



STATUTORY INSTRUMENT

**S.I. No.            of 2007**

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EUROPEAN COMMUNITIES (ANIMAL REMEDIES) (No. 2)  
REGULATIONS 2007

**(Prn.            )**

S.I. No. of 2007

EUROPEAN COMMUNITIES (ANIMAL REMEDIES) (No. 2)  
REGULATIONS 2007

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S.I. No. of 2007

EUROPEAN COMMUNITIES (ANIMAL REMEDIES) (No. 2)  
REGULATIONS 2007

I, MARY COUGHLAN, Minister for Agriculture, Fisheries and Food, in exercise of the powers conferred on me by section 3 of the European Communities Act 1972 (No. 27 of 1972) for the purpose of giving effect to Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to veterinary medicinal products<sup>1</sup> as amended by Directive 2004/28/EC of the European Parliament and of the Council of 31 March 2004<sup>2</sup> and to give further effect to Council Regulation (EEC) No. 2377/90 of 26 June 1990<sup>3</sup> and to give full effect to Regulation (EC) No. 726/2004 of the European Parliament and of the Council of 31 March 2004<sup>4</sup>, so far as that Regulation relates to a veterinary medicinal product, hereby make the following regulations:

PART I

PRELIMINARY AND GENERAL

***Citation and commencement.***

1. (1) These Regulations may be cited as the European Communities (Animal Remedies) (No. 2) Regulations 2007.

(2) Regulation 43(9) comes into operation on 1 January 2008.

***Interpretation.***

2. (1) In these Regulations—

“Act” means Animal Remedies Act 1993 (No. 23 of 1993);

“Agency” means European Medicines Agency established by Regulation (EC) No. 726/2004;

“animal remedies authorisation” means—

(a) a veterinary product authorisation within the meaning of Article 5 of the Directive, issued by the Board,

(b) a licence granted under the Therapeutic Substances Act 1932 (No. 25 of 1932) in respect of an animal remedy named on the licence, until the date of expiry of the licence,

<sup>1</sup>O.J. L 311, 28.11.2001

<sup>2</sup>O.J. L 136, 30.04.2004

<sup>3</sup>O.J. L 224, 18.08.1990

<sup>4</sup>O.J. L 136, 30.04.2004

- (c) a licence under Regulation 16, 17, or 19,
- (d) a marketing authorisation granted under Regulation (EC) No. 726/2004,
- (e) a registration granted by the Board in accordance with Regulation 7(2), or
- (f) such other document, registration, licence or authorisation deemed by these Regulations to be an animal remedies authorisation;

“animal” has the same meaning as it has in Section 2 of the Act and in the Animal Remedies Act 1993 (Section 2) Order 2005 (S.I. No. 733 of 2005);

“authorised officer” means a person who is an authorised officer within the meaning of the Act;

“Board” means Irish Medicines Board;

“companion animal” includes a domestic dog, cat, rabbit (other than a rabbit kept for human consumption), a small rodent, cage bird, homing pigeon, terrarium animal and an aquarium fish or an equid declared as not intended for use as food for human consumption in accordance with the European Communities (Equine Stud-Book Competition) Regulations 2004 (S.I. No. 399 of 2004));

“companion animal medicine” means an animal remedy authorised by the Board for administration to a companion animal only;

“companion animal medicine seller” means a person registered under Regulation 33;

“Council Regulation (EEC) No. 2377/90” means Council Regulation (EEC) 2377/90 of 26 June, 1990, as amended and any act of an institution of the European Union which amends, extends or replaces the said Council Regulation (EEC) No. 2377/90;

“Directive” means Directive 2001/82/EC of the European Parliament and of the Council, of 6 November 2001, as amended by Directive 2004/28/EC, of the European Parliament and of the Council of 31 March 2004;

“EEA Agreement” means the Agreement on the European Economic Area signed in Oporto on 2 May 1992 as adjusted by the Protocol to that Agreement done at Brussels on 17 March 1993<sup>5</sup>;

“EEA State” means a state which is a contracting state to the EEA Agreement within the meaning given to that phrase in the European Communities (Amendment) Act 1993 (No. 25 of 1993);

“European Economic Area” means the European Economic Area created by the EEA Agreement;

<sup>5</sup>O.J. L 1, 3.1.1994

“food producing animal” means an animal of the bovine, caprine, ovine or porcine species, poultry, rabbits, deer, fish or honey bees, if such rabbits, deer or fish are intended for use as food for human consumption, or equidae intended for use as food for human consumption in accordance with the European Communities (Equine Stud-Book and Competition) Regulations 2004, (S.I. No. 399 of 2004);

“group veterinary practice” means a formally associated group of registered veterinary practitioners who are available to provide services of veterinary medicine and surgery and to carry out clinical procedures on animals under their care;

“holder” in respect of a registration, licence, approval or animal remedies authorisation means the person to whom the registration, licence, approval, or animal remedies authorisation is granted and who is identified as the holder on the registration, licence, approval or animal remedies authorisation, and reference to a holder includes a reference to a representative, employee, servant or agent of the holder;

“homeopathic animal remedy” has the same meaning as a homeopathic veterinary medicinal product;

“human consumption” includes a thing intended for incorporation in, or manufacture into, a food intended for human consumption and kindred words shall be construed accordingly;

“immunological animal remedy” has the same meaning as immunological veterinary medicinal product;

“imported” means brought into the State from outside the State and “importation” shall be construed accordingly;

“intramammary animal remedy” means an animal remedy which is licensed for sale (whether being packaged or otherwise) as an intramammary preparation for the prevention or treatment of mastitis in an animal, is intended for use exclusively as such preparation and whose container and any other outer packaging bears a notice clearly indicating that the animal remedy is sold or supplied for such use only;

“meat” includes the edible produce of fish;

“medicinal product” has the meaning assigned to it by Directive 2001/83/EC of 6 November 2001<sup>6</sup>;

“medicated feedingstuff” means a mixture of an animal remedy or remedies and feed or feeds which is ready prepared for placing on the market or for use and which is intended to be fed to animals without further processing because of its curative or preventative or other properties as an animal remedy;

<sup>6</sup>O.J. L 311, 28.11.2001

“pharmacist” means a person lawfully keeping open for dispensing or compounding medical prescriptions or for the sale of poisons under the Pharmacy Acts 1875 to 1977;

“pharmacy” means a shop being lawfully kept open for the dispensing or compounding of medical prescriptions or for the sale of poisons under the Pharmacy Acts 1875 to 1977;

“pre-mix for a medicated feedingstuff” means an animal remedy prepared in advance with a view to the subsequent manufacture of medicated feedingstuffs;

“record” means a record in writing and—

- (a) a disc, tape, sound-track or other device, including an electronic device, in which information, sounds or signals are embodied so as to be capable (with or without the aid of some other instrument) of being reproduced in legible or audible form,
- (b) a film, tape or other device, including an electronic device, in which visual images are embodied so as to be capable (with or without the aid of some other instrument) of being reproduced in visual form, and
- (c) a photograph, and a reference to a copy of a record includes—
  - (i) in the case of a record to which paragraph (a) refers, a transcript of the sounds or signals embodied in it,
  - (ii) in the case of a record to which paragraph (b) refers, a still reproduction of the images embodied in it, and
  - (iii) in the case of a record to which paragraphs (a) and (b) refer, such a transcript together with such a still reproduction;

“registered veterinary practitioner” means a veterinary practitioner registered under the Veterinary Practice Act 2005 (No. 22 of 2005);

“Regulation (EC) No. 726/2004” means Regulation (EC) No. 726/2004 of the European Parliament and of the Council of the 31 March 2004 and any act of an institution of the European Union which amends, extends or replaces that Regulation;

“third country” means a state other than a member state of the European Union;

“veterinary prescription” means a written prescription (containing the information specified in Schedule 3) issued by a registered veterinary practitioner in respect of an animal under his or her care that provides for the administration of an animal remedy to the animal.

(2) A word or expression used in these Regulations and also used in an act of the institutions of the European Communities has, unless the contrary intention

appears, the meaning in these Regulations that it has in the act of the institutions of the European Communities in which it occurs.

(3) A word or expression that is used in these Regulations and is used in the Act has, in these Regulations, unless the contrary intention appears, the same meaning as it has in the Act.

## PART II

### AUTHORISATION OF AN ANIMAL REMEDY

#### ***Requirement for an animal remedies authorisation.***

3. (1) Without prejudice to Regulations 15, 18 and 21, a person shall not import, possess, sell or supply an animal remedy, unless there is in force an animal remedies authorisation in respect of the animal remedy.

(2) Paragraph (1) does not apply to a homeopathic animal remedy (other than an immunological homeopathic animal remedy) which, on or before 31 December 1993, was registered under the Animal Remedies (Registration of Manufacturers, Importers and Wholesalers) Regulations 1980 (S.I. No. 115 of 1980).

(3) (a) The Board may, on application, determine—

(i) that a substance does not come within the Directive, or

(ii) in accordance with Article 4(2) of the Directive that an animal remedy, intended solely for an aquarium fish, a caged bird, a homing pigeon, a terrarium animal, a small rodent, a ferret and a rabbit (kept exclusively as a pet), is exempt from the requirements of paragraph (1).

(b) An application under this paragraph shall be made in a form, be accompanied by any material and contain any particulars that the Board specifies.

(c) If the Board proposes to refuse an application under this paragraph, it shall—

(i) notify the applicant in writing of the proposal and of the reasons for the proposal, and that he or she may make representation to the Board in relation to the proposal within 14 days of notification,

(ii) consider a representation duly made before deciding whether to proceed with, modify or annul the proposal, and

(iii) notify the applicant of the decision and the reasons for the decision.

(4) If the Board makes a determination in accordance with paragraph (3)(a), it shall notify the applicant and the Minister.

***Application for a veterinary product authorisation.***

4. (1) An application for a veterinary product authorisation shall be made to the Board and shall be in a form and contain the information that the Board requires and be accompanied by the particulars and documents specified in the first subparagraph of Article 12(3) and in Article 14 of the Directive and Annex 1 to the Directive.

(2) If the documents and particulars which relate to matters referred to in point (j) of the first subparagraph of Article 12(3) of the Directive are accompanied by detailed and critical summaries, these summaries shall be drafted and signed by experts with the requisite qualifications as specified in Article 15(1) and (3) of the Directive.

(3) If an application for a veterinary product authorisation is made in respect of an animal remedy authorised, or under examination, by the competent authority in another member state, the Board may not consider the application unless it is satisfied that the first subparagraph of Article 32(1) of the Directive has been complied with.

(4) If the Board decides not to consider an application to which paragraph (3) applies, it shall inform the applicant.

(5) (a) The Board may not consider an application for a veterinary product authorisation in respect of an animal remedy intended for administration to a food producing animal unless six months have elapsed since the lodgement of a valid application for the establishment of a maximum residue limit with the Agency.

(b) Subparagraph (a) does not apply to an animal remedy containing a pharmacologically active substance not listed in Annexes I, II or III to Council Regulation (EEC) No. 2377/90 intended for administration to an equid which is a companion animal.

(6) The Board may not consider an application for a veterinary product authorisation unless the applicant is established in a member state.

***Examination of an application for a veterinary product authorisation.***

5. (1) In examining an application for a veterinary product authorisation, the Board shall take into consideration such criteria as it considers relevant to comply with Articles 12 to 14 of the Directive and in particular, information supplied by the applicant relating to—

(a) the quality, safety and efficacy of the animal remedy,

(b) the proposed indications, sales presentation, labelling and where appropriate, package leaflet relating to the animal remedy, and

- (c) the measures, in the case of an animal remedy to be imported from a third country, to ensure that the animal remedy is produced to an equivalent standard to those applicable in the European Community, and an inspection of the manufacturing facility by the Board may be required.

(2) The Board may require an applicant to furnish, without charge, a sample of an animal remedy, its starting materials, active substances, intermediate product, reference standard or other constituent material for testing by a laboratory designated by the Board.

(3) In order to verify the analytical detection methods proposed by the applicant, the Board may consult with any expert it considers appropriate and may require the applicant to supply sufficient quantities of a substance or other material it considers necessary.

(4) If the Board requires further information as specified in Article 23(4) of the Directive, the time limit referred to in Regulation 9(2) is suspended until the information required is supplied to the satisfaction of the Board.

(5) When determining an application for a veterinary product authorisation, the Board shall comply with the Council Directives within the meaning of the European Communities (Control of Animal Remedies and their Residues) Regulations 2007 (S.I. No. 143 of 2007).

***Authorisation of an animal remedy referred to in Articles 13, 13a-d of the Directive ('generics', 'bibliographics' etc.).***

6. (1) Notwithstanding Regulation 4(1) and without prejudice to the Patents Act 1992 (No. 1 of 1992), if an applicant can demonstrate to the satisfaction of the Board that—

- (a) the animal remedy is a generic animal remedy, and
- (b) the reference animal remedy, is or was authorised for not less than 8 years,

he or she need not provide the results of safety and residue tests or of pre-clinical and clinical trials referred to and in accordance with Annex I to the Directive.

(2) If a reference animal remedy is authorised in another member state, the applicant shall identify the member state and the Board shall request the competent authority of that member state to transmit confirmation that the animal remedy is or has been authorised, together with the full composition of the animal remedy and any other relevant information.

(3) For the purposes of paragraph (1)—

- (a) different salts, esters, ethers, isomers, mixtures of isomers, complexes or derivatives of an active substance are considered to be the same active substance, and

- (b) if, in the opinion of the Board, salts, esters, ethers, isomers, mixtures of isomers, complexes or derivatives of a substance differ significantly from those in the reference animal remedy, the applicant shall provide additional information as specified in Article 13(2)(b) of the Directive.

(4) If, in the opinion of the Board, an animal remedy is not a generic animal remedy, or if bio-equivalence cannot be demonstrated through bio-availability studies or in the case of changes to an active substance, therapeutic indications, strength, pharmaceutical form or route of administration vis-à-vis the reference animal remedy, the applicant shall provide results of appropriate safety and residue tests and pre-clinical tests or clinical trials in accordance with Annex I to the Directive.

(5) If, in the opinion of the Board, a biological animal remedy does not meet in full the definition of a generic animal remedy owing to, in particular, differences relating to raw materials or differences between the manufacturing processes of the biological animal remedy and the reference biological animal remedy, the applicant shall comply with Article 13(4) of the Directive.

- (6) (a) An applicant need not provide the results of safety and residue tests or of pre-clinical and clinical trials referred to and in accordance with Annex I to the Directive, if he or she can satisfy the Board, on the basis of appropriate scientific literature, that the active substances in the animal remedy have been present in an authorised animal remedy meeting the requirements of Annex 1 to the Directive, for at least 10 years.

- (b) The use of scientific literature referred to in subparagraph (a) shall be justified, to the satisfaction of the Board, by the experts referred to in Regulation 4(2).

- (c) For the purposes of subparagraph (a), the Board may accept the assessment report published by the Agency as appropriate scientific literature following the evaluation of an application for the establishment of a maximum residue limit pursuant to Council Regulation (EEC) No. 2377/90.

(7) Notwithstanding paragraph (1), an application for a veterinary product authorisation in respect of an animal remedy containing two or more active substances, each having been used in an authorised animal remedy, but not previously used in combination in an authorised animal remedy shall, as may be required by the Board, be accompanied by the results of—

- (a) safety and residue tests relating to the combination, and
- (b) new pre-clinical tests or new clinical trials, relating to the combination that fulfils the requirements of Article 12(3)(j) of the Directive.

(8) Notwithstanding paragraph (1), if an application is made for a veterinary product authorisation in respect of an immunological animal remedy, in exceptional circumstances, the Board may, if it receives a duly substantiated case from the applicant on the basis of Article 13(d) of the Directive and following consultation with the Minister, exempt the applicant from the requirements of Article 12(3)(j) of the Directive in relation to field trials on a target species.

(9) (a) Notwithstanding Regulation 9(2), the Board shall not issue a veterinary product authorisation in respect of a generic animal remedy authorised pursuant to paragraph (1) until 10 years have elapsed from the date of the grant of a marketing authorisation for the reference animal remedy.

(b) Notwithstanding subparagraph (a), in the case of an application for an animal remedy for fish or bees or other species designated in accordance with Article 89(2) of the Directive, the Board shall not issue a veterinary product authorisation until thirteen years have elapsed from the date of the grant of a marketing authorisation for the reference animal remedy.

(c) Notwithstanding subparagraphs (a) and (b), in the case of a reference animal remedy containing a new active substance—

(i) intended for administration to a food producing species, and

(ii) that was not authorised, by 30 April 2004,

the Board shall not issue a veterinary product authorisation in respect of a generic animal remedy for an additional food producing species unless the periods specified in Article 13(5) of the Directive have elapsed.

(d) Subparagraph (c) only applies when—

(i) the extension to the veterinary product authorisation referred to in subparagraph (c) is granted within five years of the grant of the original marketing authorisation for the reference animal remedy, and

(ii) the veterinary product authorisation holder is the person who applied to the Agency for the maximum residue limit for the active substance in the reference animal remedy for the species concerned.

(10) If a person, having availed of the provisions of paragraph (6)(a), submits new residue studies and clinical trials, with a view to obtaining a veterinary product authorisation in respect of a further food-producing species, another person shall not use the studies or trials in an application for a generic animal remedy for a period of three years thereafter.

(11) The Board, having obtained permission in writing from the holder of a veterinary product authorisation, may take into account data referred to in Article 13c of the Directive when examining another application for a veterinary product authorisation for an animal remedy having the same qualitative and quantitative composition in active substances and the same pharmaceutical form.

(12) This Regulation applies only to a reference animal remedy for which an application for a marketing authorisation is submitted after 30 October 2005.

(13) In this Regulation—

“authorised”, in relation to an animal remedy, means authorised in the State, in another Member State or in accordance with Regulation (EC) No. 726/2004;

“generic animal remedy” means an animal remedy which has the same qualitative and quantitative composition in active substances and the same pharmaceutical form (which includes various immediate-release oral pharmaceutical forms) as the reference animal remedy and whose bio-equivalence with the reference animal remedy has been demonstrated by bio-availability studies where appropriate;

“reference animal remedy” has the meaning assigned to a reference medicinal product by Article 13(2)(a) of the Directive.

***Authorisation of a homeopathic animal remedy.***

7. (1) An application for a veterinary product authorisation for a homeopathic animal remedy shall comply with Regulation 4.

(2) (a) Notwithstanding paragraph (1) and without prejudice to Council Regulation (EEC) No. 2377/90, an application for registration of a homeopathic animal remedy (other than an immunological homeopathic animal remedy) in respect of which it has been demonstrated to the satisfaction of the Board that it—

(i) is to be administered by a route described in the European Pharmacopoeia or in the absence thereof, in the official pharmacopoeias used in a Member State,

(ii) contains no specific therapeutic indications, and

(iii) has, in the opinion of the Board, a sufficient degree of dilution and in particular, does not contain more than one part per 10 000 of the mother tincture,

is subject to Article 17(2) of the Directive.

(b) An application for registration of a homeopathic animal remedy to which sub-paragraph (a) refers shall be made to the Board and be in such form as the Board may require and be accompanied by the particulars and documents specified in Article 18 of the Directive.

- (c) Notwithstanding subparagraphs (a) and (b), the requirements of Regulation 5 apply to an application under this paragraph with the exception of proof of efficacy.
- (d) A homeopathic animal remedy, registered in accordance with this paragraph shall be labelled as prescribed by paragraph (2) of Part I of Schedule 2.

