

S.I. No. of 2005.

ANIMAL REMEDIES REGULATIONS 2005

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S.I. No. of 2005.

ANIMAL REMEDIES REGULATIONS 2005

I, Mary Coughlan, Minister for Agriculture and Food, in exercise of the powers conferred on me by section 8 of the Animal Remedies Act 1993 (No 23 of 1993)(as adapted by the Agriculture, Food and Forestry (Alteration of name of Department and Title of Minister) Order 2002 (S.I. No 306 of 2002)) and in respect of Regulation 63(5), section 3 of the European Communities Act 1972 (No 27 of 1972) for the purpose, *inter alia*, of giving effect to Directive 2001/82/EC on the Community code relating to veterinary medicinal products¹ as amended by Directive 2004/28/EC of the European Parliament and of the Council of 31 March 2004² and to give further effect to Council Regulation (EEC) No. 2377/90 of 26 June 1990³ and to give full effect to Regulation (EC) No. 726/2004 of the European Parliament and the Council of 31 March 2004⁴ and, following consultation with the Animal Remedies Consultative Committee, hereby make the following regulations:

PART I

PRELIMINARY AND GENERAL

Citation and commencement

1. (1) These Regulations may be cited as the Animal Remedies Regulations 2005.

(2) Regulations 44 and 45 come into operation on the 1 January 2006.

Interpretation

2. (1) In these Regulations -

"animal remedies authorisation" means -

¹ OJ L 311, 28.11.2001

² OJ L 136, 30.4.2004

³ OJ L 224, 18.8.1990

⁴ OJ L 136, 30.4.2004

- (a) a veterinary product authorisation within the meaning of Article 5 of the Directive,
- (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,
- (c) a licence under Regulation 16, 17, 18(5), or 20,
- (d) a marketing authorisation granted under Regulation (EC) No. 726/2004,
- (e) a registration granted by the Board in accordance with Regulation 8(2), or
- (f) such other document, registration, licence or authorisation deemed by these Regulations to be an animal remedies authorisation;

" Act" means the Animal Remedies Act 1993 (No. 23 of 1993);

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

"Board" means the Irish Medicines Board;

"companion animal" includes 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 1993⁵;

"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;

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

⁵ OJ L 1, 3.1.1994

"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;

"meat" includes the flesh of fish;

"medicinal product" has the meaning assigned to it by Directive 2001/83/EC of 6 November 2001⁶;

"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;

“Member State” means a Member State of the European Communities or of the European Union;

"pharmacist" means a person lawfully keeping open shop 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,

⁶ OJ L 311, 28.11.2001

(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 dentist" means a person entered in the register established under the Dentists Act 1985 (No. 9 of 1985);

"registered medical practitioner" means a person entered in the register established under the Medical Practitioners Act 1978 (No. 4 of 1978);

"registered veterinary practitioner" means a veterinary surgeon registered under the Veterinary Surgeons Act 1931 (No. 36 of 1931);

"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 this Regulation;

"Regulations of 1998" means the Control of Animal Remedies and their Residues Regulations, 1998 (S.I. No. 507 of 1998);

"risk-benefit balance" means an evaluation of the positive therapeutic effects of an animal remedy in relation to the risks relating to use of the animal remedy;

"risks relating to use of an animal remedy" means -

(a) any risk relating to the quality, safety and efficacy of the animal remedy as regards animal or human health, or

(b) any risk of undesirable effects on the environment;

“third country” means a state other than a member state;

“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 cited in the preamble to these Regulations or paragraph (1) 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) In these Regulations, unless the contrary intention appears, a reference to a Part, Regulation or Schedule is to a Part or Regulation of, or Schedule to, these Regulations and a reference to a paragraph or subparagraph is to the paragraph or subparagraph of the provision in which the reference occurs.

Bulk substances

3. (1) A person shall not import, manufacture, sell or supply a substance that consists of or contains a thing that has anabolic, anti-infectious, anti-parasitic, anti-inflammatory, hormonal or psychotropic properties unless his or her name and the substance are entered in the Register (“register of bulk animal remedies”).

(2) A person whose name is entered in the register of bulk animal remedies —

(a) shall keep a record available for inspection by an authorised officer for at least five years detailing, in chronological order, quantities of each substance imported, acquired, manufactured, sold, supplied or used as, or for the production of, an animal remedy,

(b) shall make returns to the Minister as and when and in a form that the Minister directs, and

(c) shall not sell or supply a substance unless the outer container bears a label indicating the commercial name or scientific name of the substance, the name and address of the manufacturer and, if the substance is sold or supplied in bulk, the name and address of the consignee.

