ANIMAL REMEDIES REGULATIONS, 1996

I, Ivan Yates, Minister for Agriculture, Food and Forestry in exercise of the powers conferred as me by section 8 of the Animal Remedies Act, 1993 (No. 23 of 1993), for the purpose of giving effect to Council Directive 81/851/EEC1 of 28 September, 1981, Council Directive 81/852/EEC of 28 September, 19812, Council Directive 87/20/EEC of 22 December, 19863, Council Directive 87/22/EEC of 22 December, 19864, Council Directive 90/676/EEC of 13 December, 19905, Council Directive 90/677/EEC of 13 December, 19906, Commission Directive 91/412/EEC of 23 July 19917, Commission Directive 92/18/EEC of 20 March 19928, Council Directive 92/74 of 22 September, 19929 Council Directive 93/40/EEC of 14 June, 199310 and Council Directive 93/41/EEC of 14 June, 199311 , and to give further effect to Council Regulation (EEC) 2377/90 of 26 June, 199012 and Council Regulation (EEC) 2309/93 of 22 July, 199313, and after consultation with the Animal Remedies Consultative Committee, hereby make the following Regulations:

1 O.J. No.L. 317 of 6.11.81 p.1
2 O.J. No.L.317 of 6.11.81, p.18.
3 O.J. No.L. 15 of 17.1.87, p. 38.
4 O.J. No.L. 15 of 17.1.87, p. 38.
5 O.J. No.L.373 of 31.12.90, p. 15.
6 O.J. No.L.373 of 31.12.90, p.26.
7 O.J. No.L.228 of 17.8.91, p.70.
8 O.J. No.L. 97 of 10.4.92, p. 1.
9 O.J. No L 297 of 13.10.92 p.12.
10 O.J. No L. 214 of 24.8.93, p.31.
11 O.J. No.L.214 of 24.8.93, p.40.
12 O.J. No L 224 of 18.8.90 p. 1.
13 O.J. No.L. 214 of 24.8.93 p.1.

PART I

PRELIMINARY AND GENERAL

REG 1

1 CITATION AND COMMENCEMENT
1. (a) These Regulations may be cited as the Animal Remedies Regulations, 1996.
(b) These Regulations shall come into operation on the 1st day of August, 1996.

REG 2

2 DEFINITIONS
2. (1) In these Regulations:
"animal remedies authorisation" means
(a) a veterinary product authorisation granted by the Competent Authority, or
(b) a licence granted by the Minister under Regulation 7, or
(c) a licence granted by the Minister under Regulation 16, or