***Mutual recognition.***

8. The Board shall comply with Articles 32 to 41 of the Directive in so far as these Articles apply to the Board and may act as a reference or concerned member state (within the meaning of those Articles).

***Decision etc. on an application.***

9. (1) The Board may grant a veterinary product authorisation, arising from an application under Regulation 4, 6, 7 or 8, refuse an application, attach conditions to a veterinary product authorisation or registration, revoke or vary a condition, or suspend or revoke a veterinary product authorisation or registration.

(2) Subject to Regulations 5(4) and 8, the Board shall, within 210 days of the receipt of a valid application, notify the applicant of its decision.

(3) The Board may, following consultation with the applicant, grant a veterinary product authorisation subject to annual review and subject to the holder undertaking to meet specific obligations, including—

- (a) introduction of specific procedures, in particular, concerning the safety of the animal remedy, and
- (b) notification to the Board of all incidents relating to use of the animal remedy.

(4) The Board, except in the case of a homeopathic animal remedy referred to in Regulation 7(2), shall have regard to Article 25 of the Directive.

(5) The Board shall specify the manner in which an animal remedy shall be packaged, presented and labelled and the particulars which shall appear on the label, container or package leaflet.

(6) For the purposes of paragraph (5) and without prejudice to Regulation 7(2), the form of label or package leaflet shall comply with the Directive and Schedule 2 and include any particulars specified by the Board for the purpose of safety or health protection, including any special precautions for use or other warnings resulting from clinical and pharmacological trials, or, from experience gained during the use of the animal remedy and, in particular, matters arising as a result of pharmacovigilance reports.

(7) Without prejudice to paragraph (1), the Board, where it grants a veterinary product authorisation, shall—

- (a) as a condition of the veterinary product authorisation, designate the route of sale for an animal remedy in accordance with Part II of Schedule 1, and
  - (b) specify the route of sale (for which purpose the symbols set out in Part IV of Schedule 2 may be used) to appear on the container, label and package leaflet relating to the animal remedy.
- (8) If the Board proposes to refuse an application, it shall—
  - (a) notify the applicant in writing of the proposal and of the reasons therefor, and that he or she may make representation to the Board in relation to the proposal within 30 days of the notification,
  - (b) consider a representation duly made before deciding whether to proceed with, modify or annul the proposal, and
  - (c) notify the applicant concerned of the decision and the reasons for the decision.
- (9) The Board shall refuse an application if, in its opinion—
  - (a) the risk-benefit balance of the animal remedy is unfavourable under the proposed conditions of use,
  - (b) the animal remedy has no therapeutic effect or the applicant has not provided sufficient proof of such effect in the species of animal to be treated,
  - (c) the qualitative or quantitative composition of the animal remedy is not as stated,
  - (d) the withdrawal period recommended by the applicant is not long enough to ensure that a foodstuff obtained from an animal does not contain residues which exceed those prescribed by Council Regulation (EEC) No 2377/90, or other act of the institutions of the European Union, or a limit prescribed by regulations made under the Act or the European Communities Act 1972, or which might constitute a health hazard to a consumer of produce from an animal,
  - (e) the labelling or package leaflet proposed by the applicant for the animal remedy does not comply with the Directive or these Regulations,
  - (f) the animal remedy is, or is to be, offered for sale or supply for a use that is unlawful,
  - (g) the animal remedy consists of, or contains, a substance the administration of which to the particular class or classes of animal for which the animal remedy is intended, is unlawful,

- (h) the animal remedy consists of or contains a substance to which Regulation 3(1) of the European Communities (Control of Animal Remedies and their Residues) Regulations 2007 (S.I. No. 143 of 2007) applies,
- (i) such action is necessary to protect public health, animal health or the environment,
- (j) the animal remedy is not manufactured in accordance with the principles and guidelines referred to in Article 50(f) of the Directive,
- (k) a request by the Board for further particulars, to enable compliance with the Directive to be considered, has not been complied with, within the time specified, or
- (l) the application does not comply with Regulations 4, 6, 7 or 8.

(10) For the purposes of paragraph (9)(a), in the case of an animal remedy intended for zootechnical use, the Board shall have particular regard to the benefits for animal health and welfare and consumer safety.

(11) For the purposes of paragraph (9)(b), an animal remedy is considered to have no therapeutic effect unless it can be shown that it produces the appropriate therapeutic effect for the condition to be treated in the species of animal for which the treatment is intended.

(12) (a) Subject to paragraph (9) and without prejudice to subparagraph (b), the Board shall not grant a veterinary product authorisation or a registration in respect of an animal remedy intended for administration to a food producing animal unless each substance capable of pharmacological action contained in the animal remedy is mentioned in Annex I, II or III to Council Regulation (EEC) No. 2377/90.

(b) Notwithstanding subparagraph (a), the Board may authorise an animal remedy containing a substance not listed in Annexes I, II or III to Council Regulation (EEC) No. 2377/90 for administration to an equid which is a companion animal, except where—

- (i) the substance is listed in Annex IV to Council Regulation (EEC) No. 2377/90, or
- (ii) there is already in force an animal remedies authorisation for treatment of the same condition.

***Validity of a veterinary product authorisation.***

10. (1) Without prejudice to Regulations 9(3) and 11, a veterinary product authorisation is, unless previously revoked, valid for five years, commencing on the date of the grant of the authorisation.

(2) (a) A veterinary product authorisation may be renewed by the Board on the basis of an application made by the holder.

(b) An application for renewal of a veterinary product authorisation shall be made in a form, be accompanied by any material and contain any particulars that the Board specifies and, in particular, the information specified in the second subparagraph of Article 28(2) of the Directive and be submitted no later than six months before expiry of the authorisation which it is to replace.

(3) If application for renewal of a veterinary product authorisation is made no later than six months before the expiry date, that veterinary product authorisation remains in force until determination of the application.

(4) Without prejudice to Regulation 9(1), a veterinary product authorisation, if renewed, is subject to these Regulations, valid for an unlimited period, unless the Board considers at the time of the grant of a first renewal, on the basis of pharmacovigilance information, that the validity should be limited to one additional five year period following which the Board shall, if it considers it appropriate to do so, renew the authorisation for an unlimited period.

(5) (a) If an animal remedy in respect of which a veterinary product authorisation has been issued by the Board—

(i) is not placed on the market in the State within three years from the date of authorisation, or

(ii) is not marketed in the State for a period of three consecutive years,

the authorisation ceases to be valid on the day following expiry of the three year period.

(b) This paragraph does not apply if the Board is satisfied that the validity of the authorisation should be continued, in particular, on public or animal health grounds.

***Certain obligations of a marketing authorisation holder.***

11. (1) The holder of an animal remedies authorisation shall, at the request of the Board, supply, within the period specified by the Board, data which the Board considers appropriate in order to demonstrate that the risk-benefit balance of the animal remedy remains favourable.

(2) (a) The holder of an animal remedies authorisation shall take all reasonable steps to ensure that he or she takes account of ongoing scientific progress as regards the manufacturing and control methods specified in Articles 12(3)(d) and (i) of the Directive for the purposes of compliance with Article 27 of the Directive.

(b) The holder of an animal remedies authorisation shall submit for the approval of the Board changes to the methods referred to in subparagraph (a).

(3) The holder of an animal remedies authorisation shall immediately provide to the Board new information relating to an animal remedy which would give rise to an amendment to the particulars or documents furnished for the purposes of Regulations 4, 6, 7 and 8 and in particular,—

- (a) new information which would affect the risk-benefit balance of the animal remedy,
- (b) prohibitions or restrictions placed on the marketing of an animal remedy in another State or jurisdiction, and
- (c) serious unexpected adverse reactions arising out of the administration of the animal remedy.

(4) The holder of an animal remedies authorisation shall submit, for the approval of the Board, amendments to the particulars or documents referred to in paragraph (3).

(5) The holder of an animal remedies authorisation shall, on request, make available to the Board or an authorised officer—

- (a) a quantity of a substance as may be necessary to carry out routine checks for the presence of residues of an animal remedy, and
- (b) technical expertise to facilitate implementation of an analytical method for detecting residues of an animal remedy,

in a food producing animal or in the flesh or produce of a food producing animal.

(6) The holder of an animal remedies authorisation shall maintain for at least five years records of all undesirable effects observed in animals or humans arising out of the administration of the animal remedy, and shall make them available to the Board on request and shall have arrangements in place to comply with the pharmacovigilance requirements specified in Regulation 12.

(7) The holder of an animal remedies authorisation shall inform the Board of—

- (a) the date an animal remedy is placed on the market in the State, and
- (b) the date an animal remedy is to cease to be placed on the market in the State and the reasons for this action at least two months in advance of the proposed withdrawal date, except where the applicant demonstrates the existence of exceptional circumstances, to the satisfaction of the Board.

(8) The holder of an animal remedies authorisation shall, at the request of the Board, furnish details of sale or supply of the animal remedy and any data in his or her possession relating to prescriptions of the animal remedy.

- (9) (a) The holder of an animal remedies authorisation, or a person carrying out activities on his or her behalf, shall maintain a system designed to ensure, in accordance with Article 95a of the Directive, that an animal remedy sold or supplied by him or her in the State, which is unused or reaches its expiry date, is disposed of lawfully.
- (b) For the purposes of subparagraph (a), the holder of an animal remedies authorisation or a person carrying out activities on his or her behalf shall put in place the necessary arrangements with—
- (i) the holder of an animal remedies wholesaler's licence,
  - (ii) a registered veterinary practitioner,
  - (iii) a pharmacist,
  - (iv) the holder of an animal remedies merchant's licence, or
  - (v) a person registered in accordance with Regulation 33,
- to whom he or she sells or supplies an animal remedy, with a view to receiving animal remedies referred to in subparagraph (a) from those persons having been returned to them.

(10) Without prejudice to Regulation 7(2), the holder of an animal remedies authorisation shall not sell or supply an animal remedy unless and until the package and label comply with Schedule 2 and the veterinary product authorisation.

(11) A person shall not remove or alter a label or package leaflet prescribed by these Regulations unless authorised by the Board.

- (12) (a) In the case of an immunological animal remedy, the holder of an animal remedies authorisation shall—
- (i) if requested by the Board, submit copies of control reports referred to in Article 81(2) of the Directive, and
  - (ii) if the Board considers it necessary for the purposes of Article 82(1) of the Directive, submit samples of batches of bulk product or an immunological animal remedy before the product is placed on the market in the State.

(b) If subparagraph (a)(ii) applies, the Board shall comply with the second subparagraph of Article 82(2), and 82(5) of the Directive.

(13) This Regulation is in addition to and not in substitution for any other obligation imposed on a holder of an animal remedies authorisation by these Regulations or by an animal remedies authorisation.

***Pharmacovigilance.***

12. (1) The Board shall maintain and implement a pharmacovigilance system in accordance with Title VII of the Directive.

- (2) (a) If, as a result of evaluation of a report under this Regulation, the Board considers that an animal remedies authorisation should be:—
- (i) revoked, varied or suspended,
  - (ii) restricted as to the indications or availability,
  - (iii) varied as to the posology, or
  - (iv) varied by the addition of a contra-indication or precautionary measure,

it shall make this information available to the Minister, the Agency, the appropriate authorities in other member states and the holder of the animal remedies authorisation (who shall be afforded an opportunity to make representations within a period as may be fixed by the Board) forthwith.

- (b) An animal remedies authorisation shall not be revoked, varied or suspended until the representations, if any, of the holder of the animal remedies authorisation have been considered.
  - (c) Notwithstanding sub-paragraph (b), in case of urgency if public or animal health is threatened, the Board may suspend the distribution, sale and supply of an animal remedy.
- (3) (a) The holder of an animal remedies authorisation shall have permanently and continuously at his or her disposal an appropriately qualified person responsible for pharmacovigilance, (“qualified person for pharmacovigilance”).
- (b) A qualified person for pharmacovigilance shall reside in a member state and be responsible for carrying out the functions referred to in Article 74 of the Directive.
- (4) The holder of an animal remedies authorisation shall comply with Article 75 of the Directive and shall furnish the reports required by and in accordance with that Article.
- (5) Notwithstanding paragraph (4), the Board may, in accordance with Article 74(7) of the Directive, at the request of the holder of an animal remedies authorisation, amend the periods referred to in Article 75(5) of the Directive.
- (6) (a) The holder of an animal remedies authorisation shall not release to the general public information to which this Regulation relates without giving prior or simultaneous notification to the Board.

- (b) If information relating to adverse reactions is released to the general public, the holder of the animal remedies authorisation shall present the information in a manner that is objective and not misleading.
- (7) (a) The holder of an animal remedies wholesaler's licence, an animal remedies merchant's licence or a person registered under Regulation 33, a registered veterinary practitioner or a pharmacist shall report to the Board or the holder of the animal remedies authorisation, any suspected serious or unexpected adverse reaction or human adverse reaction which is reported to him or her, or which otherwise come to his or her attention.
- (b) In the case of an adverse reaction referred to in subparagraph (a), the report shall be made at the earliest opportunity and not later than 15 days following receipt of the information.
- (c) The Board may prescribe the form in which a report under this paragraph is made.
- (8) A person who sells or supplies an animal remedy shall notify the Board of any action taken by him or her to—
- (a) suspend the sale or supply, or
- (b) recall,

an animal remedy together with the reasons for the action if it concerns the efficacy or safety (including the protection of public health) of the animal remedy.

- (9) In this Regulation—

“adverse reaction” means a reaction which is harmful and unintended and which occurs at doses normally used in animals for the prophylaxis, diagnosis or treatment of disease or modification of physiological function;

“human adverse reaction” means a reaction which is noxious and unintended and which occurs in a human being following exposure to an animal remedy;

“qualified person for pharmacovigilance” means a person who, as a result of professional qualification, and or education and training, is competent to discharge the responsibilities prescribed by this Regulation;

“serious adverse reaction” means an adverse reaction which is fatal, life threatening, lesion producing, disabling, incapacitating or which results in permanent or prolonged symptoms in the animals treated and includes a human adverse reaction;

“serious unexpected adverse reaction” means an adverse reaction which is both serious and unexpected;

“unexpected adverse reaction” means an adverse reaction, the nature, severity or outcome of which is not consistent with the summary of the product characteristics.

***Suspension, revocation or variation of a veterinary product authorisation.***

13. (1) Without prejudice to the generality of these Regulations, the Board shall suspend, revoke or vary a veterinary product authorisation if it is of the opinion that a circumstance referred to in Article 83(1) of the Directive applies or if an undertaking given under Regulation 9(3) has not been honoured or fulfilled.

(2) Without prejudice to Regulation 9(1), the Board may suspend, revoke or vary a veterinary product authorisation if it is of the opinion that—

- (a) a circumstance referred to in Article 83(2) of the Directive applies,
- (b) the animal remedy is not manufactured in accordance with the principles and guidelines referred to in Article 50(f) of the Directive,
- (c) the animal remedy is not labelled in accordance with the veterinary product authorisation, or
- (d) the animal remedy is not manufactured to the specification of the animal remedies authorisation.

(3) The Board may modify or annul a suspension, revocation or variation.

(4) A person shall comply with a decision of the Board under paragraph (1).

(5) A person shall not sell or supply an animal remedy to which a suspension or revocation under paragraph (1) or (2) relates (including a suspension or revocation subject to representation under paragraph (7)).

(6) Without prejudice to paragraph (7), if the Board proposes to suspend, revoke or vary a veterinary product authorisation, it shall—

- (a) notify the holder in writing of the proposal and of the reasons therefor, and that he or she may make representation to the Board in relation to the proposal within 7 days of the date of the notification,
- (b) consider a representation duly made before deciding whether to proceed with, modify or annul the proposal, and
- (c) notify the holder of the decision and the reasons for the decision,

and the suspension, revocation or variation (under this paragraph) shall not have effect until the Board issues a notification of its decision in accordance with subparagraph (c).

(7) If the Board, for urgent public or animal health reasons, suspends or revokes a veterinary product authorisation it shall—

- (a) notify the holder in writing of the decision and the reasons therefor, and that he or she may (without prejudice to paragraph (4)) make representations to the Board in relation to the decision within 14 days of the date of the notification,
- (b) consider a representation duly made, and
- (c) confirm, modify or annul the decision and notify the holder of the decision and the reasons for the decision.

***Recall of an animal remedy.***

14. (1) The Board may, by notice (“recall notice”), order the recall of an animal remedy or a batch of an animal remedy if it is of the opinion that—

- (a) a circumstance referred to in Article 84(1) of the Directive applies,
- (b) the animal remedy consists of or contains a substance the administration of which, to a class of animal for which the animal remedy is intended, is unlawful,
- (c) the animal remedy is not manufactured in accordance with the animal remedies authorisation or in accordance with the principles and guidelines referred to in Article 50(f) of the Directive, or
- (d) the animal remedy is not labelled in accordance with the animal remedies authorisation.

(2) The Board may modify or annul a recall notice.

(3) The Board may confine a recall notice to wholesaler or retailer level if it considers such action appropriate for the protection of animal or public health or environmental safety.

(4) A person shall comply with a recall notice (including a notice subject to representation under paragraph (8)).

(5) If a recall notice is issued by the Board, the marketing authorisation holder shall consult with and agree to a requirement or amendment notified by the Board regarding the text of a recall notice or to the publication of the notice.

(6) Records of the recall of an animal remedy shall be available for inspection by an authorised officer of the Board.

(7) Without prejudice to paragraph (8), if the Board proposes to issue a recall notice, it shall—

- (a) notify the holder in writing of the proposal and of the reasons therefor, and that he or she may make representation to the Board in relation to the proposal within 7 days of the notification,
- (b) consider a representation duly made before deciding whether to proceed with, modify or annul the proposal, and

(c) notify the holder of the decision and the reasons therefor,

and the notice shall not have effect until the Board issues a notification of its decision in accordance with subparagraph (c).

(8) If the Board, for urgent public or animal health reasons, issues a recall notice, it shall—

(a) notify the holder in writing of the decision and the reasons therefor, and that he or she may (without prejudice to paragraph (4)) make representations to the Board in relation to the decision within 14 days of the date of the notification,

(b) consider a representation duly made, and

(c) confirm, modify or annul the decision and notify the holder of the decision and the reasons therefor.

### PART III

#### EXCEPTIONAL AUTHORISATION AND ADMINISTRATION OF AN ANIMAL REMEDY

##### ***Cross border practice.***

15. (1) A veterinary practitioner established in another member state who provides cross border veterinary services within the State in accordance with section 43(7) of the Veterinary Practice Act 2005 (No. 22 of 2005), may, in accordance with Regulation 43 and subject to this Regulation, import, possess, prescribe, sell, supply or administer a small quantity of an animal remedy, (other than an immunological animal remedy), in respect of which there is not in force an animal remedies authorisation.

(2) Paragraph (1) applies only in respect of an animal remedy—

(a) authorised in accordance with the Directive in the member state where the veterinary practitioner is established, and brought into the State and supplied by the veterinary practitioner in the manufacturer's original packaging, and

(b) in the case of an animal remedy intended for administration to a food producing animal, that has the same qualitative and quantitative composition in terms of active substances as an animal remedy authorised within the State.

(3) A veterinary practitioner who administers an animal remedy in accordance with this Regulation shall inform the owner or person in charge of an animal of the appropriate withdrawal period (in accordance with the law of the State) and shall indicate this period on the label.

(4) A veterinary practitioner, for the purposes of this Regulation, shall only possess an animal remedy to which paragraph (2) applies in a range and quantity

as are required for the daily needs of good veterinary practice and, in any event, for a period not greater than 5 days.