(3) (a) Paragraph (1) does not apply to the sale or supply of a substance if the sale or supply is by -

- (i) a pharmacist,
 - (ii) a registered veterinary practitioner,
 - (iii) a registered medical practitioner, or
 - (iv) a registered dentist.
- (b) Paragraph (1) does not apply to the manufacture or wholesale supply of an animal remedy or a medicinal product if the person is lawfully entitled (otherwise than by reference to this Regulation) to manufacture, sell or supply the animal remedy or medicinal product.

PART II

AUTHORISATION OF AN ANIMAL REMEDY

Requirement for an animal remedies authorisation

4. (1) Without prejudice to Regulation 18,19 and 21, a person shall not import, possess, sell or supply an animal remedy, unless there is in force an animal remedies authorisation.

(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 that a substance does not come within the terms of the Directive.

(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 therefor, 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 therefor.

(4) If the Board determines in accordance with paragraph (3)(a) that a substance does not come within the terms of the Directive, it shall notify the applicant and forward a copy to the Minister.

Application for a veterinary product authorisation

5. (1) An application for a veterinary product authorisation shall be made to the Board and shall -

- (a) 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, and
- (b) 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.

(2) 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.

(3) If the Board decides not to consider an application to which paragraph (2) applies, it shall inform the applicant.

(4) (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 has 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 Regulation (EEC) No 2377/90 intended for administration to equidae, not 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).

(5) 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.

6. (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 13(d) 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) The Board may (to verify the analytical detection methods proposed by the applicant for the carrying out of checks for residues of an animal remedy in food producing animals or, in the flesh or produce of those animals) consult with experts 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 10(2) is suspended until the information required is supplied to the satisfaction of the Board.

(5) The Board shall, when determining an application for a veterinary product authorisation, comply with the Council Directives within the meaning of the Regulations of 1998.

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

7. (1) Notwithstanding Regulation 5(1) and without prejudice to the Patents Act 1992 (No. 1 of 1992), if an applicant can demonstrate to the satisfaction of the Board -

- (a) that 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 salts, esters, ethers, isomers, mixtures of isomers, complexes or derivatives of a substance, in the opinion of the Board, 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 5(1)(b).

(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 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 10(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 an 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 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 bioequivalence with the reference animal remedy has been demonstrated by bioavailability 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

8. (1) An application for a veterinary product authorisation for a homeopathic animal remedy shall comply with Regulation 5.

(2) (a) Notwithstanding paragraph (1) and without prejudice to 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 subparagraph (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), Regulation 6 applies to an application under this paragraph with the exception of requirements in relation to efficacy.

Mutual recognition

9. 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

10. (1) The Board may grant a veterinary product authorisation or registration, arising from an application under Regulations 5, 7, 8 or 9, 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 6(4) and 9, 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 8(2), shall comply with 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 8(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), -

(a) the Board shall, as a condition of a veterinary product authorisation or registration, designate the route of sale for an animal remedy in accordance with Part II of Schedule 1, and

(b) the route of sale (for which purpose the symbols set out in Part IV of Schedule 2 may be used) shall 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 instrument of Community Law, or a limit prescribed by regulations made under the Act, 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 Regulations of 1998 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 Regulation 5.
- (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) 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 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 Regulation (EEC) No 2377/90 for administration to equidae which are not intended for use as food for human consumption in accordance with European Communities (Equine Stud Book and Competition) Regulations 2004 (S.I. No 399 of 2004).
- (c) Subparagraph (b) does not apply –
- (i) to an animal remedy containing a substance listed in Annex IV to Regulation (EEC) No 2377/90, or
 - (ii) if an animal remedies authorisation has issued in respect of an animal remedy for treatment of the same condition in equidae.

Validity of a veterinary product authorisation

11. (1) Without prejudice to Regulations 10(3) and 12, 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 10(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

12. (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 5 and 7 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)(a).

(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 13.

- (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 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 an animal remedy and 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 sub-paragraph (a) from those persons having been returned to them.
- (10) Without prejudice to Regulation 8(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 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.

- (13) (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.
- (14) 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

- 13.** (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 inform 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 is 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, at the request of the holder of an animal remedies authorisation, amend the periods referred to in Article 75 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 suspected serious or unexpected adverse reactions and human adverse reactions which are reported to him or her, or, which otherwise come to his or her attention, to the Board or the holder of the animal remedies authorisation.
- (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

14. (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 10(3) has not been honoured or fulfilled.