(d) a marketing authorisation granted under Council Directive (EEC) 2309/93, or
(e) such other document, registration, licence or authorisation deemed by these Regulations to be an animal remedies authorisation;
"Animal Remedies Merchant's licence" means a licence granted under Regulation 31.
"Animal Remedies Wholesaler's licence" means a licence granted under Regulation 30.
"animal remedy" except where the contrary intention appears, includes an immunological animal remedy, a homeopathic animal remedy and an immunological homeopathic animal remedy;
"authorised animal remedy" means an animal remedy in respect of which there is for the time being in force an animal remedies authorisation;
"authorised pre-mix for a medicated feedingstuff" means an animal remedy which is a pre-mix for a medicated feedingstuff in respect of which there is for the time being in force a veterinary product authorisation;
"the Act" means the Animal Remedies Act, 1993 (No. 23 of 1993);
"the Agency" means the European Agency for the Evaluation of Medicinal Products established by Council Regulation (EEC) No 2309/93 of 22 July, 1993.
"bona fide client" means a person who owns or is in charge of an animal which has been placed under the care of a registered veterinary surgeon in accordance with Regulation 44 or, who has an agreement with a registered veterinary surgeon in respect of a herd or flock health scheme in accordance with Regulation 46;
"Companion Animal Medicine Seller's Licence" means a licence granted under Regulation 32;
"Competent Authority" has the meaning assigned to it by Regulation 5;
"Council Regulation (EEC) 2377/90" means Council Regulation (EEC) 2377/90 of 26 June, 1990, as last amended by Commission Regulation (EEC) 2804/9514 of 5 December, 1995 and any future Regulation of the Council, or, as the case may be, the Commission, made after the making of these Regulations which amends, extends or replaces the said Council Regulation (EEC) 2377/90;
14 O.J. L.No. L291 of 6.12.95, p.8
"the Council Directive" means Council Directive 81/851/EEC, 28 September, 1981 as amended by Council Directives 90/676/EEC, of 13 December 1990 and 93/40/EEC of 14 June, 1993 and as extended by Council Directive 90/677/EEC of 13 December, 1990 and Council Directive 92/74/EEC of 22 September, 1992 and any future directive of the Council, or, as the case may be, the Commission, made after the making of these regulations which amends, extends or replaces the said Council Directive 81/851/EEC;
"the Council Directives" means Council Directive 81/851/EEC of 28 September, 1987, Council Directive 81/852/EEC of 28 September, 1987, Council Directive 90/676/EEC of 13 December 1990, Council Directive 90/677/EEC of 13 December, 1990, Commission Directive 91/412/EEC of 23 July, 199I, Commission Directive 92/18/EEC of 20 March, 1992, Council Directive 93/40/EEC of 14 June, 1993 and Council Directive 93/41/EEC of 14 June, 1993 and any future Directive of the Council, or, as the case may be, the Commission, made after the making of these regulations which amends, extends or replaces all or any of

the aforesaid Council, or , as the case may be, Commission Directives;
"food producing animal" means an animal of the bovine, caprine, equine, ovine or porcine species or poultry or rabbits or deer or fish or honey bees where such rabbits, deer or fish are intended for use as food for human consumption;
"group veterinary practice" means a formally associated group of registered veterinary surgeons who are all available to provide services of veterinary medicine and surgery and to carry out clinical procedures on animals under their professional care;
"holder" in respect of a registration, licence or animal remedies authorisation means the person to whom such registration, licence, or, as the case may, animal remedies authorisation has been granted and who is identified as such in the relevant registration, licence, or, as the case may be, animal remedies authorisation, and reference to a holder shall include a reference to an employee, servant or agent of the holder.
"homeopathic animal remedy" means an animal remedy prepared from products, substances or compositions called homeopathic stocks in accordance with a homeopathic manufacturing procedure described by the European Pharmacopoeia or, in the absence thereof, by the pharmacopoeias currently used officially in a Member State of the European Union but does not include an immunological homeopathic animal remedy;
"human consumption" includes intended for incorporation in, or manufacture into, a food intended for human consumption and kindred words shall be construed accordingly;
"immunological animal remedy" means an animal remedy, including a homeopathic animal remedy, which is administered to animals in order to produce active or passive immunity or to diagnose the state of immunity or which is intended for use for such purpose;
"imported" means brought by any means into the State from outside the State and "importation" shall be construed accordingly;
"intermediate product" means a combination of an authorised pre-mix for a medicated feedingstuff and one or more feedingstuffs which are intended for the subsequent manufacture of a ready to use medicated feedingstuff;
"Irish Medicines Board" means the Board established by the Irish Medicines Board Act, 1995, (No. 29 of 1995);
"Manufacturer's Licence" means a licence granted under Regulation 21;
"meat" includes the flesh of fish;
"medical preparation" has the same meaning as in section 65(1) of the Health Act, 1947 (No. 28 of 1947);
"medicated feedingstuff" means any 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;
"person" includes a legal person;
"pharmacist" means a registered dispensing chemist and druggist, a registered druggist and a registered pharmaceutical chemist as defined in Section 4(10) of the Act or any other person keeping open shop for the dispensing or compounding of medical prescriptions in accordance with the Pharmacy Acts, 1875 to 1977;
"pharmacy" means a premises where the business of keeping open shop