(5) A veterinary practitioner to whom this Regulation applies shall maintain and keep records within the State of—

- (a) the identity of the animal or animals treated,
- (b) the date of examination of the animal or animals,
- (c) the number of animals treated,
- (d) the name and address of the owner or person in charge of the animal or animals,
- (e) his or her diagnosis,
- (f) the details of the animal remedies administered, prescribed, sold or supplied,
- (g) the dosage administered, prescribed, sold or supplied,
- (h) the duration of treatment, and
- (i) the withdrawal period specified.

(6) The records specified in paragraph (5) shall be maintained for five years and furnished on request for examination by an authorised officer.

***Certain health situations.***

16. (1) Notwithstanding Regulation 20, the Minister may, by licence—

- (a) if he or she considers that the health situation so requires, authorise the import, possession, sale or supply or administration of an animal remedy, if he or she is satisfied it is authorised in another member state,
- (b) in exceptional circumstances, if he or she considers that the health situation so requires, if there is no appropriate animal remedy authorised within the State or in another member state, authorise the manufacture, import, possession, sale or supply or administration of an animal remedy pending consideration of an application for authorisation by the Agency or by the Board,
- (c) if he or she considers it appropriate to deal with a serious epizootic disease in accordance with Article 8 of the Directive, authorise the import, possession, sale or supply or administration of an immunological animal remedy in respect of which there is not otherwise in force an animal remedies authorisation, or
- (d) in exceptional circumstances, if the animal concerned is to be exported to a third country, authorise the import, possession, sale or supply

or administration, of an immunological animal remedy, authorised in that country.

(2) A licence granted under this Regulation shall specify the route of sale of the animal remedy to which it relates in accordance with Schedule 1.

(3) The Minister may not grant a licence under this Regulation if, following consultation with the Board, he or she is of the opinion that it is more appropriate that an application for a veterinary product authorisation be made to, and determined by, the Board.

(4) This Regulation is in addition to and not in substitution for the Diseases of Animals Act 1966 (Control on Animal and Poultry Vaccines) Order 2002 (S.I. No. 528 of 2002).

***Miscellaneous situations.***

17. (1) Notwithstanding Regulation 20, the Minister may grant a licence to a person authorising the possession, manufacture, import, sale or supply of an animal remedy.

(2) Without prejudice to the generality of paragraph (1), the Minister shall not grant a licence unless the applicant establishes to the satisfaction of the Minister that all of the animal remedy will be—

- (a) administered to animals in the course of a test or trial authorised by a licence granted under Regulation 19,
- (b) supplied to the Board or the Minister for the purpose of an application for an animal remedies authorisation,
- (c) supplied to a University or other institution concerned with higher education or scientific research or analysis for the purposes of such education or research or analysis,
- (d) used for in vitro or other studies or analysis not involving administration to animals, or
- (e) exported from the State.

(3) The Minister shall not grant a licence if, in his or her opinion—

- (a) the grant of the licence would prejudice public or animal health or trade in animals or animal products from the State, or
- (b) in the case of a licence authorising the manufacture of an animal remedy, the staff, premises, equipment, machinery or plant are not suitable to manufacture the animal remedy.

***'The cascade.'***

18. (1) A person shall not prescribe an animal remedy for, or administer an animal remedy to, a food producing animal other than in accordance with an animal remedies authorisation, unless—

- (a) he or she is a registered veterinary practitioner, the animal is under his or her care in accordance with Regulation 43 and he or she complies with paragraphs (2) to (4), (6) and (10),
- (b) there is no animal remedy authorised in the State for the treatment of the condition in the animal, and
- (c) he or she is satisfied that the treatment is necessary, in particular, to avoid unacceptable suffering to the animal.

(2) Where the conditions in paragraph (1) are met, a registered veterinary practitioner may prescribe or administer—

- (a) an animal remedy authorised in the State for another animal species or for another condition in the same species, or
- (b) if there is no animal remedy to which sub-paragraph (a) refers—
  - (i) a medicinal product authorised by the Board in accordance with the Medicinal Products (Control of placing on the market) Regulations 2007 (S.I. No. 540 of 2007) or authorised pursuant to Regulation (EC) 726/2004, or
  - (ii) an animal remedy, imported in accordance with paragraph (11), which is authorised in another member state in accordance with Article 5 of the Directive for administration to the same species or to another species, or
- (c) if there is no animal remedy or medicinal product to which either sub-paragraphs (a) or (b) refers, an animal remedy prepared extemporaneously by—
  - (i) the registered veterinary practitioner, or
  - (ii) a pharmacist or the holder of a manufacturer's licence, in accordance with a veterinary prescription.

(3) Where the conditions in paragraphs (1) and (2) are met, a registered veterinary practitioner—

- (a) may prescribe or administer only an animal remedy or medicinal product containing a substance listed in Annex I, II or III to Council Regulation (EEC) No. 2377/90, and
- (b) may, in the case of an equid to which paragraph (1) applies, in addition to an animal remedy or medicinal product referred to in subparagraph

- (a), prescribe or administer an animal remedy consisting of or containing a substance listed in the Annex to Commission Regulation (EC) No. 1950/2006<sup>7</sup> for the purposes specified in that Annex, details of which he or she shall enter in the identification document relating to the animal,
- (c) shall, subject to paragraph (4), specify a withdrawal period to ensure that food from the animal does not contain a residue which may be harmful for consumers,
- (d) shall complete at the time of administering or prescribing the animal remedy, and retain at his or her premises for at least 5 years a record detailing—
- (i) the date of examination of the animal,
  - (ii) the identification of the animal,
  - (iii) the number of animals treated,
  - (iv) the name and address of the owner or person in charge of the animal,
  - (v) his or her diagnosis,
  - (vi) details of the substance administered or prescribed and reasons for the choice of that substance,
  - (vii) the dosage of the substance administered or prescribed,
  - (viii) the duration of treatment, and
  - (ix) the withdrawal period specified.

(4) For the purposes of paragraph (3)(c), if an animal remedy or medicinal product administered or prescribed does not indicate a withdrawal period for the species of animal to be treated, the following withdrawal periods are mandatory unless a longer withdrawal period is specified—

- (a) in the case of eggs from treated animals, 7 days,
- (b) in the case of milk from treated animals, 7 days,
- (c) in the case of meat, including fat & offal from poultry and mammals, 28 days,
- (d) in the case of meat from fish, 500 degree days, or
- (e) in the case of meat from an equid, if paragraph (3)(b) applies, at least 6 months.

<sup>7</sup>O.J. L 367, 22.12.2006

(5) Paragraphs (3)(c) and (d) do not apply in the case of a homeopathic animal remedy which contains an active substance listed in Annex II to Regulation (EEC) No. 2377/90.

(6) Paragraph (1) applies to the treatment of an individual animal or animals on a premises and does not provide for the general manufacture, possession, sale, supply or administration of a substance to which that paragraph relates.

(7) For the purposes of paragraph (3)(b), identification document has the same meaning as in the European Communities (Equine Stud-Book and Competition) Regulations 2004 (S.I. No. 399 of 2004).

(8) A person shall not prescribe an animal remedy for, or administer an animal remedy to, a companion animal other than in accordance with an animal remedies authorisation, unless—

- (a) he or she is a registered veterinary practitioner, the animal is under his or her care in accordance with Regulation 43 and he or she complies with paragraphs (9) and (10),
- (b) there is no animal remedy authorised in the State for the treatment of the condition in the animal, and
- (c) he or she is satisfied that the treatment is necessary, in particular, to avoid unacceptable suffering to the animal.

(9) Where the conditions in paragraph (8) are met, a registered veterinary practitioner may prescribe or administer—

- (a) an animal remedy authorised in the State for another animal species or for another condition in the same species, or
- (b) if there is no animal remedy to which subparagraph (a) refers—
  - (i) a medicinal product authorised by the Board in accordance with the Medicinal Products (Control of placing on the market) Regulations 2007 (S.I. No. 540 of 2007) or authorised pursuant to Regulation (EC) 726/2004, or
  - (ii) an animal remedy, imported in accordance with paragraph (11), which is authorised in another member state in accordance with Article 5 of the Directive for administration to the same species or to another species, or
- (c) if there is no animal remedy or medicinal product to which either subparagraphs (a) or (b) refers, an animal remedy prepared extemporaneously by—
  - (i) the registered veterinary practitioner, or

- (ii) a pharmacist or the holder of a manufacturer's licence, in accordance with a veterinary prescription.

(10) A registered veterinary practitioner who administers or prescribes an animal remedy under this Regulation (or a pharmacist who sells or supplies an animal remedy in accordance with a veterinary prescription) shall label the animal remedy at the time of sale or supply with a notice in the form prescribed by Regulation 28(5) and, in addition, in the case of an animal remedy imported in accordance with paragraph (11), shall include a reference to the serial number of the import licence.

(11) The Minister may, on application authorise by licence the import, possession, sale or supply of an animal remedy for the purposes of paragraph (2)(b)(ii) or (9)(b)(ii) by—

- (a) a registered veterinary practitioner,
- (b) the holder of an animal remedies wholesaler's licence, or
- (c) a pharmacist who has a veterinary prescription in his or her possession in respect of the animal remedy.

(12) Notwithstanding paragraphs (1) and (8), it shall be lawful for the owner or person in charge of an animal to possess and administer an animal remedy in accordance with a veterinary prescription issued in accordance with this Regulation.

***Research etc.***

19. (1) A person shall not administer an animal remedy to an animal—

- (a) for the purpose of tests and trials of an animal remedy referred to in Article 12(3)(j) of the Directive, or
- (b) for the purpose of scientific research or analysis not covered by subparagraph (a),

save under and in accordance with a licence, granted by the Minister following consultation with the Board (referred to in this Regulation as “a research licence”).

(2) A person shall not cause produce derived from an animal which has been administered in the course of a test, trial or research to which this Regulation applies to be used for human consumption unless the Minister determines a withdrawal period which shall—

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

- (b) ensure that the maximum residue limit will not be exceeded in food-stuffs if this limit has been established for the substance concerned in accordance with Council Regulation (EEC) No. 2377/90.

(3) Notwithstanding Regulation 40, a person, where this Regulation is complied with, may have in his or her possession or under his or her control and may slaughter, sell, supply or export an animal to which a research licence relates.

#### PART IV

#### MANUFACTURE, IMPORT AND EXPORT OF AN ANIMAL REMEDY AND STARTING MATERIALS

##### *Manufacture of an animal remedy.*

20. (1) Notwithstanding Regulation 3(1) and without prejudice to Regulations 16, 17 and 18, a person shall not manufacture an animal remedy or import an animal remedy from a third country save under and in accordance with a licence ('manufacturer's licence') granted by the Board.

(2) A manufacturer's licence may relate to animal remedies generally, to animal remedies of a particular class or description or to one or more animal remedies.

(3) (a) If the quantity to be supplied is less than that available in the smallest proprietary pack size lawfully available in the State, a manufacturer's licence is not required for dividing up, packaging or presenting an animal remedy, not carried out in advance, by—

- (i) a pharmacist in respect of an animal remedy to be sold from a pharmacy,
- (ii) a registered veterinary practitioner in respect of an animal remedy supplied by him or her for the treatment of an animal under his or her care, or
- (iii) a responsible person selling or supplying from a premises to which an animal remedies merchant's licence relates, but only in so far as an intramammary animal remedy is concerned.

(b) Without prejudice to Regulation 28(5), an animal remedy sold or supplied in accordance with subparagraph (a) shall be labelled with, or bear, a notice stating—

- (i) the proprietary name of the animal remedy,
- (ii) the words "for animal treatment only",
- (iii) the species to be treated,
- (iv) the mode of administration,
- (v) the dose rate,

- (vi) the name of the person to whom sold or supplied,
- (vii) the name and address of the supplier, and
- (viii) precautions regarding administration and withdrawal period, if any.

(4) A manufacturer's licence is not required for the extemporaneous preparation in accordance with Regulation 18 of an animal remedy or magistral formula (provided it is not prepared in advance), by—

- (a) a registered veterinary practitioner for the treatment of an animal under his or her care, or
- (b) a pharmacist in accordance with a veterinary prescription.

(5) A manufacturer's licence is not required to import an animal remedy (accompanied by a copy of the authorisation granted for its importation duly certified by the appropriate authority of the member state of destination) from a third country if the animal remedy is imported for trans-shipment to another member state and is not for sale or supply in the State.

(6) Paragraph (1) does not apply to the manufacture of an animal remedy in a laboratory engaged in veterinary or pharmaceutical education, research or analysis and used in the laboratory.

(7) This Regulation does not apply to the manufacture of a medicated feedingstuff or an intermediate product under and in accordance with a licence granted pursuant to Regulation 4 of the European Communities (Animal Remedies and Medicated Feedingstuffs) Regulations 1994 (S.I. No. 176 of 1994).

***Application for a manufacturer's licence.***

21. (1) An application for a manufacturer's licence shall be made in a form, be accompanied by any material and contain any particulars that the Board specifies.

- (2) Without prejudice to the generality of paragraph (1), an applicant shall—
  - (a) provide particulars to demonstrate that he or she has available suitable and sufficient premises, technical equipment and trained staff as regards both manufacture and control and the storage of animal remedies or substances thereof,
  - (b) demonstrate that all manufacturing will be carried out in accordance with the principles and guidelines referred to in Article 50(f) of the Directive, and
  - (c) satisfy the Board that the services of at least one qualified person, who fulfils the requirements applicable to a qualified person are available to carry out the functions of a qualified person as prescribed by the Directive and specified in Schedule 4.

***Decision on application for a manufacturer's licence.***

22. (1) The Board may grant a manufacturer's licence, refuse an application, attach conditions to a manufacturer's licence, and may revoke or vary a condition, or suspend or revoke a manufacturer's licence.

(2) Subject to paragraph (5), the Board shall, within 90 days of the receipt of a valid application, notify an applicant of a decision to grant a licence, or of a proposal to refuse an application.

(3) (a) A manufacturer's licence shall be subject to such conditions as the Board may specify which shall include the requirements set out in Schedule 5.

(b) Without prejudice to the generality of paragraph (1), the Board shall refuse an application if—

(i) the manufacture, import, sale, supply or use of an animal remedy to which the application relates is unlawful, or, in the opinion of the Board, the animal remedy would be sold, supplied or used in the State otherwise than for the purpose specified in the application for an animal remedies authorisation,

(ii) in the opinion of the Board, the staff, premises, equipment, machinery or plant used or to be used by the applicant or licence holder are not suitable to manufacture an animal remedy,

(iii) the applicant or licence holder does not have the services of a qualified person in relation to the manufacture of an animal remedy to which the application or licence relates,

(iv) the applicant or licence holder is, in the opinion of the Board, incapable of complying with the principles and guidelines referred to in Article 50(f) of the Directive, or

(v) in the opinion of the Board, the applicant or licence holder is not, for any other reason (including conviction for an offence or a failure to comply with a condition attached to a manufacturer's licence or animal remedies authorisation), or having regard to Article 25 of Council Directive 96/23/EC of 29 April 1996<sup>8</sup>, a fit and proper person to hold a manufacturer's licence.

(4) If the Board proposes to refuse an application, it shall—

(a) notify the applicant in writing of the proposal and of the reasons therefor, and that he or she may make representation to the Board in relation to the proposal within 30 days of the notification,

(b) consider a representation duly made before deciding whether to proceed with, modify or annul the proposal, and

<sup>8</sup>O.J. L 125, 23.5.1996

(c) notify the applicant of the decision and the reasons therefor.

(5) If the Board requires information from an applicant to consider an application, the time limit referred to in paragraph (2) is suspended until the information is supplied.

(6) The Board, having carried out an inspection at the premises of an animal remedies authorisation holder or a manufacturer of animal remedies or a manufacturer of starting materials or a person carrying out activities on their behalf, shall comply with Article 80(3), (5), (6) and (7) of the Directive.

***Certain obligations of a holder of a manufacturer's licence.***

23. (1) The holder of a manufacturer's licence shall—

(a) keep at his or her premises detailed records of an animal remedy manufactured, sold or supplied by him or her,

(b) not sell or supply an animal remedy to a person unless the person, to whom the animal remedy is to be sold or supplied, is lawfully entitled to sell or supply the animal remedy.

(2) The record referred to in paragraph (1)(a) shall show in respect of each incoming and outgoing transaction for each sale or supply of an animal remedy—

(a) the date,

(b) the name of animal remedy,

(c) the batch number and expiry date,

(d) the quantity supplied, and

(e) the name and address of the recipient.

(3) A record maintained under this Regulation shall be available for inspection by an authorised officer for a period of not less than five years from the date of manufacture, or for a period which ends one year after the labelled expiry date of the animal remedy, whichever is the longer period.

(4) The holder of a manufacturer's licence, a manufacturer of starting materials or a person, including a contract laboratory carrying out activities on their behalf, shall submit to an inspection and shall make available records which the Board considers necessary for the purpose of verifying compliance with the Directive and these Regulations.

(5) In this Regulation and Schedules 4 and 5, 'starting materials' means active substances used as ingredients in the manufacture of an animal remedy.

(6) This Regulation is in addition to and not in substitution for any other obligation imposed on a holder of a manufacturer's licence by these Regulations or by a manufacturer's licence.

***Validity of a manufacturer's licence.***

24. (1) A Manufacturer's licence, unless previously revoked, remains in force for three years or a shorter period specified in the licence.

(2) A manufacturer's licence may be renewed by the Board on the basis of an application by the holder.

(3) An application for renewal of a manufacturer's licence shall be in a form, be accompanied by material and contain information that the Board specifies.

(4) If application for renewal of a manufacturer's licence is made not later than 90 days before the expiry date of the existing licence, that licence remains in force until the Board determines the application.

(5) A manufacturer's licence granted by way of renewal is, subject to Regulation 25(1), valid for an unlimited period.

***Revocation, suspension or variation of a manufacturer's licence.***

25. (1) (a) Without prejudice to Regulation 22(1), the Board may revoke, suspend or vary the conditions of a licence if in its opinion the holder no longer satisfies the requirements for the grant of a licence or if, in the course of a routine inspection or as a result of investigation of pharmacovigilance reports or other complaints, it has been established that an animal remedy to which the licence relates is not being manufactured in accordance with the specification stated in the veterinary product authorisation or other standard relating to the animal remedy.

(b) Notwithstanding subparagraph (a), the Board may, on application from the holder, vary the conditions attaching to a manufacturer's licence, within the periods specified in Article 48 of the Directive.

(2) Without prejudice to paragraph (7), if the Board proposes to suspend, revoke or vary a licence, it shall—

(a) notify the holder in writing of the proposal and of the reasons therefor, and that he or she may make representation to the Board in relation to the proposal within 30 days of the notification,

(b) consider a representation duly made before deciding whether to proceed with, modify or annul the proposal, and

(c) notify the holder of the decision and the reasons therefor,

and a suspension, revocation or variation shall not have effect until the Board issues a notification of its decision.

(3) A person shall comply with a decision of the Board under paragraph (1).