(2) Without prejudice to Regulation 10(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 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 (6)).

(5) Without prejudice to paragraph (6), 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 therefor,

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).

(6) 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 therefor.

Recall of an animal remedy

15. (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 111

EXCEPTIONAL AUTHORISATION AND ADMINISTRATION OF AN ANIMAL REMEDY

Certain health situations

16. (1) Notwithstanding Regulation 21, the Minister may, by licence -

- (a) if he or she considers that the health situation so requires, authorise the import, possession, sale or supply and administration of an animal remedy, in respect of which there is not otherwise in force an animal remedies authorisation, 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, sale or supply and administration of an animal remedy pending consideration of an application for authorisation 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 and 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 and 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), as amended.

Miscellaneous situations

17. (1) Notwithstanding Regulation 21 and subject to this Regulation, 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 20,
- (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) Notwithstanding Regulations 4(1) and 40(2) and subject to this Regulation, if there is no authorised animal remedy for the treatment of a condition in a food producing animal and, in particular, to avoid unacceptable suffering to the animal, a registered veterinary practitioner may, under his or her direct responsibility, administer or prescribe (in accordance with Regulations 44 and 45)—

(i) an animal remedy authorised in the State for another animal species or for another condition in the same species, or

(ii) if there is no animal remedy to which sub-paragraph (i) refers -

(I) a medicinal product authorised by the Board pursuant to Title III of Directive 2001/83/EC of the European Parliament and of the Council or authorised pursuant to Regulation (EC) 726/2004, or

(II) an animal remedy imported in accordance with paragraph (5), authorised in another member state for administration in the same species, or in another species for the condition in question or for another condition,

(iii) if there is no animal remedy or medicinal product to which either sub-paragraphs (i) or (ii) refers, an animal remedy prepared extemporaneously by —

(I) a pharmacist in accordance with a veterinary prescription,

(II) the registered veterinary practitioner, or

(III) a person licensed to manufacture an animal remedy.

(b) Subparagraph (a), applies only to the administration or prescription of –

(i) in the case of a food producing animal, an animal remedy or medicinal product containing a substance listed in Annex I, II or III to Council Regulation (EEC) No 2377/90, and

(ii) in the case of an equid, in addition, a substance designated in accordance with Article 10(3) of the Directive.

(c) If a registered veterinary practitioner administers or prescribes an animal remedy in accordance with subparagraph (a), he or she shall specify an appropriate withdrawal period to ensure that food produced from the treated animal does not contain a residue which may be harmful for consumers of produce from a treated animal.

(d) (i) If an animal remedy or medicinal product administered or prescribed in accordance with subparagraph (a) 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 in accordance with subparagraph (c) —

(I) in the case of eggs from treated animals, 7 days,

(II) in the case of milk from treated animals, 7 days,

- (III) in the case of meat, including fat & offal from poultry and mammals, 28 days,
 - (IV) in the case of meat from fish, 500 degree days, or
 - (V) in the case of meat from an equid, if subparagraph (b)(ii) applies, at least 6 months.
- (ii) subparagraphs (c) and (d) (i) do not apply to a homeopathic animal remedy which contains an active substance listed in Annex II to Regulation (EEC) No 2377/90.
- (e) If a registered veterinary practitioner administers or prescribes an animal remedy in accordance with subparagraph (a), he or she shall keep 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 animals,
 - (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.
- (f) The records specified in subparagraph (e) shall be completed at the time of administration and shall be maintained at the premises of the veterinary practitioner for five years and be furnished on request for examination by an authorised officer.
- (g) This Regulation applies to the treatment of an individual animal or animals on a premises and does not provide for the general manufacture, sale, supply or administration of a substance to which subparagraph (a)(ii) or (iii) applies.

(2) (a) Notwithstanding Regulations 4(1) and 40(2) and subject to this Regulation, if there is no authorised animal remedy for the treatment of a condition in a companion animal and, in particular, to avoid unacceptable suffering to the animal, a registered veterinary practitioner may, under his or her direct responsibility, administer, or prescribe —