for the dispensing or compounding of medical prescriptions in carried on in accordance with the Pharmacy Acts, 1875 to 1977;
"pre-mix for a medicated feedingstuff" means an animal remedy prepared in advance with a view to use in the subsequent manufacture of a medicated feedingstuff;
"prescription" in these Regulations means a prescription issued by a registered veterinary surgeon in accordance with, and in the form prescribed by, Regulation 45.
"registered dentist" means a person currently entered in the register established under the Dentists Act, 1985 (No. 9 of 1985);
"registered medical practitioner" means a person currently entered in the register established under the Medical Practitioners Act, 1978 (No. 4 of 1978);
"registered veterinary surgeon" means a person currently entered in the register established under the Veterinary Surgeon Act, 1931 (No. 6 of 1931);
"veterinary product authorisation" means an authorisation granted pursuant to Regulation 6;
(2) Subject to paragraph (1), a word or expression that is used in these Regulations and is also used in an act of the institutions of the European Communities cited in the aforesaid 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 any reference to a Regulation or Schedule shall be construed as a reference to a Regulation contained in these Regulations, or, as the case may be, to a Schedule thereto, unless it is indicated that a reference to some other provision is intended, and any reference in a Regulation to a paragraph or sub-paragraph shall be construed as a reference to a paragraph or a sub-paragraph of that Regulation, unless it is indicated that a reference to some other provision is intended.

REG 3

3 GENERAL PROVISIONS RELATING TO THE MANUFACTURE, IMPORT, SALE AND SUPPLY OF BULK SUBSTANCES.
3. (1) This Regulation applies to a substance which has anabolic, anti-infectious, anti-parasitic, anti-inflammatory, hormonal or psychotropic properties,
(2) Subject to paragraph (7) a person shall not engage in —
(a) the manufacture of a substance, or
(b) the sale or supply of a substance, or
(c) the manufacture or production of an animal remedy, medical preparation or any other pharmaceutical product based on a substance,
unless and until —
(i) the person and the substance has been entered in the register maintained by the Minister in accordance with this Regulation, and
(ii) such registration has been confirmed in writing by, or on behalf of, the Minister.
(3) A person entered in the register under this Regulation —
(a) shall keep a record available for inspection by an authorised officer for at least three years detailing, in chronological order, quantities of a substance acquired, manufactured, sold, supplied or used as, or for, the production of an animal remedy, a medical

preparation or other pharmaceutical product, and
(b) shall make such returns to the Minister as and when, and in such form as, the Minister may from time to time direct,
(c) shall not sell or supply a substance unless and until the outer container bears a label indicating the appropriate commercial name or scientific name of the substance, the name and address of the manufacturer and, where the substance is sold or supplied in bulk, the name and address of the consignee; or where road tankers or similar containers are used for the transport of the substance it shall be sufficient for this information to be contained in the accompanying documents.
(4) Notwithstanding paragraph (2), a person lawfully engaged in the manufacture, sale or supply of a substance, an animal remedy, a medical preparation, or other pharmaceutical product consisting of, or containing a substance, and who is lawfully carrying on such business on the date on which these Regulations come into force shall, within six calendar months of that date, apply to be registered and furnish to the Minister the particulars required to be furnished pursuant to paragraph (5).
(5) An application for registration shall be in writing and be accompanied by the following particulars in regard to such manufacture, sale or supply —
(a) the name and address of the manufacturer, seller or supplier, and
(b) in the case of a body corporate, the address of its registered office, the names of its directors and other officers, and the company registration number, and
(c) the address and location of the premises at which the business of manufacture, sale, or supply and storage of such substances is, or is to be, carried on, and
(d) the appropriate commercial common name or appropriate scientific name and active principles of the substance , animal remedy, medical preparation or pharmaceutical product being, or to be, manufactured, sold or supplied.
(6) (a) No person shall be registered under this Regulation unless the person applying for registration is lawfully entitled (otherwise than by reference to this Regulation) to so manufacture, sell, or, as the case may be, supply the substance, animal remedy, medical preparation or pharmaceutical product to which the application relates.
(b) Where a person registered by the Minister is not lawfully entitled to manufacture, sell or, as the case may be, supply, the substance, animal remedy, medical preparation or pharmaceutical product in relation to which the registration relates, or ceases to be so entitled, such registration shall be cancelled by the Minister.
(7) (a) The provisions of paragraph (2) shall not apply to a person who engages in the sale or supply of any substance to which paragraph (1) refers where such person is
(i) a pharmacist, or
(ii) a registered veterinary surgeon, or
(iii) a registered medical practitioner, or
(iv) a registered dentist.
(b) The provisions of paragraph (2) shall not apply to the manufacture, wholesale or retail sale or supply of an animal remedy or a medical preparation where the person is lawfully entitled