(4) If the Board is of the opinion that, in respect of a premises for which there is in force a manufacturer's licence, there is a grave and immediate risk—

- (a) to public or animal health arising from the manner in which the premises is managed, maintained or operated,
- (b) that an animal remedy, manufactured on the premises and intended to be sold or supplied for administration to animals, is liable, if so administered, to cause illness or injury to a treated animal or the consumer of the produce of the treated animal, or
- (c) that an animal remedy, which is on the premises and is intended to be sold or supplied for administration to animals, is, or may become, unfit for such purpose by virtue of non-compliance with a provision of these Regulations or the Directive,

it may serve a notice in writing requiring the cessation of—

- (i) the manufacture of an animal remedy or batch of an animal remedy at the premises or part thereof, or
- (ii) the import, distribution, sale or supply of an animal remedy or batch of an animal remedy,

and the notice, or a subsequent notice, may specify the steps to be taken, or the things to be done, before the premises or part thereof, may be used for the manufacture of an animal remedy to which the notice relates.

(5) A person upon whom a notice is served under paragraph (4) shall comply with the terms of the notice (including a notice subject to representation under paragraph (7)).

(6) The Board may, by notice in writing, revoke or vary a notice served under paragraph (4).

(7) If the Board serves a notice under paragraph (4), it shall—

- (a) notify the holder in writing of the decision and the reasons for the decision, and that he or she may (without prejudice to paragraph (5)) make representation to the Board in relation to the decision within 21 days of the notification,
- (b) consider a representation duly made, and
- (c) confirm, modify or annul the notice and notify the holder of the decision and the reasons for the decision.

***Certification by the Board.***

26. (1) The Board may, at the request of the holder of a manufacturer's licence, an exporter, or the appropriate authority in a third country, issue a certificate stating that—

- (a) the manufacturer is in possession of a manufacturer's licence to manufacture an animal remedy, and
- (b) there is in force an animal remedies authorisation relating to the animal remedy to be exported, or
- (c) the animal remedy has been manufactured for export under a licence granted in accordance with Regulation 17.

(2) The Board shall have regard to the prevailing administrative arrangements of the World Health Organisation regarding the issue of certification.

(3) If there is an animal remedies authorisation in force, the Board shall, if requested, supply a copy of the approved summary of product characteristics.

(4) If there is not an animal remedies authorisation in force in respect of the animal remedy to be exported, an application for a certificate under paragraph (1) shall be accompanied by a declaration stating why an animal remedies authorisation has not been sought.

***Consignment to a person or address in another member state.***

27. (1) If a person resident or having a place of business in the State sells or supplies an animal remedy to a person or address in another member state, the sale or supply of the animal remedy is, for the purposes of these Regulations, governed by the law of the State.

(2) A person shall not sell or supply an animal remedy to a person in another member state unless—

- (a) the animal remedy may be lawfully sold, supplied or administered in that member state, and
- (b) the manner in which the animal remedy is sold or supplied is in accordance with the law of that member state.

(3) In proceedings alleging a breach of paragraph (2), a certificate signed by an officer of a competent authority in another member state, stating that the authority is the competent authority and that on a particular date or during a particular period—

- (a) it was not lawful to sell, supply or administer a particular animal remedy in that member state, or
- (b) the manner in which a particular animal remedy was sold or supplied into that member state was not in accordance with the law of that member state, is, until the contrary is shown, sufficient evidence of the facts stated in the certificate and it is not necessary to prove the signature of the person signing the certificate, that he or she is an officer of the authority or that the authority is a competent authority.

## PART V

## SALE, SUPPLY AND POSSESSION OF AN ANIMAL REMEDY

***Restriction on sale of an animal remedy.***

28. (1) Without prejudice to the generality of these Regulations, a person shall not sell or supply an animal remedy other than in accordance with the routes of sale stipulated in Part I of Schedule 1.

(2) Subject to paragraph (3), a person shall not sell or supply an animal remedy except under and in accordance with a licence or registration granted under Regulation 30, 31 or 33.

(3) Paragraph (2) does not apply to—

- (a) the sale or supply of an authorised animal remedy by, or under the supervision of, a pharmacist from a pharmacy, in accordance with these Regulations,
- (b) the sale or supply of an authorised animal remedy by a registered veterinary practitioner in accordance with Regulation 43, or
- (c) the sale or supply by wholesale of an authorised animal remedy by the holder of a manufacturer's licence, if the animal remedy is manufactured by him or her under and in accordance with the manufacturer's licence.

(4) Notwithstanding paragraphs (2) and (3), a person shall not sell or supply an animal remedy designated prescription only unless—

- (a) he or she is a pharmacist and he or she has a veterinary prescription relating to the animal remedy in his or her possession,
- (b) he or she is a registered veterinary practitioner, the animal is under his or her care and he or she issues a veterinary prescription in respect of the animal remedy, or
- (c) in the case of an animal remedy which comes within the scope of paragraph 3 (iii) of Part I of Schedule 1, he or she is a responsible person selling or supplying from a premises to which an animal remedies merchant's licence relates and he or she has a veterinary prescription relating to the animal remedy in his or her possession.

(5) Without prejudice to Regulation 20(3)(b), a person who sells or supplies an animal remedy designated prescription only shall affix to the animal remedy, at the time of sale or supply, (in a manner that does not obscure the information required by the animal remedies authorisation) a label indicating—

- (a) his or her name and address,
- (b) the serial number of the veterinary prescription,

- (c) the name of the prescribing veterinary practitioner,
  - (d) the date of sale or supply, and
  - (e) the dosage and duration of treatment (unless indicated on the proprietary label).
- (6) (a) Notwithstanding Paragraph (4)(b), a registered veterinary practitioner need not write a veterinary prescription in respect of an animal remedy prescribed for a companion animal, other than an equid, if he or she offers a veterinary prescription to the owner or person in charge of the animal and the offer is declined.
- (b) For the purposes of subparagraph (a), a veterinary practitioner shall display, prominently, at his or her premises, signage which makes clear that a client is entitled to receive a written veterinary prescription.
- (7) Notwithstanding Paragraphs (2) and (3), a person shall not sell or supply an animal remedy designated prescription only exempt unless—
- (a) he or she is a pharmacist, or
  - (b) he or she is a registered veterinary practitioner and the animal is under his or her care.
- (8) Notwithstanding Paragraphs (2) and (3), a person shall not sell or supply an animal remedy designated pharmacy only unless—
- (a) he or she is a pharmacist or is under the supervision of a pharmacist in a pharmacy, or
  - (b) he or she is a registered veterinary practitioner and the animal is under his or her care.
- (9) Paragraphs (1), (5), (7) and (8) do not apply to the holder of a manufacturer's licence, or the holder of an animal remedies wholesaler's licence supplying a person who may lawfully sell or supply the animal remedy.
- (10) A person shall not possess, sell or supply an animal remedy if the label or package leaflet has been altered or if the label or package leaflet has been removed unless authorised by the Board.

***Restriction on use of a premises.***

29. A person shall not use a premises for storage for the purpose of sale or supply or for the sale or supply of an animal remedy unless the premises is—
- (a) a premises in respect of which there is a manufacturer's licence,
  - (b) a premises in respect of which there is an animal remedies wholesaler's licence,

- (c) a premises in respect of which there is an animal remedies merchant's licence,
- (d) a premises owned or operated by a person registered in accordance with Regulation 33,
- (e) a pharmacy, or
- (f) a part of a premises, which is not a retail outlet to which Regulation 31 applies, used by a registered veterinary practitioner in respect of which a certificate of suitability has been granted or deemed to have been granted under Part 9 of the Veterinary Practice Act 2005 (No. 22 of 2005).

***Wholesale of an animal remedy.***

30. (1) A person shall not sell or supply an animal remedy by wholesale except under and in accordance with a licence ("animal remedies wholesaler's licence").

(2) An applicant for an animal remedies wholesaler's licence shall satisfy the Minister that he or she has suitable premises, equipment and staff and suitable arrangements for record-keeping, handling, storage and distribution of an animal remedy.

(3) An animal remedies wholesaler's licence may relate to animal remedies generally, to animal remedies of a particular class or description specified in the licence, or to one or more animal remedies specified in the licence.

(4) An animal remedies wholesaler's licence may not relate to a premises used for purposes referred to in Regulation 31 or 33.

(5) Without prejudice to Regulation 49, the holder of an animal remedies wholesaler's licence, shall—

- (a) sell or supply an animal remedy only to a person who holds an animal remedies wholesaler's licence, an animal remedies merchant's licence, or, is a person registered in accordance with Regulation 33, a pharmacist or a registered veterinary practitioner,
- (b) provide and maintain premises, equipment and staff, and have in operation arrangements to avoid deterioration of an animal remedy to which the licence relates and to notify the Minister within seven days of any material change in the premises, equipment, staff or arrangements,
- (c) undertake procedures for storage, stock rotation and maintenance of records in compliance with the particulars furnished with the application or with other arrangements as may be approved in advance by the Minister,

- (d) immediately withdraw, if directed by the Minister, the Agency, the Board or the marketing authorisation holder, from sale or supply any quantity and, in so far as is practicable, immediately recall any quantity sold or supplied of—
  - (i) a batch, or part of a batch, of an animal remedy that does not conform with an animal remedies authorisation, or the strength, quality or purity does not conform with the specification of that animal remedy, or
  - (ii) an animal remedy that has given rise to unacceptable adverse reactions,
- (e) keep, at the premises to which the licence refers, records of purchase and sale invoices in respect of each incoming and outgoing transaction detailing at least the following information—
  - (i) the date of transaction,
  - (ii) the precise identity of the animal remedy including name and pharmaceutical form and pack sizes,
  - (iii) the manufacturer's batch number,
  - (iv) the name and address, as appropriate, of the supplier or consignee,
  - (v) the quantity received or supplied (including the quantity received and returned in accordance with subparagraph (j), or otherwise disposed of),
- (f) keep at his or her premises the records referred to in subparagraph (e) for a period of five years from the date of receipt, sale or supply of the animal remedy and make these records available to an authorised officer on request,
- (g) permit inspections and make available information as may be required to satisfy the Minister that the conditions of the licence are being complied with,
- (h) furnish to the purchaser with each supply of an animal remedy, information detailing—
  - (i) the date of supply,
  - (ii) the precise identity of the animal remedy including proprietary name and pharmaceutical form and pack size,
  - (iii) the quantity supplied, and
  - (iv) the manufacturer's batch number,

- (i) comply with Article 65(5) of the Directive, and
- (j) have in place the necessary systems to receive from—
  - (i) a registered veterinary practitioner,
  - (ii) a pharmacist,
  - (iii) the holder of an animal remedies merchant's licence, or
  - (iv) a person registered under Regulation 33,

an animal remedy which is unused or has reached its expiry date, for return to the marketing authorisation holder or other person acting on his or her behalf in accordance with the arrangements put in place by that person.

(6) The holder of an animal remedies wholesaler's licence shall not sell or supply an animal remedy to a person unless—

- (a) that person is lawfully entitled to sell or supply an animal remedy, and
- (b) the sale or supply of the animal remedy by that person would not contravene these Regulations.

(7) The holder of an animal remedies wholesaler's licence shall, at least once a year, carry out a detailed audit to reconcile incoming and outgoing supplies with supplies currently held in stock and any discrepancies shall be specifically recorded and such record shall be retained and made available at the premises for inspection by an authorised officer for a period of not less than five years.

(8) This Regulation does not apply to the—

- (a) sale or supply of an animal remedy by a person who manufactured or imported it in accordance with a manufacturer's licence, or
- (b) sale or supply by a pharmacist to a registered veterinary practitioner for use in accordance with Regulation 18.

(9) An animal remedies wholesaler's licence remains in force for a period of three years or for a shorter period as may be specified in the licence, unless it is suspended, varied or revoked at an earlier date.

***Retail sale of an animal remedy.***

31. (1) (a) A person shall not sell or supply an animal remedy by retail except under and in accordance with a licence ("animal remedies merchant's licence"),

- (b) Subparagraph (a) does not apply to a person registered in accordance with Regulation 33, but only in so far as sale or supply of an animal remedy designated 'companion animal medicine' is concerned.

(2) An applicant for an animal remedies merchant's licence shall satisfy the Minister that he or she has suitable premises, equipment and staff and suitable arrangements for record-keeping, handling, storage and distribution of an animal remedy or class of animal remedy.

(3) An animal remedies merchant's licence may relate to animal remedies generally, to animal remedies of a particular class or description specified in the licence, or to one or more animal remedies specified in the licence.

(4) An animal remedies merchant's licence may not relate to a premises used for purposes referred to in Regulation 30.

(5) Without prejudice to Regulation 49, the holder of an animal remedies merchant's licence, shall—

- (a) provide and maintain premises, equipment and staff and have in operation arrangements necessary to avoid deterioration of an animal remedy and to notify the Minister within seven days of a material change in the premises, equipment, staff or arrangements,
- (b) keep, at the premises to which the licence relates, records of purchase or sale invoices in respect of each incoming and outgoing transaction detailing at least the following information—
  - (i) the date of transaction and in the case of an animal remedy designated prescription only, the serial number of the veterinary prescription,
  - (ii) the precise identity of the animal remedy including name and pharmaceutical form and pack sizes,
  - (iii) the manufacturer's batch number,
  - (iv) the name and address, as appropriate, of the supplier or consignee, and
  - (v) the quantity received or supplied (including the quantity received and or returned in accordance with subparagraph (g), or otherwise disposed of),
- (c) keep at his or her premises, the records referred to in subparagraph (b) for a period of five years from the date of receipt, sale or supply of the animal remedy and make these records available to an authorised officer on request,
- (d) permit inspections and make available information required to satisfy the Minister that the conditions of the licence are being complied with,
- (e) undertake procedures for storage, stock rotation and maintenance of records specified with the particulars furnished with the application

or with such other arrangements as may be approved in advance by the Minister,

- (f) immediately withdraw, if directed by the Minister, the Agency, the Board, the marketing authorisation holder or the holder of an animal remedies wholesalers licence, from sale or supply any quantity, and, in so far as is practicable, immediately recall any quantity sold or supplied of—
  - (i) a batch or part of a batch of an animal remedy that does not conform with an animal remedies authorisation or the strength, quality or purity does not conform with the specification of that animal remedy, or
  - (ii) an animal remedy that has given rise to unacceptable adverse reactions,
- (g) have in place arrangements to receive from customers for return to the person from whom he or she purchased it, an animal remedy that is unused or has reached its expiry date and in addition take steps to ensure that customers are aware of the arrangements, and
- (h) ensure that an animal remedy is not sold from the premises other than by a responsible person.

Subparagraph (b) does not apply in the case of an animal remedy designated ‘companion animal medicine’.

(6) The Minister may not grant a licence in respect of a premises unless the premises conforms to the general conditions set out in Schedule 6.

(7) The holder of an animal remedies merchant’s licence shall not sell or supply an animal remedy for the purpose of sale or supply to a person to whom Regulation 30(5)(a) refers.

(8) An animal remedies merchant’s licence remains in force for a period of three years, or for a shorter period if specified in the licence unless it is suspended, varied or revoked at an earlier date.

(9) The holder of an animal remedies merchant’s licence shall, at least once a year, carry out a detailed audit to reconcile incoming and outgoing supplies with supplies currently held in stock and any discrepancies shall be specifically recorded and the record shall be retained and made available at the premises for inspection by an authorised officer for a period of not less than five years.

(10) This Regulation does not apply to—

- (a) a pharmacy, or
- (b) a part of a premises, which is not a retail outlet to which this Regulation applies, used by a registered veterinary practitioner, in respect

of which a certificate of suitability has been granted or deemed to have been granted under Part 9 of the Veterinary Practice Act 2005 (No. 22 of 2005).

***Training.***

32. (1) The Minister may approve appropriate training courses for the purpose of ensuring that a person, other than a registered veterinary practitioner or a pharmacist, has adequate training in the proper and safe handling and storage of animal remedies to be responsible for the retail sale or supply of such remedies.

(2) Without prejudice to Regulation 49, it shall be a condition of approval that the person providing the course shall furnish the Minister with the names and addresses of persons who have successfully completed the course.

(3) (a) A person who has successfully completed a training course approved under paragraph (1) is referred to as “a responsible person”.

(b) Notwithstanding subparagraph (a), the Minister may require a responsible person to undergo additional training, if the Minister considers it necessary.

(4) The Minister may refuse to accept the nomination of a person to be a responsible person if, notwithstanding that the person has successfully completed an approved training course, the person has been convicted of an offence under the Act or these Regulations.

***Sale of an animal remedy designated ‘companion animal medicine’.***

33. (1) A person shall not sell or supply by retail an animal remedy designated ‘companion animal medicine’ unless he or she is registered in the register maintained under this Regulation (“companion animal medicine sellers register”).

(2) The Minister shall maintain a register of persons selling an animal remedy designated ‘companion animal medicine’ by retail.

(3) Registration of a person under this Regulation ceases if—

(a) a notice in writing is served on the Minister by or on behalf of a person to whom an entry in the register relates, stating that the person has ceased to carry on the business of selling an animal remedy designated ‘companion animal medicine’, or

(b) a person is notified in writing by the Minister of the Minister’s belief that he or she has ceased to carry on the business of selling an animal remedy designated ‘companion animal medicine’.

(4) On the death of a person registered in the register, the Minister may, on application by the personal representative of that person, enter in the register the name of the personal representative.

(5) A person registered under this Regulation shall comply with the storage requirements for an animal remedy as specified by the outer packaging, immediate packaging or package leaflet.

(6) A person registered under this Regulation shall have in place arrangements to receive and return to the person from whom he or she purchased it, an animal remedy that is unused or has reached its expiry date and shall take steps to ensure that customers are aware of these arrangements.

(7) This Regulation does not apply to—

- (a) a registered veterinary practitioner,
- (b) a pharmacist,
- (c) the holder of an animal remedies merchant's licence, or
- (d) the holder of an animal remedies wholesaler's licence.

***Record-keeping and other requirements for a veterinary practitioner and a pharmacist.***

34. A registered veterinary practitioner or a pharmacist shall—

- (a) keep, at his or her premises, a record of purchases and sales (including quantities administered) in respect of each incoming and outgoing transaction, detailing at least—
  - (i) the date of transaction, and in the case of an animal remedy designated 'veterinary practitioner only (VPO-1)', 'veterinary practitioner only (VPO)', or prescription only (POM), the serial number of the veterinary prescription,
  - (ii) the precise identity of the animal remedy or where Regulation 18 applies, the medicinal product, including name, pharmaceutical form and pack size,
  - (iii) the manufacturer's batch number,
  - (iv) the name and address of the supplier or consignee, and
  - (v) the quantity received or supplied (including the quantity received or returned in accordance with subparagraph (c) or otherwise disposed of),
- (b) keep the records referred to in subparagraph (a) for a period of five years from the date of receipt, sale or supply or administration of the animal remedy and these records shall be made available to an authorised officer on request, and
- (c) have in place arrangements to receive from consignees and return to the person from whom he or she purchased it, an animal remedy that

is unused or reached its expiry date and shall take steps to ensure that clients are aware of these arrangements.

Subparagraphs (a) and (b) do not apply in the case of an animal remedy designated ‘companion animal medicine’.

***Prohibition on sale of an animal remedy after expiry date.***

35. A person shall not sell or supply an animal remedy after the date specified by the manufacturer as the expiry date.

***Fixed premises.***

36. (1) A person shall not sell or supply an animal remedy other than from a fixed premises.

(2) Paragraph (1) does not apply to the sale or supply of an animal remedy in the course of the provision of a veterinary service by a registered veterinary practitioner for the treatment of an animal under his or her care.