- (i) an animal remedy authorised in the State for another animal species or for another condition in the same species, or
 - (ii) if there is no animal remedy to which subparagraph (i) refers, -
 - (I) a medicinal product authorised by the Board pursuant to Title III of Directive 2001/83/EC of the European Parliament and of the Council or authorised pursuant to Regulation (EC) 726/2004, or
 - (II) an animal remedy imported in accordance with paragraph (5), authorised in another Member State for administration in the same species, or in another species, for the condition in question or for another condition,
 - (iii) if there is no animal remedy or medicinal product to which either subparagraphs (i) or (ii) refers, an animal remedy prepared extemporaneously by —
 - (I) a pharmacist in accordance with a veterinary prescription,
 - (II) the registered veterinary practitioner, or
 - (III) a person licensed to manufacture the animal remedy.
- (3) 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 and containing the information specified by Regulation 35 and, in addition, in the case of an animal remedy imported in accordance with paragraph (5), shall include a reference to the serial number of the import licence.
- (4) An animal remedy prescribed, administered, sold, supplied or held in possession in accordance with this Regulation, is for the purposes of the administration, sale, supply or possession an authorised animal remedy.
- (5) The Minister, may by licence, authorise a registered veterinary practitioner or the holder of an animal remedies wholesaler's licence to import an animal remedy for the purposes of paragraph (1)(a)(ii)(II) or (2)(a)(ii)(II).
- (6) A registered veterinary practitioner shall comply with paragraphs (1) or (2).

Cross border practice

19. (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 Regulations 44 and 45 and subject to this Regulation, import, 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.

(5) A veterinary practitioner shall not, sell or supply a greater quantity of an animal remedy than is necessary to complete the course prescribed in respect of an animal and in any event a quantity greater than required for 14 days.

(6) 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.

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

Research etc.

20. (1) A person shall not administer an animal remedy to an animal -

- (a) for the purposes 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 foodstuffs if this limit has been established for the substance concerned in accordance with Regulation (EEC) No 2377/90.

(3) Notwithstanding Regulation 41, a person 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

21. (1) Notwithstanding Regulation 4(1) and without prejudice to Regulations 16 and 17, 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').

(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) 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, or
- (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,

if the quantity to be supplied is less than that available in the smallest proprietary pack size lawfully available in the State.

(b) 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.

(c) This paragraph does not apply to a sterile preparation, which animal remedy may only be sold or supplied in the authorised container or package.

(4) A manufacturer's licence is not required for the extemporaneous preparation of an animal remedy or magistral formula not prepared in advance in accordance with Regulation 18 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) A licence granted under section 7 of the Therapeutic Substances Act, 1932 shall be deemed to be a manufacturer's licence in respect of an animal remedy until the date of expiry of the licence.

(8) 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) as amended.

Application for a manufacturer's licence

22. (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

23. (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) if, 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 1996⁷, 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,

⁷ OJ L125, 23.5 1996

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

(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.

24. (1) The holder of a manufacturer's licence shall –

(a) keep 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.

25. (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 26(1), valid for an unlimited period.

Revocation, suspension or variation of a manufacturer's licence

26 (1) (a) Without prejudice to Regulation 23(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 therefor, 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 therefor.

Certification by the Board

27. (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.

PART V

SALE, SUPPLY AND POSSESSION OF AN ANIMAL REMEDY

Restriction on sale of an animal remedy

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

(2) Paragraph (1) does not apply to —

- (a) the sale or supply of an authorised animal remedy by, or under the supervision of, a pharmacist, in accordance with these Regulations,
- (b) the sale or supply of an authorised animal remedy by a registered veterinary practitioner in accordance with Regulation 44, 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 licence.

(3) Notwithstanding Paragraphs (1) and (2), 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 or under his or her control,
- (b) he or she is a registered veterinary practitioner and the animal is under his or her care and he or she issues a veterinary prescription in respect of the animal remedy, or
- (c) from 1st January 2007, in the case of an animal remedy referred to in paragraph 3 (iii) of Part I of Schedule 1, he or she is a responsible person 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 or under his or her control.

(4) Notwithstanding Paragraphs (1) and (2), 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.

(5) Notwithstanding Paragraphs (1) and (2), a person shall not sell or supply an animal remedy designated pharmacy only unless -

- (a) he or she is a pharmacist or 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,

(6) Paragraphs (3), (4), and (5) 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 under these Regulations.

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, not being a retail outlet used by a registered veterinary practitioner and from the date the Veterinary Council of Ireland prescribes matters under Section 108 of the Veterinary Practice Act 2005 (No. 22 of 2005), in respect of which a certificate of suitability has been granted or deemed to have been granted under that Act.

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) The Minister shall notify the applicant of his or her proposed decision to grant a licence or refuse an application within 90 days of receipt of a valid application.

(3) 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.

(4) 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.

