question.

(3) After studying the control reports referred to in regulation 73(2), the laboratory responsible for the control shall repeat, on the samples provided, all the tests carried out by the manufacturer on the finished product, in accordance with the relevant provisions shown in the dossier for marketing authorisation.

The list of tests to be repeated by the laboratory responsible for the control shall be restricted to justified tests, provided that all Member States concerned, and if appropriate the European Directorate for the Quality of Medicines, agree to this.

For immunological veterinary medicinal products authorized under European Regulation (EC) No 726/2004, the list of tests to be repeated by the control laboratory may be reduced only after agreement by the Agency.

(4) Malta shall recognise the results of the tests.

(5) Unless the European Commission is informed that a longer period is necessary to conduct the tests, the Veterinary Services shall ensure that this control is completed within 60 days of receipt of the samples.

The Veterinary Services shall notify the other Member States concerned, the European Directorate for the Quality of Medicines, the marketing authorisation holder and, if appropriate, the manufacturer, of the results of the tests within the same period of time.

If the Veterinary Services concludes that a batch of a veterinary medicinal product is not in conformity with the control report of the manufacturer or the specifications provided for in the marketing authorisation, it shall take all the necessary measures vis-a-vis the marketing authorisation holder and the manufacturer, where appropriate, and shall inform accordingly the other Member States in which the veterinary medicinal product is authorised.";

Amends regulation 75 of the principal regulations.

51. Regulation 75 of the principal regulations shall be amended as follows:

(a) subregulation (1) shall be amended as follows:

(i) for the words from "(1) The Veterinary Services" to the words "is clear that-" there shall be substituted the words:

"The Veterinary Services shall suspend, revoke, withdraw or vary marketing authorisations when it is clear that:";

(ii) for paragraph (a) there shall be substituted the following:

"(a) the risk-benefit assessment of the veterinary medicinal product is, under the authorized conditions of use, unfavourable, particular regard being had to the benefits for animal health and welfare and to consumer safety, when the authorisation concerns a veterinary medicinal product for zootechnical use;";

(iii) the words from "However, pending" to the words "or animal health;" in paragraph (e) shall be deleted;

(iv) for paragraph (f) there shall be substituted the following:

"(f) information given in the application documents pursuant to regulations 12 to 13D and 27 is incorrect;";

(v) paragraph (h) shall be deleted; and

(vi) immediately at the end of paragraph (h), the following second paragraph shall be added:

"However, when a Community legislative framework is in the course of being adopted, the Veterinary Services may refuse authorisation for a veterinary medicinal product where such action is necessary for the protection of public health, consumer and animal health."; and

(b) subregulation (2) shall be amended as follows:

(i) for the words from "(2) Authorisation" to the words "established that-" there shall be substituted the following words:

"Marketing authorisations may be suspended, revoked, withdrawn or varied when it is established that:"; and

(ii) for paragraph (a) there shall be substituted the following:

"(a) the particulars supporting the application, as provided for in regulations 12 to 13D, have not been amended in accordance with regulations 27(1) and (5);".

Amends regulation 76 of the principal regulations.

52. In regulation 76 of the principal regulations, for paragraph (a) of subregulation (1) there shall be substituted the following:

"(a) it is clear that the risk-benefit assessment of the veterinary medicinal product is, under the authorized conditions of use, unfavourable, particular regard being had to the benefits for animal health and welfare and to the safety and health benefits for the consumer, when the authorisation concerns a veterinary medicinal product for zootechnical use.".

Amends regulation 77 of the principal regulations.

53. In regulation 77 of the principal regulations, immediately after subregulation (2) thereof, there shall be added the following new subregulation:

"(3) The Veterinary Services shall prohibit the advertising to the general public of veterinary medicinal products that:

(a) in accordance with regulation 60, are available on veterinary prescription only; or

(b) contain psychotropic drugs or narcotics, such as those covered by the United Nations Conventions of 1961 and 1971.".

Substitutes regulation 81 of the principal regulations.

54. Regulation 81 of the principal regulations shall be substituted as follows:

"81. The Veterinary Services shall communicate the appropriate information to competent authorities in other Member States, particularly regarding compliance with the requirements adopted for the authorisations referred to in regulation 38, for the certificates referred to in regulation 72(5) or for authorization to place products on the market.

Upon reasoned request, the Veterinary Services shall forthwith communicate the reports referred to in regulation 72(3) to the competent authorities of another Member State.

The conclusions reached following an inspection as referred to in regulation 72(1) carried out by the inspectors of the Veterinary Services shall be valid for the European Community.

However, by way of exception, if Malta has not been able, for serious reasons of human or animal health, to accept the conclusions of an inspection as referred to in regulation 72(1), the Veterinary Services shall forthwith inform the Commission and the Agency.

When the European Commission is informed of such serious reasons, it may, after consulting the Veterinary Services, ask the inspector of the Veterinary Services to carry out a new inspection; the inspector may be accompanied by two other inspectors from Member States that are not parties to the disagreement.".

Amends regulation 85 of the principal regulations.

55. In regulation 85 of the principal regulations, for the words from "Marketing authorizations" to the words "Government Gazette" there shall be substituted the following:

"Decisions to grant or revoke a marketing authorization shall be made publicly available.".

Substitutes regulation 86 of the principal regulations.

56. Regulation 86 of the principal regulations shall be substituted as follows:

"86. The Veterinary Services shall not permit foodstuffs for human consumption to be taken from test animals unless an appropriate withdrawal period has been established. The withdrawal period shall either:

(a) be at least as laid down in regulation 11(2) including, where appropriate, a safety factor reflecting the nature of the substance being tested; or

(b) if maximum residue limits have been established by the Community in accordance with Regulation (EEC) No 2377/90, ensure that this maximum limit will not be exceeded in foodstuffs.".

Adds new regulation 87 to the principal regulations.

57. Immediately after regulation 86 of the principal regulations there shall be added the following new regulation:

"Collection.

87. The Veterinary Services shall ensure that appropriate Systems collection systems are in place for veterinary medicinal products that are unused or expired.".

Ippubblikat mid-Dipartiment ta' l-Informazzjoni (doi.gov.mt) — Valletta — *Published by the Department of Information (doi.gov.mt) — Valletta*
Mitbugh fl-Istamperija tal-Gvern — *Printed at the Government Printing Press*
Prezz Lm2.00ċ – *Price Lm2.00c*