(3) Subject to paragraph (4)(a), a person shall not—

- (a) except under and in accordance with a licence granted by the Minister, sell or supply an animal remedy by retail, via the internet or by mail order,
- (b) except under and in accordance with a licence granted by the Minister, make a visit from house to house to collect, solicit or obtain an order for an animal remedy,
- (c) sell or supply an animal remedy from a travelling shop, vehicle or automatic vending machine, or
- (d) sell or supply an animal remedy at a trade fair or at a public or private place where animals are placed for exhibition or competition.

Subparagraph (b) does not apply in the case of a visit made by the representative of the holder of an animal remedies wholesaler’s licence to any of the following persons at his or her place of business—

- (i) a registered veterinary practitioner,
- (ii) a pharmacist,
- (iii) the holder of an animal remedies merchant’s licence, or
- (iv) a person entered in the ‘companion animal medicine sellers register’.

(4) (a) The Minister shall not grant a licence under paragraph (3)(a) or (b) unless the applicant is—

- (i) the holder of an animal remedies merchant’s licence, or
- (ii) a pharmacist.

- (b) A licence granted under paragraph (3)(a) or (b) may only relate to an animal remedy referred to in paragraphs 6 and 7 of Part I of Schedule 1.

(5) In this Regulation:—

“house” includes land or other premises;

“fixed premises” does not include a vehicle, trailer, caravan, or other thing which may be transported on, in, or attached to a vehicle, or, a tent, awning, or hut, shed, or an unroofed or temporary structure or stall or a yard, field, roadway, or casual trading area.

***Advertising.***

37. (1) A person shall not publish or cause to be published an advertisement or other promotion for an animal remedy unless the animal remedy is an authorised animal remedy.

(2) Notwithstanding paragraph (1), a person shall not advertise an animal remedy—

- (a) which contains a substance subject to restrictions resulting from implementation of United Nations Conventions on narcotic and psychotropic substances,
- (b) which is designated Veterinary Practitioner Only (VPO-1), veterinary practitioner only (VPO) or Prescription Only, or
- (c) in contravention of an animal remedies authorisation.

(3) Paragraph (2) does not apply to the advertisement of an animal remedy, which is solely directed at the holder of an animal remedies wholesaler’s licence, a registered veterinary practitioner, a pharmacist or the holder of an animal remedies merchant’s licence.

(4) A registered veterinary practitioner, the holder of an animal remedies merchant’s licence, a pharmacist or the holder of a registration under Regulation 33 shall display a list of prices of animal remedies held in stock.

***Possession of certain animal remedies.***

38. (1) A person shall not have an animal remedy, which is designated prescription only, in his or her possession or under his or her control, unless he or she has a veterinary prescription relating to the animal remedy in his or her possession.

(2) Paragraph (1) does not apply to—

- (a) the holder of a manufacturer’s licence,
- (b) the holder of an animal remedies wholesaler’s licence,
- (c) a registered veterinary practitioner,

- (d) a pharmacist,
- (e) the holder of an animal remedies merchant's licence, but only in the case of an animal remedy referred to in paragraph 3(iii) of Part I of Schedule 1, or
- (f) a person in charge of a companion animal (other than an equid) in the circumstances referred to in Regulation 28(6).

(3) Paragraph (2) does not make it lawful for a person to whom that paragraph applies, other than a person referred to in subparagraph (c) or (f), to have an animal remedy designated prescription only in his or her possession or under his or her control on a farm or other premises where a food producing animal is kept.

(4) A person, other than a registered veterinary practitioner, shall not have an animal remedy designated 'veterinary practitioner only (VPO-1)' or 'veterinary practitioner only (VPO)' in his or her possession or under his or her control on a premises where an animal is kept, sold, supplied or slaughtered.

(5) A registered veterinary practitioner shall not cause or permit a person (other than a registered veterinary practitioner) to have an animal remedy designated 'veterinary practitioner only (VPO-1)' or 'veterinary practitioner only (VPO)' in his or her possession or under his or her control.

## PART VI

### ADMINISTRATION OF AN ANIMAL REMEDY AND PROVISIONS RELATING TO ANIMALS AND ANIMAL PRODUCE

#### ***Administration of an animal remedy.***

39. (1) Without prejudice to Regulations 15(1) and 18 and subject to paragraph (2), a person shall not administer, cause or permit administration of an animal remedy to an animal unless—

- (a) there is in force an animal remedies authorisation in respect of the animal remedy,
- (b) the administration is carried out in accordance with the animal remedies authorisation,
- (c) the animal remedies authorisation authorises administration of the animal remedy to the animal, class of animal or species,
- (d) the animal remedies authorisation permits administration of the animal remedy by the person, and
- (e) the Act and these Regulations have been complied with in respect of the animal remedy.

(2) Notwithstanding paragraph (1) a person shall not administer—

- (a) an animal remedy designated ‘veterinary practitioner only (VPO-1)’ to an animal unless he or she is a registered veterinary practitioner and the animal is under his or her care,
- (b) an animal remedy designated ‘veterinary practitioner only (VPO)’ to an animal unless—
  - (i) he or she is a registered veterinary practitioner and the animal is under his or her care,
  - (ii) he or she carries out the administration in the presence and under the direct supervision of the prescribing veterinary practitioner, or
  - (iii) in the case of administration of an animal remedy to an animal in a user establishment registered under the Cruelty to Animals Act 1876 (39 & 40 Vict.), he or she has been duly authorised in writing to do so by the appropriate authority of the institution concerned and by the supervising veterinary practitioner, or
- (c) an animal remedy designated ‘prescription only’, unless it has been prescribed by a registered veterinary practitioner and, without prejudice to Regulation 28(6), the person administering the animal remedy has a veterinary prescription in his or her possession relating to that animal remedy and to the animal concerned.

***Administration of an animal remedy to a food producing animal.***

40. (1) A person shall not—
- (a) notwithstanding Regulations 15 and 18, administer to a food producing animal, an animal remedy which consists of or contains a substance, the administration of which to the animal, species or class of animal, is unlawful,
  - (b) import, export, sell, supply, or slaughter for human consumption, a food producing animal to which an animal remedy has been administered in contravention of subparagraph (a),
  - (c) without prejudice to Regulation 41, import, export, sell or supply for human or animal consumption meat, milk, eggs or honey derived from, or produced by, an animal to which an animal remedy has been administered in contravention of subparagraph (a),
  - (d) process meat, milk, eggs or honey referred to in subparagraph (c) or import, export or sell produce of any meat, milk, eggs or honey prepared from, or with, such meat, milk, eggs or honey, or
  - (e) have in his or her possession or under his or her control a food producing animal to which an animal remedy has been administered in contravention of subparagraph (a) or meat, milk, eggs or honey derived from, or produced by, the animal.

- (2) (a) The owner or person in charge of an animal to which an animal remedy has been administered shall—
- (i) comply with the conditions of use of the animal remedy to be complied with after administration,
  - (ii) ensure that the animal is not slaughtered in order to be offered for human consumption (or sold, supplied or exported in order to be so offered) before the end of the withdrawal period and that produce obtained from the animal before the end of a withdrawal period is not disposed of with a view to being offered for human consumption.
- (b) If a person, other than the owner or person in charge of the animal, administers an animal remedy to that animal, he or she shall inform the owner or person in charge of the animal of the obligations specified in subparagraph (a).

(3) In paragraph (2), “conditions of use” means information and directions that, pursuant to the animal remedies authorisation, are required to appear on the container, outer package and package leaflet of the animal remedy.

***Import of an animal.***

41. An animal lawfully imported is considered to have been treated with an authorised animal remedy, if—

- (a) the animal remedy was administered prior to import,
- (b) the animal remedy was administered in accordance with the law of the state where administration occurred, and
- (c) the animal remedy does not consist of or contain a substance the administration of which to the class or classes of animal is unlawful.

***Animal remedies record and disposal of animal remedies.***

42. (1) The owner or person in charge of a food producing animal shall keep at his or her premises a record (“Animal Remedies Record”) of all animal remedies purchased and administered, which shall conform to Schedule 7.

(2) The owner or person in charge of a food producing animal to which an animal remedy has been administered shall—

- (a) enter in the Animal Remedies Record, on each occasion when the animal remedy is administered, the required details in chronological order, and
- (b) retain the Animal Remedies Record at his or her premises for five years after administration of the animal remedy and make this Record available on request to an authorised officer.

(3) The owner or person in charge of a food producing animal to which an animal remedy designated veterinary practitioner only (VPO-1), veterinary practitioner only (VPO) or prescription only has been administered shall keep, in date order, for five years, a copy of each veterinary prescription issued by a registered veterinary practitioner for the supply and use of the animal remedy administered to an animal under his or her control and make the copies and the record available for inspection on request by an authorised officer.

(4) The owner or person in charge of an animal shall return an unused animal remedy or an animal remedy which has reached its expiry date to the person from whom he or she purchased that animal remedy and shall record this in the Animal Remedies Record.

## PART VII

### VETERINARY PRACTICE AND VETERINARY MEDICINE

#### *Prescribing and dispensing.*

43. (1) A person shall not prescribe an animal remedy unless he or she is a registered veterinary practitioner, the animal to which the veterinary prescription relates is under his or her care and he or she is satisfied that—

- (a) the veterinary prescription will be used to treat the animal to which the prescription relates,
- (b) use of the animal remedy is justified for the animal,
- (c) administration of the animal remedy is, to the best of his or her knowledge and belief, not incompatible with a current or previous treatment, (where appropriate, by consulting with any other veterinary practitioner who has responsibility for the care of the animals), and
- (d) there is no contra-indication and there will not be an adverse reaction if other animal remedies have been, or are to be, administered or prescribed.

(2) A registered veterinary practitioner shall only prescribe an animal remedy in a quantity necessary for the treatment of the condition in respect of which the animal remedy is prescribed subject, in the case of a food producing animal, to a maximum quantity of 12 months supply from the date the veterinary prescription is issued.

(3) Without prejudice to Regulation 28(6), a registered veterinary practitioner who prescribes or administers an animal remedy designated veterinary practitioner only (VPO-1), veterinary practitioner only (VPO), or prescription only for or to an animal shall, at that time, issue a veterinary prescription to the owner or person in charge of the animal.

(4) Without prejudice to Regulation 28(6), a veterinary prescription shall—

- (a) be issued by a registered veterinary practitioner,

- (b) be written in ink or printed, legible and indelible and be signed in ink by, and bear, in block capital letters, the name and address of, the registered veterinary practitioner,
  - (c) be issued in triplicate of which the original and one copy shall be given to the owner or person in charge of the animal to be treated and a copy retained by the registered veterinary practitioner, and
  - (d) contain at least the particulars listed in Schedule 3.
- (5) A registered veterinary practitioner shall retain, at his or her premises, a copy of a veterinary prescription for 5 years and make the copy available for inspection on request by an authorised officer.
- (6) If a registered veterinary practitioner issues a veterinary prescription, he or she shall (if there is more than one authorised animal remedy suitable for treatment of the condition to which it applies) specify at least two animal remedies on the veterinary prescription.
- (7) A person—
- (a) who dispenses a veterinary prescription in part, shall immediately record on the prescription and on the copy, in a conspicuous, legible and indelible manner, the quantity of an animal remedy sold or supplied by him or her on foot of the veterinary prescription and the date of each such sale or supply and shall attest to this by means of his or her signature and shall retain a copy (which could be a photocopy) of the prescription,
  - (b) who has completed dispensing a veterinary prescription shall—
    - (i) at that time write on the prescription and on the copy thereof in a conspicuous, legible and indelible manner, the word “dispensed” and shall attest to this by means of his or her signature and the date,
    - (ii) return a copy of the veterinary prescription to the person who presented it, and
    - (iii) he or she shall retain, at his or her premises, the original veterinary prescription for five years and shall make this available on request to an authorised officer, and
  - (c) not complete dispensing an animal remedy on foot of a veterinary prescription later than 12 months after the date the veterinary prescription is issued.
- (8) For the purposes of this Regulation, an animal is considered to be under the care of a registered veterinary practitioner if—

- (a) the registered veterinary practitioner (or another member of the group veterinary practice of which he or she is a member) has been consulted and has been given responsibility for the professional veterinary care of the animal, herd or flock by the owner or person in charge,
- (b) the registered veterinary practitioner (or other member of the group veterinary practice of which he or she is a member) has sufficient knowledge of the animal, herd or flock to form an opinion of the condition of the animal and for this purpose he or she (or another member of the group veterinary practice), shall have visited the farm or other premises on which the animal, herd or flock is kept (or otherwise examined the animal), sufficiently often and recently enough and, in any event, at least once in a 12 month period, to have acquired an accurate picture of the current health, welfare and disease status of the animals on that farm or premises,
- (c) the registered veterinary practitioner (or other member of the group veterinary practice) is available to respond to requests to provide services of veterinary medicine and surgery and clinical procedures on the animal (or in the herd or flock) in accordance with ethical veterinary practice,
- (d) the registered veterinary practitioner is readily available for follow up consultation or monitoring of the condition and evaluation of the therapy, and
- (e) the records kept by the registered veterinary practitioner make it evident that the professional veterinary responsibility for the animal, herd or flock in question is real and not merely nominal.

(9) The 12 month period, referred to in paragraph (8)(b), does not apply to the prescribing of an intramammary animal remedy, if the animal to be treated belongs to a herd covered by a programme meeting the requirements of Schedule 8.

(10) In order to comply with paragraph (8)(e), a registered veterinary practitioner shall maintain, at his or her premises, records as follows:

- (a) in relation to each client, a record, containing at least the following—
  - (i) the date of each visit to the premises on which the animal, herd or flock is kept or on which the animal was seen,
  - (ii) the identity or other reference to animals clinically examined,
  - (iii) the condition identified,
  - (iv) details of treatment of each condition, and
  - (v) a cross-reference to any relevant results of laboratory tests

undertaken for the purpose of diagnosis, or any other test results,

and

- (b) copies of invoices and statements regarding professional services and supply of medicines in respect of each client.
- (11) (a) Invoices referred to in paragraph (10)(b) shall detail the cost of an animal remedy, administered, sold or supplied separately from a professional veterinary service.
- (b) These records may be maintained in the form of a herd health programme.

***Emergency supply of certain animal remedies by a pharmacist.***

44. (1) It is not a contravention of these Regulations for a pharmacist to sell or supply an authorised animal remedy which is designated prescription only, if—

- (a) the pharmacist is requested to sell or supply the animal remedy for the treatment of an animal by a registered veterinary practitioner who, by reason of an emergency, is unable to furnish a veterinary prescription immediately,
- (b) the registered veterinary practitioner undertakes to furnish a veterinary prescription within 72 hours,
- (c) the animal remedy is sold or supplied in accordance with the directions of the registered veterinary practitioner requesting it,
- (d) the animal remedy is not a controlled drug specified in Schedule 1 or 2 to the Misuse of Drugs Regulations 1988, (S.I. No. 328 of 1988),
- (e) the animal remedy is labelled in accordance with Regulation 28(5), and
- (f) the pharmacist maintains the records prescribed by Regulation 34.

(2) A registered veterinary practitioner who makes a request in accordance with paragraph (1) shall immediately issue a veterinary prescription for the animal remedy and shall ensure that the prescription reaches the pharmacist and the owner or person in charge of the animal within the period specified in paragraph 1(b).

(3) If a registered veterinary practitioner fails to comply with an undertaking under paragraph (1)(b), the pharmacist shall not, at any future date, sell or supply an animal remedy under this Regulation at the request of that registered veterinary practitioner.

***Certain animal disease situations.***

45. (1) These Regulations, in so far as they relate to an animal under the care of a registered veterinary practitioner, do not apply to the administration of an animal remedy, if the animal remedy is administered for the purpose, or in the course of an official or voluntary scheme or programme authorised and operated by, or on behalf of, the Minister for the treatment, control, eradication, monitoring, or surveillance of disease (within the meaning of the Diseases of Animals Act, 1966 (No. 6 of 1966)) in an animal or for the determination of the health or disease status of an animal.

(2) An animal to which an animal remedy has been administered under and in accordance with a scheme or programme under paragraph (1) is considered, subject to the terms and conditions of the scheme or programme, to have had an authorised animal remedy administered to it.

## PART VIII

## MISCELLANEOUS

***Publication of certain decisions.***

46. The Board shall publish notice of the grant or revocation of a veterinary product authorisation in *Iris Oifigiúil*.

***Information to the Agency.***

47. (1) The Board shall inform the Agency of a decision to grant, refuse, suspend or revoke a veterinary product authorisation or a manufacturer's licence, or to prohibit the sale or supply, or to recall an animal remedy and the reasons for the decision.

(2) The Board shall make available to the Agency information relating to reports received by it under Regulation 12.

(3) The Board shall ensure that appropriate information about actions taken pursuant to paragraph (1) or Regulation 12, which may affect the protection of health in a third country, is brought to the attention of the relevant international organisations and the Agency.

***Forgery.***

48. (1) A person shall not forge a document purporting to be—

- (a) a veterinary prescription,
- (b) an animal remedies authorisation,
- (c) a licence, registration or approval,
- (d) a record required to be kept pursuant to these Regulations, or
- (e) any other document issued or maintained pursuant to these Regulations,

(which document is, in this Regulation, referred to as a “forged document”).

(2) A person shall not forge an endorsement or other entry purporting to be for any purpose of these Regulations on any document whatsoever required to be kept for the purposes of these Regulations (which document with such entry in this Regulation is referred to as a “falsely endorsed document”).

(3) A person shall not, with intent to deceive, alter—

- (a) a veterinary prescription issued under these Regulations,
- (b) an animal remedies authorisation,
- (c) a licence, registration or approval,
- (d) a record required to be kept pursuant to these Regulations, or
- (e) any other document issued or maintained pursuant to these Regulations,

(which document if so altered is, in this Regulation, referred to as an “altered document”).

(4) A person shall not utter a forged document, a falsely endorsed document or an altered document.

(5) A person shall not have in his or her possession or under his or her control, a forged document, a falsely endorsed document or an altered document.

(6) Paragraph (5) does not apply to—

- (a) an authorised officer or a member of the Garda Síochána or an officer of Customs and Excise, when acting in the course of his or her duty, or
- (b) a person who has taken into his or her possession a document for the purpose of—
  - (i) preventing another from committing or continuing to commit an offence, or
  - (ii) delivering it into the custody of a person specified in subparagraph (a).

***Licences, registrations and approvals granted under a specified Regulation.***

49. (1) The Minister may grant a licence, registration or approval under a specified Regulation or refuse an application and may attach conditions to a licence, registration or approval, revoke or vary a condition or suspend or revoke the licence, registration or approval.

(2) An application to the Minister for a licence, registration or approval under a specified Regulation shall be made in a form, be accompanied by any material, and fee and contain any particulars that the Minister specifies.

(3) In the case of an application for an animal remedies wholesaler's licence, the decision to grant a licence or refuse an application is notified to the applicant within 90 days of receipt of a valid application.

(4) Without prejudice to the generality of paragraph (1), the Minister may refuse an application or revoke a licence, registration or approval if—

- (a) the applicant or holder has been convicted of, or committed, an offence, whether he or she has been convicted or not, under the Act or these Regulations,
- (b) the applicant or holder has failed to comply with a condition attached to a licence, registration or approval,
- (c) the applicant or holder is not, in the opinion of the Minister, a fit and proper person to hold the licence, registration or approval, or
- (d) in relation to the application, information required has not been furnished or information that is, in the opinion of the Minister, false or misleading, has been furnished.

(5) Without prejudice to the generality of paragraph (1) and the specified Regulation concerned, the Minister shall refuse an application or revoke a licence, registration or approval under a specified Regulation, if the applicant or person to whom it is granted is convicted, on indictment, of an offence under the Act or these Regulations.