(5) An animal remedies wholesaler's licence shall specify the location and premises from which the business of sale or supply of animal remedies by wholesale may be carried out and the premises may not be used for purposes referred to in Regulation 31 or Regulation 33.

(6) Without prejudice to Regulation 51, the Minister, when granting an animal remedies wholesaler's licence, shall require the holder to —

- (a) sell or supply an animal remedy only to a person who holds an animal remedies wholesaler's licence, or, 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) have in place an emergency plan to ensure that, on being informed, by the Minister, the Board, the Agency or the manufacturer that -
 - (i) a batch or part of a batch of an animal remedy is found not to conform with an animal remedies authorisation or as regards strength, quality or purity, with the specification of that animal remedy, or
 - (ii) an animal remedy has been found to give rise to unacceptable adverse reactions,if so directed, he or she shall immediately withdraw from sale or supply any quantities held and, so far as is practicable, immediately recall all quantities sold or supplied,
- (e) keep 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 and expiry date,
 - (iv) the quantity received or supplied,
 - (v) the name and address, as appropriate, of the supplier or consignee,
 - (vi) quantities received and returned in accordance with subparagraph (k);
- (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 these records shall be made 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) give, without payment, a sample of an animal remedy to a person authorised to take the sample,
 - (i) 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,
 - (j) comply with Article 65(5) of the Directive, and
 - (k) have in place the necessary systems to receive and ensure that animal remedies returned which are unused or have reached their expiry date, are returned 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.
- (7) 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, by virtue of these Regulations or a licence granted there under, 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.
- (8) 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.
- (9) This Regulation does not apply to -
- (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.

(10) An animal remedies wholesaler's licence remains in force for a period of three years or for a shorter period as may be specified by the Minister, unless it is sooner suspended, varied or revoked.

Retail sale of an animal remedy

31. (1) 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”) except for a person selling a companion animal medicine in accordance with Regulation 33.

(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 shall specify the location and premises from which the business of retail sale or supply of an animal remedy is to be carried out and the premises may not be used for purposes referred to in Regulation 30.

(5) Without prejudice to Regulation 51, the Minister when granting an animal remedies merchant’s licence, shall require the holder to —

- (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 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,
 - (ii) the precise identity of the animal remedy including name and pharmaceutical form and pack sizes,
 - (iii) the manufacturer's batch number and expiry date,
 - (iv) the quantity received or supplied,
 - (v) the name and address, as appropriate, of the supplier or consignee,
 - (vi) quantities received and or returned in accordance with subparagraph (h),

- (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 these records shall be made 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) give, without payment, a sample of an animal remedy to a person authorised to take a sample,
 - (f) 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,
 - (g) ensure, on being informed by the Minister, the Board, the Agency, the holder of a manufacturer's licence or the holder of an animal remedies wholesaler's licence that in respect of -
 - (i) a batch or part of a batch of an animal remedy found not to conform with an animal remedies authorisation or as regards strength, quality or purity, with the specification of that animal remedy, or
 - (ii) an animal remedy found to give rise to unacceptable adverse reactions,if so directed, he or she shall immediately withdraw from sale or supply any quantities, and, in so far as is practicable, immediately recall all quantities sold or supplied,
 - (h) have in place arrangements to receive and return to the person from whom he or she purchased them, 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
 - (i) ensure that an animal remedy is not sold from the premises other than by a responsible person.
- (6) The Minister shall 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(6)(a) refers.
- (8) An animal remedies merchant's licence, unless it is sooner suspended, varied or revoked, shall remain in force for a period of three years, or for a shorter period if specified by the Minister.
- (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, not being a retail outlet used by a registered veterinary practitioner and from the date the Veterinary Council of Ireland prescribes matters under section 108 of the Veterinary Practice Act 2005 (No. 22 of 2005) in respect of which a certificate of suitability has been granted or deemed to have been granted under that Act.

Training

32. (1) 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, the Minister may approve appropriate training courses.

(2) Without prejudice to Regulation 51, 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.

Sale of a companion animal medicine

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

(2) The Minister shall maintain a register of persons selling companion animal medicines 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 a 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 a 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 them, 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 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,
 - (ii) the precise identity of the animal remedy, including name, pharmaceutical form and pack size,
 - (iii) the manufacturer's batch number and expiry date,
 - (iv) the quantity received or supplied,

- (v) the name and address of the supplier or consignee,
 - (vi) the quantity of each animal remedy received or returned, in accordance with subparagraph (c).
- (b) keep at his or her premises, the records referred to in subparagraph (a) for a period of five years from the date of receipt, sale or supply 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.