(otherwise than by reference to this Regulation) to so manufacture, sell or supply the said preparation or remedy.
(8) The Minister may grant registration or may refuse an application under this Regulation.

REG 4

4 RESTRICTION ON POSSESSION, SALE OR SUPPLY OF CERTAIN ANIMAL REMEDIES
4. (1) A person shall not have possession of, sell or supply a ready made animal remedy otherwise than in the form of a proprietary animal remedy unless —
(a) the person is the holder of a Manufacturer's Licence, and
(b) the container or outer wrapper and accompanying document bears a notice stating the information required by section 4 of the Act or Regulations made thereunder and, where appropriate, the name of the consignee.
(2) In this Regulation —
"proprietary animal remedy" means a ready made animal remedy sold or supplied under a special name and in a special pack, as specified in the animal remedies authorisation relating to the said animal remedy;
"ready made animal remedy" means any animal remedy prepared in advance which is presented in a pharmaceutical form which may be used without further processing and which does not comply with the definition of proprietary animal remedy.

PART II

AUTHORISATION OF ANIMAL REMEDIES

REG 5

5 COMPETENT AUTHORITY
5. (1) Subject to the subsequent provisions of this Regulation, the Competent Authority in the State for the purpose of the Council Directive shall be the Irish Medicines Board.
(2) (a) The Competent Authority in the State for the purpose of an animal remedy to which Council Directive 90/677/EEC applies shall be the Minister.
(b) The Minister may delegate or by contract appoint persons whether officers of the Minister or otherwise to carry out the examination of applications for product authorisations in respect of animal remedies, or any part of such examination, for the purpose of these Regulations.

REG 6

6 PROHIBITION ON SALE OR SUPPLY OF ANIMAL REMEDIES THAT ARE NOT AUTHORISED
6. (1) A person shall not sell or supply an animal remedy save under and in accordance with an animal remedies authorisation for the time being in force.
(2) Subject to Regulation 7 or, as the case may, Regulation 16, a

person shall not sell or supply an animal remedy which is a veterinary medicinal product within the meaning of the Council Directive unless there is for the time being in force a veterinary product authorisation relating to such animal remedy.
(3) A marketing authorisation granted or renewed by the European Agency for the Evaluation of Medicinal Products in accordance with the provisions of Council Regulation (EEC) 2309/93 is hereby deemed to be a veterinary product authorisation for the purposes of these Regulations.
(4) A licence granted under the Therapeutic Substances Act, 1932 (No. 25 of 1932) shall be deemed to be a veterinary product authorisation in respect of the animal remedy or remedies named therein until the date of expiry of such licence.
(5) A homeopathic animal remedy, other than an immunological homeopathic animal remedy, which, on the date of making of these Regulations, is registered under the Animal Remedies (Registration of Manufacturers, Importers and Wholesalers) Regulations, 1980 shall be deemed to be an authorised animal remedy provided application is made for a licence under Regulation 7 within three calendar months of the coming into force of these Regulations until such application is determined.