(6) If the Minister proposes to refuse an application, or to revoke a licence, registration or approval under a specified Regulation, or to attach a condition or vary or revoke a condition attached to a licence, registration or approval, he or she shall—

- (a) notify the applicant or holder in writing of the proposal and of the reasons for the proposal, and that he or she may make representations to the Minister in relation to the proposal within twenty one days of the notification,
- (b) consider a representation duly made before deciding whether to proceed with, modify or annul the proposal, and
- (c) notify the applicant or holder of the decision and the reasons for the decision.

(7) The holder shall not transfer a licence, registration or approval to any other person and any purported transfer is void and of no effect.

(8) A licence, registration or approval granted under these Regulations has no effect if the holder—

- (a) ceases trading or operation,

- (b) is adjudged bankrupt or, in the case of a body corporate, goes into liquidation, or, in the case of an unincorporated body or partnership is dissolved, or
- (c) sells or otherwise ceases to occupy the premises to which the licence relates.

(9) In this Regulation “a specified Regulation” means Regulation 16, 17, 18(11), 19, 30, 31, 32, 33 or 36(3)(a) or (b).

***Fixed Penalty Notice.***

50. (1) If an officer authorised in that behalf has reasonable grounds for believing that a person has committed an offence under Regulation 18(3)(d) or (10), 20(3)(b), 28(5) or (6)(b), 30(5) or (7), 31(5) or (9), 33, 34, 36(3), 37, 43(4), (5) or (7), or 44(2), he or she may serve a notice in writing on that person stating that—

- (a) the person is alleged to have committed the offence or contravention,
- (b) the person may during the period of 28 days from the date of the notice, make to the Minister a payment of €250 accompanied by the notice, and
- (c) a prosecution in respect of the alleged offence will not be instituted during the period specified in the notice and, if the payment specified in the notice is made during that period, no prosecution in respect of the alleged offence will be instituted.

(2) If notice is given under paragraph (1)—

- (a) the person to whom the notice applies may, during the period specified in the notice, make the payment specified in the notice to the Minister,
- (b) the Minister shall receive the payment, issue a receipt for it and retain the money so paid, and any payment so received shall not be recoverable in any circumstances by the person who made it, and
- (c) a prosecution in respect of the alleged offence shall not be instituted in the period specified in the notice, and if the payment so specified is made during that period, no prosecution in respect of the alleged offence shall be instituted.

(3) In a prosecution for an offence under the Act or these Regulations, the onus of proving that a payment, pursuant to a notice under this Regulation, has been made, lies on the defendant.

***Implied condition in certain contracts of sale.***

51. (1) In every contract of sale there shall be an implied condition on the part of the seller that all reasonable precautions have been taken and all due diligence has been exercised to ensure—

- (a) in the case of the sale of an animal, that the animal was not treated with any animal remedy and, in the case of an agreement to sell an animal, the animal was not so treated and will not be so treated prior to the time when the property is to pass, and
- (b) in the case of the sale of, or an agreement to sell, the carcase of any animal or food derived from any animal, that the animal had not been treated with any animal remedy,

otherwise than in accordance with these Regulations.

- (2) (a) Subject to subparagraph (b), any term of a contract, implied by virtue of paragraph (1), may be negated or varied by an express term in the contract, in so far as the first-mentioned term relates to an animal remedy—
  - (i) which has been administered to an animal before being imported into the State, and
  - (ii) in respect of which the Minister has granted an exemption from destruction,

but only if the express term is fair and reasonable and has been specifically brought to the attention of the buyer.
- (b) Subparagraph (a) shall not apply to an animal imported into the State where the sale of the animal would not be in accordance with a condition imposed by the Minister on the exemption.

(3) Any term of a contract implied by virtue of paragraph (1) may not be negated or varied in so far as it relates to an animal remedy other than in respect of an animal remedy to which paragraph (2) relates.

***Inspection by authorised officers, etc.***

52. (1) If an authorised officer or member of the Garda Síochána or an officer of Customs and Excise has reasonable cause to suspect that—

- (a) the manufacture, importation, preparation, handling, storage, transport, exportation, distribution, sale, supply or use of an animal remedy or any ingredient for an animal remedy is taking place or has taken place in, on, under or from any land, premises or in, on or from any vehicle,
- (b) an offence is being or has been committed under these Regulations in, on, under or from any land, premises or in, on or from any vehicle,
- (c) any land or premises is used for or in connection with the breeding, rearing, fattening, keeping, exhibiting, selling or transporting of animals,

- (d) any land or premises is a slaughterhouse or is used for or in connection with the slaughter of animals,
- (e) in, on, under or from any land or premises or in, on or from any vehicle, there is or was any animal of any species to which an animal remedy is being or has been administered or there is or was any food derived from such an animal or any carcase of such an animal, or
- (f) in, on, under or from any land or premises or in, on or from any vehicle, there is or was any animal remedy, or any ingredients for animal remedies, or any machinery, instruments or other thing used in the manufacture, preparation, handling, storage, transport, exportation, distribution, sale, supply or use of animal remedies or ingredients for animal remedies,

the authorised officer or member of the Garda Síochána or officer of Customs and Excise (in this section referred to as “the relevant person”) may, subject to paragraph (2), stop any such vehicle or enter (if necessary by force) any such land or premises, or land or premises used in connection with such land or premises, or any such vehicle, and there, or at any other place, and with such authorised officers, members of the Garda Síochána and officers of Customs and Excise (if any) as the relevant person considers appropriate—

- (i) search for and examine, inspect or test any animals, food derived from animals or carcasses of animals or anything believed to be an animal remedy or an ingredient for an animal remedy or anything to which subparagraph (f) relates,
- (ii) take such specimens (including blood, urine, faeces, tissue or remains of implants) from any animals, food derived from animals or carcasses of animals, and may for that purpose perform or cause to be performed any procedure (including surgery) as is considered necessary on such animals, food or carcasses,
- (iii) take such reasonable samples of, or from, any substances, or of or from a thing which may be considered appropriate for the purposes of these Regulations,
- (iv) seize and detain anything to which subparagraph (f) relates or anything which is believed to be or to contain an animal remedy or an ingredient for an animal remedy kept, used or intended to be used in contravention of the provisions of these Regulations,
- (v) search for and examine any document and take extracts from and copies of any such document,
- (vi) seize and detain an animal—
  - (I) in respect of which it is, with reasonable grounds, believed by the relevant person that a prohibited animal remedy or

ingredient for an animal remedy has been administered to it in contravention of these Regulations, and

(II) in relation to which either or both—

(A) the relevant person is aware that an application has been made or will be made for the destruction of the animal, and

(B) the relevant person has reasonable grounds for believing that the animal has been or may be moved in contravention of any notice duly served, in accordance with these Regulations,

(vii) require any person who is suspected to be, or to have been engaged in the importation, manufacture, preparation, handling, storage, transport, exportation, distribution, sale, supply or use of, or any person who is suspected to have possession or control of or to have kept or to keep, any animal remedy, ingredient for an animal remedy, animal, food derived from animals, carcasses of animals or anything to which subparagraph (f) relates, or any person who is suspected to be, or to have been, engaged in the breeding, rearing, fattening, keeping, exhibiting, selling or transporting or in the possession or control of any animal—

(I) in the case of any documents in the possession or control of that person or any such remedy, ingredient, animal, food, carcase or thing, to produce them to the relevant person or any authorised officer, member of the Garda Síochána or officer of Customs and Excise,

(II) in the case of any information in relation to such document, animal remedy, animal, food, carcase or thing which may be required (including the source of that document, remedy, animal, food, carcase or thing), to furnish them to the relevant person or any authorised officer, member of the Garda Síochána or officer of Customs and Excise,

(viii) require any person, being the owner or the person in charge of animals, or the owner or occupier of, or employed in or on, lands or premises so entered to give assistance, to carry out such instructions and to give such information as may be reasonably necessary for the purposes of subparagraphs (i) to (vii), and

(ix) require any person who is for the time being in charge or control of any vehicle so stopped or entered—

(I) to refrain from moving it, and

(II) to give assistance, to carry out such instructions and to give such information as may be reasonably necessary for the purposes of subparagraphs (i) to (vii).

(2) The functions of a relevant person under this Regulation may only be exercised in respect of a dwelling or so much of a vehicle or premises as constitutes a dwelling where the relevant person has reasonable cause to suspect that, before a search warrant could be sought in relation to the dwelling under Regulation 53, anything to which the said paragraph (1) relates—

(a) is being destroyed or disposed of, or

(b) is likely to be destroyed or disposed of.

(3) An authorised officer, member of the Garda Síochána or officer of Customs and Excise accompanying the relevant person may exercise all the functions conferred on the relevant person by virtue of paragraph (1) or (2).

***Search warrant.***

53. (1) If a judge of the District Court is satisfied by information on oath of an authorised officer, member of the Garda Síochána or an officer of Customs and Excise that there is reasonable cause for suspecting that—

(a) evidence of or relating to the commission or intended commission of an offence under these Regulations is to be found in, on or under any land or premises or in or on any vehicle and that such land, premises or vehicle or any part thereof consists of a dwelling,

(b) there is or was or is intended to be in, on or under any land or premises, in or on any vehicle and that such land, premises or vehicle or any part thereof consists of a dwelling, any animal remedy or ingredient for an animal remedy in relation to which a contravention of these Regulations, is being or has been or is intended to be committed, or

(c) a document directly or indirectly relating to, or connected with, a transaction or dealing which was, or an intended transaction or dealing which would if carried out be, an offence under these Regulations, is in the possession or under the control of a person in, on or under any land or premises or in or on any vehicle and that such land, premises or vehicle or any part thereof consists of a dwelling,

the judge may issue a search warrant under this Regulation.

(2) A search warrant issued under this Regulation shall be expressed and operate to authorise a named authorised officer, named member of the Garda Síochána or named officer of Customs and Excise, accompanied by such authorised officers, members of the Garda Síochána and officers of Customs and Excise as the named officer or member thinks necessary, at any time or times within one month from the date of issue of the warrant, on production if so requested of the warrant to enter (if necessary by force) the land, premises or vehicle named in the warrant.

(3) Where any premises, land or vehicle is entered pursuant to a warrant issued under this Regulation, an authorised officer, a member of the Garda Síochána or an officer of Customs and Excise so entering may—

- (a) stop and detain any person found in, on or under such land or premises, or in or on such vehicle, for the purpose of searching that person and to search or cause to be searched that person, and
- (b) exercise all or any of the powers referred to in Regulation 52.

***Search of suspects, etc.***

54. (1) If with reasonable cause a member of the Garda Síochána or an officer of Customs and Excise suspects that a person is in possession, in contravention of these Regulations, of an animal remedy or an ingredient for an animal remedy, the member or officer may without warrant—

- (a) search or cause to be searched by such a member or officer the person and, if the member or officer considers it necessary for that purpose, detain the person for such time as is reasonably necessary to carry out the search,
- (b) search or cause to be searched by such a member or officer any vehicle in which the member or officer suspects that such substance may be found and for the purpose of carrying out the search, if any such member or officer thinks fit, require the person who is, for the time being, in charge or control of the vehicle to bring it to a stop and when stopped to refrain from moving it or, in case the vehicle is already stationary, to refrain from moving it, or
- (c) seize and detain, or cause to be seized and detained by such a member or officer, anything found in the course of a search under this section which any such member or officer reasonably suspects to be something which might be required as evidence in proceedings for an offence under these Regulations.

(2) Where a member of the Garda Síochána or an officer of Customs and Excise decides to search or cause to be searched a person under this section the member or officer may require the person to accompany that member or officer to either a Garda Síochána station or a customs office for the purpose of being so searched at that station or office.

***Power of arrest.***

55. (1) Where with reasonable cause a member of the Garda Síochána suspects that—

- (a) an offence under these Regulations has been committed and so suspects a person of having committed the offence, or
- (b) a person is committing or has committed an offence under these Regulations in relation to the manufacture, importation, preparation, handling, storage, transport, exportation, distribution, sale, supply or use

of any animal remedy or any ingredient for an animal remedy, the possession of which by such a person would be prohibited by these Regulations,

the member may arrest the person without warrant.

(2) Where with reasonable cause a member of the Garda Síochána—

- (a) suspects that an offence under these Regulations has been committed or attempted, and
- (b) suspects a person of having committed the offence or having made the attempt,

the member may arrest the person without warrant if—

- (i) with reasonable cause the member suspects that the person, unless arrested, either will abscond for the purposes of evading justice or will obstruct the course of justice, or
- (ii) having enquired of the person, the member has reasonable doubts as to the person's identity or place of abode, or
- (iii) having enquired of the person, the member knows that the person does not ordinarily reside in the State, or has reasonable doubts as to whether the person so resides.

(3) Nothing in subparagraphs (i), (ii) and (iii) of paragraph (2) shall apply where a person is required to accompany a member of the Garda Síochána or an officer of Customs and Excise to a Garda Síochána station or a customs office for the purpose of Regulation 54(2) and who fails to comply with the requirement.

***Saving for certain power.***

56. Nothing in these Regulations shall operate to prejudice any power to search, or to seize or detain property, which may, apart from these Regulations, be exercised by a member of the Garda Síochána or an officer of Customs and Excise.

***Obstruction.***

57. A person shall not obstruct or impede an authorised officer, member of the Garda Síochána or officer of Customs and Excise in the due exercise of any of the functions conferred or exercisable by the authorised officer, member of the Garda Síochána or officer of Customs and Excise under these Regulations.

***Impersonation of an authorised officer, etc. and possession of certain identity documents.***

58. (1) A person shall not, with the intention to deceive—

- (a) purport to be, or

- (b) act in a manner that would lead another person to believe that he or she is,

a person duly appointed as an authorised person, officer, inspector, examiner or other officer of the Minister or a person otherwise duly appointed by or with the authority of the Minister or of any other purported member of the Government exercising any functions of the Minister either—

- (i) generally, or  
 (ii) for the purposes of these Regulations.

(2) A person shall not, without lawful excuse, have in his or her possession any document which—

- (a) has been,  
 (b) purports to be, or  
 (c) could lead another person to believe that it has been,

duly issued for the purpose of identifying the person in possession of the document as a person duly authorised by, or a duly authorised officer, inspector, examiner or other officer of, the Minister or otherwise duly appointed by or with the authority of the Minister or, in the case of subparagraph (b) or (c), of any other purported member of the Government exercising any functions of the Minister either—

- (i) generally, or  
 (ii) for the purposes of these Regulations.

***Evidence of class of animal remedies to which a contravention relates.***

59. In any proceedings for an offence under these Regulations in which it is alleged that a contravention of these Regulations has occurred in relation to a class of animal remedy or a class of ingredient for an animal remedy, it shall not be necessary to show that the contravention relates to a particular animal remedy or ingredient for an animal remedy where it can be shown that it relates to a thing which is a member of such a class of animal remedy or class of ingredient for an animal remedy.

***Disposal of things seized.***

60. If, in the course of exercising a power under these Regulations, a person, being an authorised officer, a member of the Garda Síochána or an officer of Customs and Excise, finds or comes into possession of any thing which such a person believes to be evidence of any offence or suspected offence under these Regulations, it may be seized and retained for use in evidence in any criminal proceedings, for such period from the date of seizure as is reasonable or, if proceedings are commenced in which the thing so seized is required for use in evidence, until the conclusion of the proceedings, and thereafter the Police (Property) Act, 1897 (59 & 60 Vict.), and where appropriate, *section 25* of the

*Criminal Justice Act, 1951* (No. 2 of 1951), shall apply to the thing so seized in the same manner as that Act and the said section 25 shall apply to property which has come into the possession of the Garda Síochána in the circumstances mentioned in that Act.

***Recoupment of costs of certain disposals.***

61. If any thing which is seized from a person under these Regulations is duly disposed of by or on behalf of the State, the costs of such disposal, less any moneys arising from such disposal, shall (except where such costs have been waived in writing) be recoverable from such person as a simple contract debt in any court of competent jurisdiction.

***Fees and levies, etc.***

62. (1) There shall be paid—

- (a) on an application for the grant of any licence, the issue of an authorisation or a certificate or the provision of a service under these Regulations or a renewal or amendment of any of them, such fee (if any), and
- (b) in respect of a licence, authorisation or certificate under these Regulations which is in force for a definite or indefinite period of more than 12 months, such fee (if any),

as may be fixed by the Minister with the consent of the Minister for Finance.

(2) Different fees may be fixed in respect of different classes of licences, authorisations, certificates or services.

***Evidence on certificate etc.***

63. (1) In proceedings for an offence consisting of a contravention of these Regulations, a certificate purporting to be signed by a person employed at a laboratory named in the certificate stating the capacity in which that person is so employed and stating one or more of the following, namely—

- (a) that the person received a sample submitted to the laboratory,
- (b) that, for a period as is specified in the certificate, the person had in his or her custody a sample so submitted,
- (c) that the person gave to such other person as is specified in the certificate a sample so submitted,
- (d) that the person carried out a laboratory examination for the purpose of detecting the presence, in a sample so submitted, of a substance, ingredient for an animal remedy or animal remedy, or
- (e) that a particular substance, ingredient for an animal remedy or animal remedy was present in the sample,

is, unless the contrary is proved, evidence of the matters stated in the certificate.

(2) A certificate purporting to be signed by an officer of the Minister and to certify that on a specific day or days or during the whole of a specified period—

- (a) a particular person did not stand registered in the companion animal medicines sellers register,
- (b) the registration of a particular person in the companion animal medicines sellers register had been revoked,
- (c) a person was or was not the holder of a licence or approval under Regulations 16, 17, 18(11), 19, 30, 31, 32 or 36,
- (d) that a particular registration, licence or approval referred to in this paragraph, was subject to a particular condition or conditions,

is, without proof of the signature of the person purporting to sign the certificate or that he or she is an officer of the Minister, evidence, unless the contrary is shown, of the matters stated in the certificate.

(3) A certificate purporting to be signed by the secretary of the Board or other officer of the Board authorised by the Board in that regard, certifying that on a specific day or days or during the whole of a specified period—

- (a) a person was or was not the holder of a veterinary product authorisation or registration granted under Regulation 9 or the holder of a manufacturer's licence granted under Regulation 22,
- (b) that a particular authorisation, licence or registration, referred to in this paragraph, was subject to a particular condition or conditions,

is, without proof of the signature of the person purporting to sign the certificate or that he or she is the Secretary or an officer of the Board, evidence, unless the contrary is shown, of the matters stated in the certificate.

(4) In proceedings for an offence under these Regulations the court may, if it considers that the interests of justice so require, direct that oral evidence of the matters stated in a certificate under paragraph (1), (2) or (3) be given, and the court may for the purpose of receiving oral evidence adjourn the matter.

(5) In proceedings for an offence, evidence of the Directive, Council Regulation (EEC) 2377/90, or Regulation (EC) No. 726/2004 may be given by production of a copy of the said Directive or Regulation certified by an officer of the Minister to be a copy of the said Directive or Regulation, and it is not necessary to prove the signature of the officer or that he or she is an officer of the Minister.

(6) Paragraph (5) is in addition to and not in substitution for the European Communities (Judicial Notice and Documentary Evidence) Regulations 1972 (S.I. No. 341 of 1972).

***Evidential Burden.***

64. In proceedings for an offence consisting of a contravention of these Regulations, it is not necessary to negative by evidence the existence of a marketing authorisation granted under Regulation (EC) No 726/2004 and accordingly the onus of proving the grant or issue of such authorisation lies on the defendant.