Labelling of certain animal remedies

35. A registered veterinary practitioner who prescribes an animal remedy designated prescription only or a pharmacist who dispenses a veterinary prescription shall, at the time of sale or supply, affix (in such manner as not to obscure the information required by the animal remedies authorisation) to the animal remedy a label indicating his or her name and address, the serial number of the prescription, the name of the prescribing practitioner and the date of sale or supply.

Prohibition on sale of an animal remedy after expiry date

36. A person shall not sell or supply an animal remedy after the date specified on the container, label or package leaflet of an animal remedy by the manufacturer in accordance with the terms and conditions of the animal remedies authorisation.

Fixed premises

37. (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 except for a visit made to a person at his or her place of business if that person is lawfully entitled to sell or supply an animal remedy from his or her place of business,
 - (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.
- (4) (a) The Minister shall not grant a licence under paragraph (3)(a) or (b) unless the applicant is –
- (i) the holder of a licence under Regulation 31, or
 - (ii) a pharmacist.
- (b) A licence under paragraph (3) shall not relate to an animal remedy other than 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

38. (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 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, or a pharmacist.

(4) 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 all animal remedies held in stock.

Possession of certain animal remedies

39. A person, other than the holder of a manufacturer's licence, the holder of an animal remedies wholesaler's licence, a registered veterinary practitioner or a pharmacist, or from 1st January 2007, the holder of an animal remedies merchant's licence, shall not have an animal remedy intended for a food producing animal, 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 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

40. (1)(a) A person, other than a registered veterinary practitioner, shall not administer an animal remedy referred to in Regulation 10(1), 11(1), 12(1) or 12A of the Regulations of 1998.

- (b) If an animal remedy is designated veterinary practitioner only, a person shall not administer the animal remedy unless he or she is a registered veterinary practitioner, or unless a registered veterinary practitioner, who prescribed the animal remedy, is present, supervises administration and is able to render immediate veterinary assistance.

(2) Without prejudice to paragraph (1) and Regulation 18, a person shall not administer, cause or permit administration of an animal remedy to an animal unless -

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

Administration of an animal remedy to a food producing animal

41. (1) A person shall not —

- (a) notwithstanding Regulation 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 42, 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) If an animal remedy is administered to a food producing animal, the owner or person in charge of the animal shall 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.

(3) A food producing animal to which an animal remedy, which is not an authorised animal remedy, has been administered and meat or any other produce derived from that animal are, for the purposes of any enactment, unfit for human consumption.

(4) Meat or meat produce, milk or milk produce, or an egg or egg produce or honey that contains an amount of an animal remedy or residue thereof or of a substance contained in an authorised animal remedy or residue thereof in excess of the maximum levels permitted by law or authorised by the law of the State or by Council Regulation (EEC) No. 2377/90 or otherwise authorised by a decision of the European Communities, is unfit for human consumption.

(5) (a) A person, including a registered veterinary practitioner, who administers, directs or permits the administration of an authorised animal remedy to a food producing animal shall -

(i) act in conformity with the conditions of use of the animal remedy (other than those relating to the treated animal to be complied with after administration), and

(ii) if the person is not the owner or person in charge of the animal, inform the owner or person in charge of the animal -

(I) of the conditions of use of the animal remedy relating to the animal to be complied with after administration, and

(II) that the animal may not be slaughtered for human consumption or sold or exported if it is intended to be slaughtered for human consumption, during the withdrawal period specified in the conditions of use of the animal remedy.

(b) The owner or person in charge of an animal to which an authorised animal remedy has been administered shall —

(i) comply with the conditions of use of the animal remedy relating to the animal to be complied with after administration,

(ii) not slaughter the animal for human consumption, or export or sell the animal, if it is intended to slaughter it for human consumption, during the withdrawal period specified in the conditions of use of the animal remedy, and

(iii) shall not sell, supply or use for human consumption, or permit the sale, supply or use for human consumption, of produce taken from the animal during the withdrawal period specified in the conditions of use of the animal remedy.

(6) In paragraph (5) "conditions of use", means -

- (a) 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, or
- (b) if the animal remedy is sold or supplied by a registered veterinary practitioner in accordance with Regulation 18, the conditions of use stated on the marketing authorisation.