REG 7

7 LICENSING OF CERTAIN ANIMAL REMEDIES BY THE MINISTER
7. (1) (a) Notwithstanding Regulation 6 (2), the Competent Authority may, following consultation with the Minister, where it is considered appropriate, exempt from that paragraph —
(i) an animal remedy intended solely for aquarium fish, cage birds, homing pigeons, terrarium animals and small rodents provided that the animal remedy so exempted is presented, packaged and labelled in an appropriate manner to render it unsuitable for use in other species or classes of animal, or,
(ii) an animal remedy which, in the opinion of the Competent Authority, does not come within the terms of the Council Directive
(b) This paragraph shall not apply to an animal remedy which consists of, or contains, an active ingredient which requires an animal remedy containing it to be designated as veterinary surgeon only, prescription only, prescription only exempt or pharmacy only.
(c) Where the Competent Authority
(i) exempts an animal remedy from Regulation 6, or
(ii) is of the opinion that an animal remedy does not come within the terms of Council Directive
the Competent Authority shall issue a notification setting out the exemption or, as the case may be, the opinion.
(d) A notification issued pursuant to subparagraph (c) shall contain a declaration to the effect that the animal remedy to which the said notification relates is not an authorised animal remedy, that it should not be sold or supplied within the State, and the person to whom the notification issues may make application to the Minister for a licence to possess, sell or supply the said animal remedy within the State.
(2) (a) The Minister may, by licence, authorise the possession, sale or supply and the administration to an animal of an animal remedy to which a notification issued under paragraph (1) or to which

Regulation 6(5) applies.
(b) The Minister may grant a licence under this Regulation or he or she may refuse an application.
(3) (a) An animal remedy to which this Regulation applies shall be labelled in accordance with the provisions of the Act or Regulations made under section 4 of the Act.
(b) The label or outer container and package insert of a homeopathic animal remedy licensed under this Regulation shall, in addition to the particulars prescribed by section 4 of the Act bear the words "homeopathic medicinal product for veterinary use"
(4) An animal remedy licensed under this Regulation and to which paragraph 1(a)(i) applies shall be designated a companion animal medicine.
(5) (a) The Minister shall if he or she considers it appropriate to do so for the purpose of compliance with these Regulations or the law of the State attach conditions to a licence granted under this Regulation at the time of the grant of the licence or subsequently and may amend or revoke any such condition.
(b) A licence granted under this Regulation shall specify the route of sale or supply of the animal remedy to which it relates in accordance with Regulation 13.
(6) The Minister shall not grant a licence under this Regulation for the administration of an animal remedy to a food producing animal unless he or she is satisfied that the administration, and the conditions attached thereto, of such animal remedy will not result in produce derived from treated animals containing residues harmful to consumers of such produce.

REG 8

8 PROVISIONS FOR APPLICATIONS FOR VETERINARY PRODUCT AUTHORISATIONS
8. (1) An application for a veterinary product authorisation shall be made to the Competent Authority and the application shall –
(a) be in such form as the Competent Authority may require and be accompanied by the particulars and documents specified in Article 5 of the Council Directive, and
(b) where the documents and particulars relate to matters referred to in points 8, 9 or 10 of the said Article 5, be drafted and signed by experts with the requisite technical or professional qualifications as specified by the Council Directive.
(2) Prior to making an application for a veterinary product authorisation the requirements of Council Directive 81/852/EEC as amended by Council Directive 87/20/EEC and Commission Directive 92/18/EEC relating to analytical, pharmac-toxicological and clinical standards and protocols in respect of the testing of the animal remedy shall have been complied with.
(3) Notwithstanding paragraph (1), where an application is made for a veterinary product authorisation in respect of an animal remedy which has been authorised in accordance with the provisions of the Council Directives in another Member State, the Competent Authority may, and with effect from 1 January, 1998, shall, consider the application on the basis of the summary of product characteristics as laid down by Articles 5 (a) of the Council Directive furnished by the applicant and the assessment report as laid down by Article 5 (b) of the Council Directive furnished by the appropriate

authority of the Member State which has granted the authorisation.
(4) Where application for a veterinary product authorisation is made in respect of an animal remedy which is already under active examination in another Member State, the Competent Authority may suspend the detailed examination of the application in order to await the assessment report prepared by the appropriate authority in the other Member State and then consider the application in accordance with paragraph (3).
(5) Where the Competent Authority suspends the examination of an application in accordance with the provisions of paragraph(4), the Competent Authority shall inform the appropriate authority in the other Member State and the applicant accordingly.