***Service.***

65. (1) A notification under these Regulations (hereinafter in this Regulation referred to as a “notification”) shall be addressed to the person concerned by name, and may be served on or given to the person in one of the following ways—

- (a) by delivering it to the person,
- (b) by leaving it at the address at which the person ordinarily resides or if an address for service has been furnished, at that address,
- (c) by sending it by post in a prepaid registered letter to the address at which the person ordinarily resides or, if an address for service has been furnished, at that address, or
- (d) if the address at which the person ordinarily resides cannot be ascertained by reasonable enquiry and the notice relates to a premises, by delivering it to some person over sixteen years of age resident or employed on the premises or by affixing it in a conspicuous position on or near the premises.

(2) A person shall not at any time within six months after a notification or notice is affixed under paragraph (1)(d), remove, damage or deface it without lawful authority.

(3) For the purposes of this Regulation, a company, within the meaning of the Companies Acts 1963 to 2003, is deemed to be ordinarily resident at its registered office and every other body corporate and every unincorporated body is deemed to be ordinarily resident at its principal office or place of business.

***Revocation and savers.***

66. (1) The European Communities (Animal Remedies) Regulations 2007 (S.I. No 144 of 2007) are revoked.

(2) Each of the following within the meaning of, or deemed to have been re-issued under, the Regulations revoked by paragraph (1), that is in force immediately before the revocation of the first cited Regulations, remains in force and may be dealt with as if granted under the corresponding provision of these Regulations—

- (a) an animal remedies authorisation,
- (b) a manufacturer’s licence,
- (c) an animal remedies wholesaler’s licence,

- (d) an animal remedies merchant's licence,
- (e) a licence issued under Regulation 18,
- (f) an approval under Regulation 32,
- (g) a registration under Regulation 33, or
- (h) a licence under Regulation 37.

(3) A person who was, immediately before the revocation of the European Communities (Animal Remedies) Regulations 2007 (S.I. No. 144 of 2007), a responsible person within the meaning of those Regulations is considered to be a responsible person for the purpose of these Regulations.

(4) Nothing in these Regulations affects the European Communities (Additives in Feedingstuffs) Regulations 1999 to 2005.

***Offences by bodies corporate, etc.***

67. (1) Where an offence under these Regulations has been committed by a body corporate and it is proved to have been so committed with the consent or connivance of or to be attributable to any neglect on the part of any person who, when the offence was committed, was a director, manager, secretary or other officer of the body corporate, or a person purporting to act in any such capacity, that person, as well as the body corporate, shall be guilty of an offence and shall be liable to be proceeded against and punished as if guilty of the first-mentioned offence.

(2) Where the affairs of a body corporate are managed by its members, paragraph (1) shall apply in relation to the acts and defaults of a member in connection with the functions of management as if such a member were a director or manager of the body corporate.

***Prosecution of summary proceedings.***

68. (1) Proceedings in relation to a summary offence under these Regulations may be brought and prosecuted by the Minister.

(2) Notwithstanding section 10(4) of the Petty Sessions (Ireland) Act, 1851(14 & 15 Vict.), summary proceedings for an offence under these Regulations may be instituted within 2 years from the date of the offence.

***Offences.***

69. (1) A person who by act or omission—

- (a) contravenes Regulation 3(1), 7(2)(d), 11, 12(3), (4), (7) or (8), 13(4) or (5), 14(4) or (6), 15(4), (5) or (6), 18(1), (8) or (10), 19(1) or (2), 20(1) or (3), 23(1) or (3), 25(3) or (5), 27(2), 28(1), (2), (4), (5), (6), (7), (8) or (10), 29, 30(1), (5), (6) or (7), 31(1),(5), (7) or (9), 33(1), (5) or (6), 34, 35, 36(1) or (3), 37(1), (2) or (4), 38(1), (4) or (5), 39, 40(1) or (2), 42, 43(1), (2), (3), (4), (5), (6), (7), (10) or (11), 44(2), 48(1), (2), (3), (4) or (5), 57, 58, or 65(2),

- (b) fails to give assistance to an authorised officer,
  - (c) fails to comply with a requirement of an authorised officer under Regulation 52,
  - (d) (i) contravenes Article 5 or 14, or
    - (ii) contravenes an act of the institutions of the European Communities adopted pursuant to Article 8, 9 or 10, of Council Regulation (EEC) No. 2377/90 of 26 June 1990, or
  - (e) (i) contravenes Article 38(4), 41(1), (2), (3), (4), the third paragraph of Article 47, Article 49(1), (2), (3) or (5) of, or
    - (ii) places a veterinary medicinal product to which it applies on the market in contravention of, Regulation (EC) No. 726/2004,
  - (f) contravenes a term or condition of an animal remedies authorisation, a licence, registration or approval within the meaning of these Regulations, or
  - (g) aids or abets a contravention to which this paragraph relates,
- commits an offence.

- (2) A person who commits an offence to which paragraph (1) refers is liable—
  - (a) on summary conviction to a fine not exceeding €5,000 or to a term of imprisonment not exceeding 6 months, or to both, or
  - (b) on conviction on indictment to a fine not exceeding €500,000 or to a term of imprisonment not exceeding 3 years, or to both.

## SCHEDULE 1

*PART I*

## ROUTES OF SALE (FOR WHICH THE SYMBOLS SET OUT IN PART IV OF SCHEDULE 2 MAY BE USED).

1. **‘Veterinary Practitioner Only (VPO-1)’** — refers to an animal remedy which may be sold or supplied only by a registered veterinary practitioner and administered in accordance with Regulation 39(2)(a).

2. **‘Veterinary Practitioner Only (VPO)’** — refers to an animal remedy which may be sold or supplied only by a registered veterinary practitioner and administered in accordance with Regulation 39(2)(b).

3. **‘Prescription Only’** — refers to an animal remedy which may be sold or supplied only by—

- (i) a pharmacist from a pharmacy in accordance with a veterinary prescription,
- (ii) a registered veterinary practitioner and the animal is under his or her care and, without prejudice to Regulation 28(6), he or she has issued a veterinary prescription in respect of the animal remedy, or
- (iii) a responsible person from a premises to which an animal remedies merchant’s licence relates in accordance with a veterinary prescription, in the case of the following animal remedies (if designated Prescription Only),—

- (I) an intramammary animal remedy;
- (II) an antifungal animal remedy;
- (III) an endo or ecto parasiticide;
- (IV) an immunological animal remedy;
- (V) an injectable digestive stimulant;
- (VI) an injectable vitamin and mineral.

4. **‘Prescription Only Exempt’** — refers to an animal remedy which may be sold or supplied only by—

- (i) a pharmacist from a pharmacy,
- (ii) a registered veterinary practitioner and the animal is under his or her care.

5. **'Pharmacy Only'** — refers to an animal remedy which may be sold or supplied only—

- (i) from a pharmacy under the personal supervision of a pharmacist, or
- (ii) by a registered veterinary practitioner and the animal is under his or her care.

6. **'Licensed Merchant'** — refers to an animal remedy which may be sold or supplied only—

- (i) from a pharmacy,
- (ii) by a registered veterinary practitioner and the animal is under his or her care, or
- (iii) from a premises to which an animal remedies merchant's licence relates.

7. **'Companion Animal Medicine'** — refers to an animal remedy which may be sold or supplied only—

- (i) from a pharmacy,
- (ii) by a registered veterinary practitioner,
- (iii) from a premises to which an animal remedies merchant's licence relates, or
- (iv) from a premises to which a companion animal medicine seller's registration relates.

## *PART II*

### CRITERIA TAKEN ACCOUNT OF BY THE BOARD IN DESIGNATING ROUTE OF SALE

1. In deciding the route of sale or supply for an animal remedy, the Board has due regard to the need to protect public health, animal health, animal welfare and the environment and accordingly has due regard to—

- (a) the need for prior professional diagnosis,
- (b) the need for particular skill or training in the administration of the animal remedy in order to avoid unnecessary risk to the target animal or the person administering the product to the animal, and
- (c) the need for professional or specialist training in relation to the storage, handling or disposal of the animal remedy.

2. If, in the opinion of the Board, in respect of an animal remedy—

- (a) the method of administration is novel,
- (b) the professional skill of a registered veterinary practitioner is necessary in order to avoid unnecessary risk to the animal to be treated or to the person administering the animal remedy, or
- (c) to comply with the Law of the State, or restrictions arising from Community Law or the relevant United Nations Conventions on narcotic or psychotropic substances,

the animal remedy is restricted to administration by, or, as the case may be, under the direct supervision or written authorisation of a registered veterinary practitioner in accordance with Regulation 39(2)(a) or (b).

3. Without prejudice to stricter provisions pursuant to the law of the State, an animal remedy to which the following conditions apply is restricted to supply in accordance with the prescription of a registered veterinary practitioner—

- (a) an animal remedy subject to official restriction on sale, supply or use, such as—
  - (i) the restrictions resulting from the implementation of the relevant United Nations conventions on narcotic and psychotropic substances,
  - (ii) the restrictions on the use of animal remedies from Community Law,
- (b) an animal remedy authorised for administration to a food producing animal, except for an animal remedy exempted in accordance with the criteria set down in Commission Directive 2006/130/EC<sup>9</sup>,
- (c) an animal remedy in respect of which special precautions shall be taken by a registered veterinary practitioner when prescribing the animal remedy in order to avoid any unnecessary risk to—
  - (i) the target species,
  - (ii) the person administering the animal remedy to the animal,
  - (iii) the environment,
- (d) an animal remedy intended for treatments or pathological processes which require a precise prior diagnosis or the administration of which may cause effects which impede or interfere with subsequent diagnostic or therapeutic measures,
- (e) officinal formulae intended for animals,

<sup>9</sup>O.J. L 349, 12.12.2006

- (f) an animal remedy containing an active substance which has been authorised for use in animal remedies for less than five years unless, having regard to the information and particulars supplied by the applicant, or experience acquired in the practical use of the product, the Board is satisfied that none of the other criteria referred to in this paragraph apply.

4. In the case of an animal remedy to which some or all of the provisions of paragraph 3 apply, other than subparagraph (b) or (d), the Board having regard to—

- (a) the purposes for which the animal remedy is intended,
- (b) the extent to which the container, label and package leaflet are specific to such purpose,
- (c) the strength of the active substance,
- (d) the maximum dose specified in the veterinary product authorisation,
- (e) the pharmaceutical form, and
- (f) the potential for misuse,

may designate the animal remedy as prescription only exempt.

5. If the Board considers that sale or supply of an animal remedy should be accompanied by professional point of sale advice regarding—

- (a) potential risks to the person administering the animal remedy,
- (b) possible contra-indications with other commonly used animal remedies,
- (c) the method of administration or use or the handling or preparation prior to use,
- (d) storage conditions, in particular unusual conditions, both prior to and during use, or
- (e) unusual conditions for safe disposal of used, or, unused, material including containers,

the animal remedy is designated pharmacy only sale.

## SCHEDULE 2

## LABELLING REQUIREMENTS FOR AN ANIMAL REMEDY

*PART I*

## GENERAL LABELLING ETC. REQUIREMENTS

The outer packaging, immediate packaging, label or package leaflet shall contain at least the following as appropriate—

(1) in the case of an animal remedy, including a homeopathic animal remedy covered by Regulation 7(1)—

- (a) the following information, which shall conform with the particulars and documents provided pursuant to Articles 12 to 13d of the Directive and the summary of product characteristics, which has been approved by the Board, shall appear in legible characters—
  - (i) name of the animal remedy as approved by the Board followed by its strength and pharmaceutical form,
  - (ii) 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 of the active substances,
  - (iii) the manufacturer's batch number,
  - (iv) the authorisation number,
  - (v) the name or corporate name and permanent address or registered place of business of the authorisation holder and where appropriate, of the representative designated by that holder,
  - (vi) the species of animal for which the animal remedy is intended including the method and where appropriate, the route of administration (adequate space shall be provided for the prescribed dose to be indicated),
  - (vii) the withdrawal period, even if nil, in the case of an animal remedy to be administered to a food-producing animal (details shall be given for each animal species and each foodstuff concerned),
  - (viii) expiry date,
  - (ix) special storage precautions,
  - (x) special precautions relating to the disposal of an unused animal remedy or its waste,
  - (xi) particulars required by Article 26(1) of the Directive,

- (xii) the words “For animal treatment only” and where appropriate in addition “to be supplied only on veterinary prescription” or in the case of a homeopathic animal remedy covered by Regulation 7(1), the words: “homeopathic animal remedy for veterinary use”.
  - (b) The pharmaceutical form and the contents by weight, volume or number of dose-units is required to be shown on the outer package only.
  - (c) The provisions of Part 1, A of Annex 1 to the Directive, in so far as they concern the qualitative and quantitative composition of an animal remedy in respect of active substances, shall apply to the particulars provided for in point (a)(ii).
  - (d) Particulars provided for in Point (a)(vi) to (xii) shall be in the English or Irish language.
  - (e) In the case of an animal remedy in respect of which a marketing authorisation has been granted under Regulation (EC) No. 726/2004, the Board may, if it considers it appropriate to do so, permit or require additional information as specified in Article 58(5) of the Directive.
- (2) In the case of a homeopathic animal remedy covered by Regulation 7(2), only the following information shall appear—
- (a) the name and address of the registration holder and where appropriate the manufacturer,
  - (b) the words: “homeopathic animal remedy without approved therapeutic indications”,
  - (c) the scientific name of the stock or stocks followed by the degree of dilution, using the symbols of the pharmacopoeia (if the homeopathic animal remedy is composed of more than one stock, the labelling may mention an invented name in addition to the scientific name of the stocks),
  - (d) the method of administration and if necessary, the route,
  - (e) the expiry date,
  - (f) the pharmaceutical form,
  - (g) the contents of the sales presentation,
  - (h) special storage precautions,
  - (i) the target species,
  - (j) any special warning,

- (k) the manufacturer's batch number,
- (l) the reference number of the registration granted by the Board.

## *PART II*

### SMALL CONTAINERS

1. (a) Where the Board considers it appropriate, the particulars listed in Part I shall be given on the outer package. However, at least the following particulars shall appear on the immediate packaging—
    - (i) name of the animal remedy,
    - (ii) quantity of the active substances,
    - (iii) route of administration,
    - (iv) manufacturer's batch number,
    - (v) date of expiry,
    - (vi) the words "For animal treatment only".
  - (b) The particulars mentioned in (a)(iii) and (vi) shall appear on the immediate packaging or container in the English or Irish language.
2. In the case of a small container on which it is impossible to give the particulars mentioned in Part I, the requirements shall apply only to the outer package and the container shall be labelled in a manner which satisfies the Board that its contents can be clearly and easily identified.
  3. If there is no outer package, all the particulars which should appear on the package pursuant to Part I shall appear on the container.

## *PART III*

### PACKAGE LEAFLET

The inclusion of a package leaflet in the packaging of an animal remedy shall be obligatory unless all the information required by this Part can be conveyed on the immediate and outer packaging. Information on the leaflet shall solely relate to the animal remedy with which it is included. The leaflet shall be comprehensible and in the English or Irish language and shall include at least the following information in the order indicated and conform with the particulars and documents provided in accordance with the application for the product authorisation (the package leaflet may contain other languages as long as the information provided is identical)—

- (a) name or corporate name and permanent address or registered place of business of the authorisation holder and of the person responsible for marketing and of the manufacturer, if different,

- (b) name of the animal remedy as approved by the Board followed by its strength and pharmaceutical form. (If the animal remedy has been authorised according to the procedure provided for in Articles 31 to 43 of the Directive, under different names in the concerned member states, a list of the names authorised in each member state),
- (c) the main therapeutic indications, contra-indications and side-effects,
- (d) the species of animal for which the animal remedy is intended, the dosage for each species, the method and route of administration and advice on correct administration, if necessary,
- (e) the withdrawal period, even if this is nil, in the case of an animal remedy to be administered to a food-producing animal,
- (f) special storage precautions,
- (g) particulars required to be indicated pursuant to Article 26(1) of the Directive,
- (h) special precautions for the disposal of unused product or waste materials.

#### *PART IV*

#### SYMBOLS DENOTING ROUTE OF SALE

1. (a) An animal remedy referred to in paragraph (1) of Part I of Schedule 1 of these Regulations may be designated by the following symbol:

VPO-1

- (b) an animal remedy referred to in paragraph (2) of Part I of Schedule 1 may be designated by the following symbol:

VPO

2. An animal remedy designated 'prescription only' may be designated by the following symbol:

POM

3. An animal remedy designated 'prescription only exempt' may be designated by the following symbol:

POM(E)

4. An animal remedy designated 'pharmacy only' may be designated by the following symbol:

PS

5. An animal remedy designated 'licensed merchant' may be designated by the following symbol:

LM

6. An animal remedy designated 'companion animal medicine' may be designated by the following symbol:

CAM

## SCHEDULE 3

## A VETERINARY PRESCRIPTION

A veterinary prescription shall bear a serial number, contain a declaration that the prescription is granted in respect of an animal under the care of the prescribing veterinary practitioner and contain at least the following—

- (a) details of the animal remedy (and if Regulation 43(6) applies, an alternative) to be administered, specifying the authorised name and the number of the veterinary product authorisation or licence issued in accordance with Regulation 18(11),
- (b) date of issue,
- (c) the manner and site of administration,
- (d) the dose rate and withdrawal period to be observed,
- (e) a description of the animal or animals to which the prescription relates,
- (f) the name and address of the person to whom the prescription is granted,
- (g) the period during which the prescription is valid,
- (h) special instructions, precautions or risks, and
- (i) the name, address and signature of the registered veterinary practitioner.

## SCHEDULE 4

## QUALIFIED PERSON FOR MANUFACTURING

*PART I*

## DUTIES OF A QUALIFIED PERSON

- (1) If the holder of a manufacturer's licence personally fulfils the requirements set down in Part 2, the holder may himself act as a qualified person.
- (2) The functions of a qualified person shall be—
- (a) in the case of an animal remedy other than those to which subparagraph (b) refers, to ensure that every batch to which the authorisation relates has been manufactured and checked in compliance with:—
    - (i) the laws in force in the State in respect of the product,
    - (ii) the provisions of the manufacturer's licence, and
    - (iii) the provisions of an animal remedies authorisation,
  - (b) in the case of an animal remedy imported by the holder of a manufacturer's licence, to ensure that every batch of the product undergoes a full qualitative analysis, a quantitative analysis of at least all of the active substances and all other tests or checks necessary to ensure that the quality of the animal remedy is in accordance with the requirements of the animal remedies authorisation, and
  - (c) in all cases, to certify in a register, or other equivalent document appropriate for the purpose, whether each production batch of the animal remedy to which the authorisation relates, satisfies the requirements set out in subparagraphs (a) or (b) and to ensure that the register or other document is regularly maintained and in particular that the appropriate entries in the register or other document are made as soon as practicable after each batch has been manufactured or imported.
- (3) A batch of an animal remedy which has undergone the controls referred to in paragraph (2) in another EEA State shall be exempt from these controls if they are marketed in the State, accompanied by the control reports signed by the qualified person.
- (4) In the case of an animal remedy imported from a third country, where appropriate arrangements in the form of a Mutual Recognition Agreement have been made by the Community with that country, ensuring that the manufacturer of the animal remedy applies standards of good manufacturing practice at least equivalent to those laid down by the Community, and ensuring that the controls referred to in paragraph (2)(b) are carried out in the exporting country, the

qualified person shall be relieved of responsibility for carrying out those controls.