Import of an animal

42. 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

43. (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) (a) The owner or person in charge of a food producing animal who administers an animal remedy to that animal shall enter in the Animal Remedies Record, on each occasion when it is administered, the required details in chronological order.
 - (b) The Animal Remedies Record shall be kept for five years after administration of the animal remedy.
- (3) The owner or person in charge of a food producing animal to which a veterinary prescription only animal remedy has been administered shall keep, 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) If an animal remedy to which this Regulation applies is administered by a registered veterinary practitioner, he or she shall give to the owner or person in charge of the animal the information to enable that person to comply with paragraphs (1) and (2).

(5) The owner or person in charge of a food-producing animal shall return to the person from whom he or she purchased them, an unused animal remedy, or an animal remedy which has reached its expiry date and record this in the Animal Remedies Record.

PART VII

VETERINARY PRACTICE AND VETERINARY MEDICINE

Under the care of a veterinary practitioner

44. (1) 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.

(2) For the purposes of paragraph (1)(e), a registered veterinary practitioner shall maintain records as follows:

- (a) in relation to each client, a register, 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 and the basis for diagnosis,
 - (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.

(3) (a) Invoices referred to in subparagraph (2)(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.

Prescribing and dispensing

45. (1) A registered veterinary practitioner shall not issue a veterinary prescription for an animal remedy unless 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 previous treatment, 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 prescribe an animal remedy only 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 6 months supply from the date the veterinary prescription is issued.

(3) A veterinary prescription shall -

(a) 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,

(b) 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

(c) contain at least the particulars listed in Schedule 3.

(4) A registered veterinary practitioner shall retain a copy of a veterinary prescription for 5 years and make the copy available for inspection on request by an authorised officer.

(5) 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 alternative animal remedies on the veterinary prescription.

(6) A person -

(a) who dispenses a veterinary prescription in part shall immediately record on the prescription and on the copy thereof 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,

(b) who has completed dispensing a veterinary prescription shall, at that time, write on the prescription and on the copy thereof in a conspicuous, legible and indelible manner, the word "dispensed" and the date and he or she shall return a copy of the veterinary prescription to the person who presented it and he or she shall retain the original veterinary prescription for five years and shall make this available on request to an authorised officer, and

(c) shall not complete dispensing an animal remedy on foot of a veterinary prescription later than 6 months after the date the veterinary prescription is issued.

Emergency supply of certain animal remedies by a pharmacist

46. (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, (SI No 328 of 1988),
- (e) the animal remedy is labelled in accordance with Regulation 35, 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 written veterinary prescription.

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

Certain animal disease situations

47. (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

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

Information to the agency.

49. (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 under Regulation 13(2).

(3) The Board shall ensure that appropriate information about actions taken pursuant to paragraph (1) or Regulation 13, 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

50. (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 in relation to —

- (a) a member of the Garda Síochána or an officer of Customs and Excise, when acting in the course of his or her duty,
- (b) an authorised officer, or
- (c) 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) or (b).

Licences, registrations and approvals granted under a specified Regulation

51. (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 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) 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 Regulations made thereunder,
- (b) the applicant or holder has failed to comply with a condition attached thereto,
- (c) the applicant or holder is not, in the opinion of the Minister, a fit and proper person to hold it, 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.

(4) 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 Regulations made under the Act.

(5) 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 thereto, he or she shall -

- (a) notify the applicant or holder in writing of the proposal and of the reasons therefor, 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 therefor.

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

(7) 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.

(8) In this Regulation "a specified Regulation" means Regulation 3, 16, 17, 18(5), 20, 30, 31, 32, 33 or 37(3)(a) and (b).

Evidence of certificate etc

52. (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 any 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 register of bulk animal remedies or the companion animal medicines sellers register,
- (b) the registration of a particular person in the register of bulk animal remedies or 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(5), 20, 30, 31, 32 and 37,

- (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 and to certify 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 10 or the holder of a manufacturer's licence granted under Regulation 23,

- (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 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).

Service

53. (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 the notice 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.

Revocations and savers

54. (1) The following are revoked –

- (a) The Animal Remedies Regulations 1996 (S.I. No 179 of 1996), other than Regulations 44 and 45,
- (b) Regulations 21 and 32 of the Regulations of 1998,
- (c) Animal Remedies (Amendment) Regulations 2002 (S.I. No 44 of 2002), and
- (d) Regulation 3 of the Control of Animal Remedies and their Residues (Amendment) Regulations 2004 (S.I. No 827 of 2004).

(2) Regulations 44 and 45 of the Animal Remedies Regulations 1996 (S.I. No 179 of 1996) are revoked from 1 January 2006.

(3) Each of the following, granted under the Animal Remedies Regulations 1996, that is in force immediately before the revocation of those 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,
- (e) a licence under Regulation 16,

- (f) a licence under Regulation 26,
- (g) a licence under Regulation 41,
- (h) an animal remedies merchant's licence,
- (i) a registration under Regulation (3) or Regulation (32) or
- (j) an approval under Regulation 37.

(4) A person who was, immediately before the revocation of the Animal Remedies Regulations 1996, a responsible person within the meaning of those Regulations is considered to be a responsible person for the purpose of these Regulations.

(5) Nothing in these Regulations affects the European Communities (Additives in Feedingstuffs) Regulations 1999 to 2003.

(6) Section 35(1)(c) of the Diseases of Animals Act 1966 (No 6 of 1966) is repealed.

Offences

55. (1) A person who by act or omission -

(a) contravenes Regulations 3(1),(2), 4(1), 12, 13(3), (4), (6), (7), (8), 14(4), 15(4), (5), (6), 18(1)(c), (e), (f), (3), (6), 19(3), (4), (5), (6), (7), 20(1), (2), 21(1), (3)(b), 24(1), (2), (3), (4), 26(3), (5), 28(1), (3), (4), (5), 29, 30(1), (7), (8), 31(1),(7), (9), 33(1), (5), (6), 34, 35, 36, 37(1), (3), 38(1), (2), (4), 39, 40, 41(1), (2), (5), 43, 44(2), (3)(a), 45, 46(2), (3) or 50,

(b) (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

(c) (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,

commits an offence to which section 20(1)(a) of the Act relates.

(2) A person who contravenes a term or condition of an animal remedies authorisation

commits an offence.

(3) For the avoidance of doubt, a contravention of a term or condition of a licence, registration, approval or authorisation or a direction or notice is an offence to which Section 20(1)(c) of the Act relates.

(4) In a prosecution for an offence under these Regulations in relation to an animal remedy which is also an additive, premix or feedingstuff within the meaning, of the European Communities (Additives in Feedingstuffs) Regulations 1999 to 2003, it is a good defence to show that those Regulations were complied with.

SCHEDULE 1

PART 1 – 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 administered only by a registered veterinary practitioner.
2. **‘Veterinary Practitioner Only (VPO)’** - which refers to an animal remedy which may be administered only by -
 - (i) a registered veterinary practitioner, or
 - (ii) under the direct supervision of a registered veterinary practitioner where the registered veterinary practitioner is present at the time of administration and is in a position to render assistance if required.
3. **‘Prescription Only (POM)’** – refers to an animal remedy which may be sold or supplied only by –
 - (i) a pharmacist from a pharmacy in accordance with the prescription of a registered veterinary practitioner,
 - (ii) a registered veterinary practitioner and the animal is under his or her care and he or she has issued a veterinary prescription in respect of the animal remedy, or
 - (iii) from 1st January 2007, 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 animal remedy presented as an intramammary preparation for the prevention or treatment of mastitis in an animal;

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

4. 'Prescription Only Exempt (POM(E))' - 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 (PS)' – 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 (LM)' – 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 (CAM)' - refers to a companion animal medicine 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, an animal remedy requires to be administered by, or, under the direct supervision of a registered veterinary practitioner, because

- (a) the method of administration is novel, or
- (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 of a registered veterinary practitioner (**VPO**).

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 (**POM**) –

- (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) with effect from 1 January 2007, an animal remedy authorised for administration to a food producing animal, except for an animal remedy

exempted in accordance with criteria established under Article 67(a)(aa), second indent, of the Directive,

- (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,
- (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 (**POM(E)**).

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 (**PS**).

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 8(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, including details of any collection system in place,
 - (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 8(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 8(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 – AMPOULES AND SINGLE DOSE CONTAINERS

1. (a) 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 single-dose 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 the 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 designated ‘veterinary practitioner only’ 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 45(5) applies, alternatives) to be administered specifying the authorised name and the number of the veterinary product authorisation,
- (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 1 – 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 sub-paragraph (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 sub-paragraphs (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 22.
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, labeled, 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/EEC⁸ 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.

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.

⁸ OJ L 228, 17.8.1991

5. The premises shall have adequate storage space to store animal remedies in accordance with good pharmaceutical practice and in accordance with manufacturers 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 43(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.

Given under my Official Seal
November 2005

SIGNED
Mary Coughlan,
Minister for Agriculture 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 Directive (EC) No. 2004/28 and providing for certain enforcement provisions for Regulation (EC) No. 726/2004.