(5) Where, after giving the holder of a manufacturer's licence and the person acting as the qualified person the opportunity of making representations (either orally or in writing), the Board is of the opinion that the person so acting is failing to carry out the functions specified in paragraph (2) and has notified the holder accordingly in writing, the holder shall not permit that person to continue to act as the qualified person so long as the said notification has not been withdrawn by the Board.

(6) The Board may require the holder of a manufacturer's licence to temporarily suspend the person acting as the qualified person upon the commencement of administrative or disciplinary proceedings against him or her for failure to fulfil his or her functions as required under paragraph (2) and the holder shall not permit that person to act as the qualified person pending the determination of such proceedings.

## *PART II*

### REQUIREMENTS APPLICABLE TO A QUALIFIED PERSON.

A person shall only have the capacity to act as a qualified person if he or she fulfils the conditions of qualification at one of (a), (b) or (c) below:

- (a) He or she is in possession of a diploma, certificate or other evidence of formal qualifications awarded on completion of a university course of study, or a course recognised as equivalent by the Board, extending over a period of at least four years of theoretical and practical study in one of the following scientific disciplines: pharmacy, medicine, veterinary medicine, chemistry, pharmaceutical chemistry and technology, biology. However, a university course of shorter duration may suffice if either of the conditions set out in clause (i) or (ii) are satisfied:
  - (i) The minimum duration of the university course may be three and a half years if the course is followed by a period of theoretical and practical training of a minimum duration of one year and including a training period of at least six months in a pharmacy open to the public, corroborated by an examination at university level;
  - (ii) If two university courses or two courses recognised by the State in question as equivalent co-exist in an EEA State and if one of these extends over four years and the other over three years, the three-year course leading to a diploma, certificate or other evidence of formal qualifications awarded on completion of a university course or its recognised equivalent shall be considered to fulfil the condition of duration referred to at clause (i) above insofar

as the diplomas, certificates or other evidence of formal qualifications awarded on completion of both courses are recognised as equivalent by the State in question.

If qualification is dependent on clause (i) or (ii), it shall be shown that the course included theoretical and practical study bearing upon at least the following basic subjects:

Experimental physics,  
 General and inorganic chemistry,  
 Organic chemistry,  
 Analytical chemistry,  
 Pharmaceutical chemistry including analysis of medicinal products,  
 General and applied biochemistry (medical),  
 Physiology,  
 Microbiology,  
 Pharmacology,  
 Pharmaceutical technology,  
 Toxicology,  
 Pharmacognosy (study of the composition and effects of the natural active substances of plant and animal origin).

Studies in these subjects should be balanced so as to enable the person concerned to fulfil the obligations specified in Part I.

If a qualification under paragraph (a) is not dependent on clause (i) or (ii), the Board shall ensure that the person in question provides evidence of adequate knowledge of the aforementioned basic subjects.

All persons qualifying under this paragraph shall have acquired practical experience, over at least two years, in one or more undertakings which are authorised to manufacture medicinal products, in the activities of qualitative analysis of medicinal products, of quantitative analysis of active substances and of the testing and checking necessary to ensure the quality of an animal remedy. The duration of practical experience may be reduced by one year if a university course lasts for at least five years and by a year and a half if the course lasts for at least six years.

- (b) He or she has engaged in the activities of a qualified person from the date referred to in Article 54 of the Directive without complying with the requirements of paragraph (a).
- (c) He or she is the holder of a diploma, certificate or other evidence of formal qualifications awarded on completion of a university course (or a course recognised as equivalent by the Board) in a scientific discipline allowing him or her to engage in the activities of a qualified person, and may, if he or she began his or her course before 9th October 1981, be considered as qualified to carry out within the State the duties of a qualified person provided that he or she has previously

engaged in the following activities for at least two years before 9th October 1991 at one or more undertakings authorised to manufacture an animal remedy: production supervision, and/or qualitative and quantitative analysis of active substances and the necessary testing and checking under the direct authority of a qualified person to ensure the quality of an animal remedy.

If the person concerned has acquired this practical experience before 9th October 1971, a further one year's practical experience of this kind will be required to be completed immediately before the person may act as a qualified person for the purposes of these Regulations.

## SCHEDULE 5

REQUIREMENTS TO BE MET BY A HOLDER OF A  
MANUFACTURER'S LICENCE

1. The holder of the manufacturer's licence shall—
  - (a) provide and maintain staff, premises, installations and equipment as are necessary for the carrying out, in accordance with the terms of his or her licence and relevant marketing authorisation, of the stages of manufacture as are undertaken by him or her; and
  - (b) not use for such purposes premises other than those specified in his or her licence or which may be approved in writing from time to time by the Board.
2. The holder of the manufacturer's licence shall—
  - (a) provide and maintain such staff, premises, installations and equipment for the handling, storage and distribution of an animal remedy that he or she handles, stores or distributes under his or her licence as are necessary to maintain the quality of an animal remedy to which the licence relates; and
  - (b) not use for such purposes premises other than those specified in his or her licence or which may be approved in writing from time to time by the Board.
3. The licence holder shall conduct all manufacturing operations in such a way as to ensure that an animal remedy conforms with the standards of strength, quality and purity applicable to them whether under the relevant marketing authorisation, or under a pharmacopoeial standard or other specification to which they may be manufactured.
4. The licence holder shall at all times provide and maintain such staff, premises, equipment and facilities as will enable the qualified person at his or her disposal to carry out the duties referred to in Part I of Schedule 4.
5. The licence holder shall give prior notice to the Board of any changes he or she may wish to make to any of the particulars supplied in his or her application made pursuant to Regulation 21.
6. The licence holder shall immediately inform the Board if the qualified person is replaced unexpectedly.
7. The licence holder shall place the quality control system under the authority of an appropriate person notified to the Board.
8. The licence holder may use a contract laboratory if the laboratory and the person operating it has been approved by the Board.

9. The licence holder shall inform the Board—

- (a) before making a material change in the premises, installations or equipment used under his or her licence, or in the operations for which they are used; and
- (b) of a change that he or she proposes to make in the personnel named in his or her licence as respectively—
  - (i) responsible for supervising production operations; or
  - (ii) responsible for quality control of an animal remedy being manufactured, divided up, packaged, labelled, presented or imported, including the person named as the qualified person for the purposes of Schedule 4.

10. The licence holder shall keep readily available for inspection by an authorised officer, durable records of the details of manufacture of each batch of an animal remedy manufactured under his or her licence and of the tests carried out thereon, in such form that the records will be easily identifiable from the number of the batch as shown on each container in which an animal remedy is sold, supplied or exported and he shall permit the officer to take copies or make extracts from the records.

The records shall be retained for at least one year after the expiry date of the batches to which they relate or at least 5 years from the date of certification by the qualified person as referred to in Schedule 4, whichever is the longer period.

11. The licence holder shall maintain a system for recording and reviewing complaints concerning reported defects associated with an animal remedy to which his licence relates and of the outcome to any investigation carried out in respect of each complaint.

12. The licence holder shall keep such documents as will facilitate the withdrawal or recall from sale, supply or exportation of an animal remedy to which the licence relates. The documents shall be readily available for inspection by an authorised officer.

13. The licence holder shall keep a sample of each batch and of each active substance used in the manufacture of an animal remedy to which the licence relates for the period which ends one year after the labelled expiry date of the product, and shall furnish on request by the Board a sample of each batch for the purpose of any test, examination or analysis which may be requested by the Board.

14. The licence holder shall ensure that any tests for determining conformity with the standards and specifications applying to an animal remedy to which the licence relates, are, except insofar as the conditions of the relevant marketing authorisation may otherwise permit or require, applied to samples taken from the animal remedy after all manufacturing processes have been completed,

and/or at such earlier stage(s) in the manufacture as may be required or approved in writing by the Board.

15. The licence holder, who is not the holder of a marketing authorisation in respect of an animal remedy to which the licence relates, shall comply with any provisions of the licence which relate to the sale or supply of that animal remedy and shall, by means of a label or otherwise, communicate the particulars of those provisions as they relate to method of sale or supply or restriction as to sale or supply to any person to whom the authorisation holder sells or supplies that animal remedy.

16. The licence holder shall supply such information as may be requested by the Board for the purposes of these Regulations about an animal remedy being manufactured and about the operations being carried out in relation to the manufacture.

17. The licence holder shall, for the purpose of enabling the Board, to—

- (a) verify a statement contained in an application for a manufacturer's licence or marketing authorisation, or
- (b) ascertain whether there are any grounds for suspending, revoking or amending any such licence or authorisation,

permit authorised officers to enter and inspect his or her premises at any time and to take samples or copies of any documents relating to an application or authorisation as may be required.

18. The licence holder shall from time to time permit an inspection and make available information as may be required to satisfy the Board that the conditions of the licence are being complied with.

19. If the licence holder has been informed by the Board that any part of a batch of an animal remedy to which his or her licence relates has been found not to conform as regards strength, quality or purity with the specifications of the relevant product, he or she shall, if so directed by the Board, immediately withhold the remainder of that batch from sale, supply or exportation and, insofar as may be practicable, immediately recall all supplies already sold, supplied or exported from that batch.

20. If the licence holder has been informed by the Board that an animal remedy to which his or her licence relates has been found to give rise to unacceptable adverse reactions, he or she shall, if so directed by the Board, immediately withhold that product from sale, supply or exportation and, insofar as may be practicable, immediately recall all supplies of the product already sold, supplied or exported.

21. If the licence holder has been informed by the Board that any batch of an animal remedy, or part thereof, to which his or her licence relates, has not been manufactured in accordance with the principles and guidelines of good

manufacturing practice, he or she shall, if so requested by the Board, immediately withhold that product from sale, supply or exportation and, insofar as may be practicable, immediately recall all supplies of the product already sold, supplied or exported.

22. If the licence holder recalls a particular batch of an animal remedy manufactured by him or her, or part thereof, he shall forthwith inform the Board of the decision to recall and of the reason for such recall.

23. If the licence holder considers that there may be grounds for the recall, or for the imposition of an abnormal restriction on the supply of an animal remedy manufactured by him or her, or of a batch or part of a batch thereof, he or she shall consult with the Board in relation to the action which may be considered appropriate in the circumstances.

24. The licence holder shall ensure that all manufacturing operations are carried out in accordance with the principles and guidelines of good manufacturing practice specified by Commission Directive 91/412/EEC<sup>10</sup> and Article 51 of the Directive.

25. The licence holder shall 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. For the purposes of paragraph 25, manufacture of active substances used as starting materials shall include both total and partial manufacture or import of an active substance used as a starting material and the various processes of dividing up, packaging or presentation prior to its incorporation into an animal remedy, including repackaging or re-labelling, such as are carried out by a distributor of starting materials.

<sup>10</sup>O.J. L 228, 17.8.1991

## SCHEDULE 6

GENERAL REQUIREMENTS FOR A LICENSED MERCHANT'S  
PREMISES

1. The premises shall be a permanent structure of sound construction.
2. The premises shall be capable of being adequately secured.
3. Premises contained within the curtilage of a domestic dwelling shall not be considered suitable. If a premises is attached to the dwelling, the limits of the premises to be used as a retail premises shall be clearly defined and it shall be possible to access the premises directly without trespass into the dwelling and animal remedies shall not be stored or kept for sale or supply outside the confines of the licensed premises.
4. The premises shall preferably be a separate unit but if part of another retail facility all activities concerning the sale, supply, display and storage of animal remedies shall take place in a separate designated area.
5. The premises shall have adequate storage space to store animal remedies in accordance with good pharmaceutical practice and in accordance with manufacturer's directions.
6. Animal remedies shall be stored in a manner that will facilitate proper rotation of stock.
7. The premises shall have a designated area for the storage, prior to return or disposal, of out of date stock and damaged stock. This area shall also be used for the temporary storage of products subject to recall due to quality defect or for reasons relating to the pharmacovigilance system provided for under these regulations.
8. The premises shall have refrigerated storage and display facilities for animal remedies which require to be kept under controlled temperature conditions.
9. Storage and display facilities shall be adequate to ensure that animal remedies do not become contaminated by other animal remedies or stock on the premises or cause such contamination.

## SCHEDULE 7

## ANIMAL REMEDIES RECORD

Form of record to be kept in accordance with Regulation 42(1):

1. **Purchase/incoming details—**

- (a) Quantity
- (b) Authorised name of the animal remedy
- (c) Date of Receipt
- (d) Name and address of supplier

2. **Administration/Outgoing details—**

- (a) Date of Administration,
- (b) Authorised name and quantity of the animal remedy administered,
- (c) Identity of animal to which the animal remedy was administered including Ear Tag No. if appropriate,
- (d) Date of expiry of a withdrawal period,
- (e) Name of person who administered the animal remedy,
- (f) Name of prescribing veterinary practitioner (if applicable),
- (g) Quantities of unused or expired animal remedies which were returned.

## SCHEDULE 8

**Requirements of the Programme referred to in Regulation 43(9).**

1. The Programme shall—
  - (a) be in writing,
  - (b) identify—
    - (i) the herd number or other relevant identifier and the owner or person in charge (referred to in this Schedule as “the farmer”) of the animals to which it relates,
    - (ii) the milk purchaser registered under the European Communities (Food and Feed Hygiene) Regulations 2005 (S.I. No. 910 of 2005), who purchases milk from the farmer referred to at (i) and who, along with this person, the veterinary practitioner referred to at (iii) and, where appropriate, the veterinary practitioner referred to at (iv), is responsible for implementing the Programme,
    - (iii) the veterinary practitioner under whose direction it operates,
    - (iv) any other person, including any other veterinary practitioner who has responsibility for the care of the animals in accordance with Regulation 43(8), who is assigned formal responsibilities under the Programme relating to its implementation in accordance with subparagraph (f),
  - (c) specify that the primary objective of the Programme is the prevention and treatment of clinical and sub-clinical bovine mastitis in a manner designed to minimise use of antibiotic treatments and, where necessary, set targets for a reduction in the number of mastitis cases for that herd,
  - (d) cover in scope the critical herd disease and husbandry factors essential for effective mastitis control,
  - (e) specify the ongoing measures under the Programme designed to meet the objectives at (c) and (d) as well as the specific measures to be implemented in cases where particular intervention is deemed to be appropriate and identifying which of the persons in (b)(i) to (iv) is responsible for the implementation of each specified measure. These measures shall include at least the measures specified in paragraphs (2) to (4),
  - (f) define the respective roles of and the reporting relationship between the persons referred to in (b)(iii) and (iv),

- (g) be signed by each of the persons at (b)(i) to (iv), such signature to be deemed as representing confirmation that each person understands and confirms that he or she will carry out his or her responsibilities, and
- (h) be updated at least on an annual basis and in any event where a change of any of the personnel referred to in (b)(i) to (iv) occurs.

Copies of the Programme shall be retained by any person who has signed it in accordance with (g) and shall be made available to an authorised officer on request.

2. The milk purchaser referred to in paragraph 1(b)(ii) shall—

- (a) Implement a structured sampling programme, at a level consistent with the aims of the Programme or as may be directed by the Minister, in respect of the milk supplied by the farmer as follows—
  - (i) Milk samples shall be taken in accordance with a written protocol which ensures the integrity of the samples and traceability to the farm of origin,
  - (ii) Milk samples shall be tested using recognised analytical methods, or, where appropriate, in accordance with methods stipulated by the Minister,
  - (iii) Milk samples shall be tested for:—
    - (A) Antibiotic residues in accordance with Regulation 22 of the European Communities (Control of Animal Remedies and their Residues) Regulations 2007 (S.I. No. 143 of 2007),
    - (B) Somatic Cell Counts,
    - (C) Where appropriate, the presence of mastitis causing pathogens and their sensitivity to a range of antimicrobial agents, including any that may be specified by the Minister, and
    - (D) Total Bacterial Count,
- (b) Compile results of testing referred to in (a) and make these available to the farmer and the registered veterinary practitioner named in the Programme,
- (c) Report to the Minister, if requested and in the form specified, data arising from the testing referred to in (a)(iii), and
- (d) Arrange for the compilation of an annual report on the implementation of the Programme and submit the report to the Minister.

3. The farmer named in the Programme shall—

- (a) Implement a management regime in respect of the herd and milking operations in the context of the programme designed to reduce the incidence of mastitis and use of antibiotic treatments,
- (b) Participate in testing conducted by the milk purchaser referred to in paragraph 1(b)(ii), or in any additional testing programmes, needed to implement the Programme,
- (c) Arrange for appropriate monitoring and testing of milking equipment on the farm and for reports arising from such testing to be made available to the milk purchaser and to the registered veterinary practitioner named in the Programme, and
- (d) Maintain (in addition to the record stipulated in Regulation 42) a record in a structured manner and supply the registered veterinary practitioner named in the Programme at the end of each lactation year details of—
  - (i) Total number of cows in herd during lactation,
  - (ii) Total number of cows infected with mastitis during lactation,
  - (iii) Total number of mastitis cases treated during lactation, and
  - (iv) Total number of intramammary animal remedies used, with a breakdown by type.

4. The registered veterinary practitioner under whose direction the Programme operates may prescribe intramammary animal remedies for animals in the herd referred to at paragraph 1(b)(i) provided that he or she complies with the following—

- (a) He or she takes full consideration of the data and recommendations of the Programme and his or her knowledge of the animals,
- (b) He or she maintains an up to date knowledge of current developments in relation to mastitis control, in particular, by participation in continuing professional development programmes on this subject,
- (c) He or she maintains an up to date knowledge of the general herd health situation on the farm and of the milking operations thereon, by reference to relevant data and reports and visits as necessary,
- (d) He or she provides, as necessary, advice and training, either directly or through the person referred to in paragraph 1(b)(iv), to the farmer designed to reduce the incidence of mastitis and use of antibiotic treatments,

- (e) He or she reviews the results of the effectiveness of the Programme in herds under his or her care with particular reference to antibiotic usage and effectiveness,
- (f) Where required by reference to the incidence of mastitis on an individual farm, he or she approves a programme of specific remedial measures, or where appropriate, additional testing required to determine the causal agents and their antibiotic sensitivity, and
- (g) He or she provides advice on the annual report on the implementation of the Programme with particular reference to achievement of the targets referred to in paragraph 1, together with any recommendations to improve the Programme.

5. Notwithstanding paragraph 4, save in exceptional circumstances, where a registered veterinary practitioner who fulfils the conditions at paragraph 1(b)(iv) has signed the Programme as provided for at paragraph 1(g), the prescription may only be written by that person. Furthermore, he or she shall, without prejudice to any other requirement of these Regulations, carry out the functions listed at paragraph 4(a), (b), (c), (d) and (f). The other functions listed at paragraph 4 must be carried out either by the veterinary practitioner under whose direction the programme operates or by the veterinary practitioner mentioned at paragraph 1(b)(iii).

GIVEN under my Official Seal,

MARY COUGHLAN,

Minister for Agriculture, Fisheries and Food.

## EXPLANATORY NOTE.

*(This note is not part of the Instrument and does not purport to be a legal interpretation)*

These Regulations update the regime governing the approval and distribution of animal remedies, in particular, by transposing Commission Directive 2006/130/EC of 11 December 2006 implementing Directive 2001/82/EC of the European Parliament and of the Council as regards the establishment of criteria for exempting certain veterinary medicinal products for food producing animals from the requirement of a veterinary prescription and providing for certain enforcement provisions for Regulation (EC) No. 726/2004.

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