REG 9

9 PROCEDURE FOR ASSESSMENT OF APPLICATIONS FOR VETERINARY PRODUCT AUTHORISATIONS.
9. (1) In the examination and determination of an application for a veterinary product authorisation, the Competent Authority shall take into consideration such criteria as appear to be relevant for the purposes of the Council Directives and, in particular, the information supplied by the applicant in relation to –
(a) the quality, safety and efficacy of the animal remedy to which the application relates;
(b) the proposed indications, sales presentation, labelling and, where appropriate, package inserts of the animal remedy;
(c) the measures, in the case of an animal remedy to be imported from a country other than a Member State of the European Community, to ensure that the animal remedy is produced to an equivalent standard to those applicable in the European Community, and, if necessary, an inspection of the manufacturing facility by the Competent Authority shall be required.
(2) For the purpose of examining an application, the Competent Authority may require the applicant to furnish, without charge, a sample of the animal remedy, its active ingredients or intermediate products for testing, by a laboratory designated by the Competent Authority for that purpose, to ensure that the testing methods employed by the applicant and described in the application documents are satisfactory.
(3) For the purpose of verifying the analytical detection methods proposed by the applicant for the carrying out of routine checks for residues of an animal remedy in food producing animals or, in the flesh or produce of such animals, the Competent Authority may require the applicant to supply sufficient quantities of any substance or other materials as may be necessary for this purpose.
(4) Subject to paragraph (5) and paragraph (7), the Competent Authority shall, within 210 days of the receipt of a valid application, notify an applicant for a product authorisation of its decision to grant a veterinary product authorisation or to refuse an application.
(5) Where an application for a veterinary product authorisation is being examined in accordance with paragraph (3) or paragraph (4) of Regulation 8 the Competent Authority shall, within 90 days of receipt of the assessment report, either recognise the decision of the other Member State and the summary of product characteristics

approved by it or, if it considers that there are grounds for supposing that the authorisation of the animal remedy concerned may pose a risk to human or animal health or the environment, apply the procedures set out in articles 18 to 22 of the Council Directive.
(6) If the Competent Authority proposes to refuse an application, the applicant shall be notified in writing of the reasons for such proposal and be invited to make representations to the Competent Authority, within 30 days of the giving of such notice, and the Competent Authority shall consider any such representations before reaching a final decision.
(7) Where the Competent Authority requires further information from an applicant for the purpose of considering an application for a veterinary product authorisation, the time limit referred to in paragraph (4) shall be suspended until the information required has been supplied.

REG 10

10 CONDITIONS OF VETERINARY PRODUCT AUTHORISATION
10. (1) The Competent Authority may, if it considers it appropriate to do so, for the purpose of safety or health protection, or, for compliance with these Regulations or the law of the State attach conditions to a veterinary product authorisation at the time of the grant of the authorisation or subsequently and may amend or revoke a condition attached to an authorisation.
(2) The Competent Authority in granting a veterinary product authorisation shall specify the manner in which an animal remedy shall be packaged, presented and labelled and the particulars which shall appear on such label or other container and package insert if appropriate.
(3) The form of label and package insert shall comply with the requirements of the Council Directive and the Second Schedule, and shall include any other particulars, which are prescribed by the Competent Authority 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.
(4) A veterinary product authorisation shall, in accordance with Regulation 13, specify the authorised routes of sale and supply and any restrictions or conditions on promotion necessary to comply with the law of the State.
(5) A veterinary product authorisation may, if deemed necessary, also require the inclusion of a tracer or marker substance.
(6) A veterinary product authorisation may require that the holder of the authorisation makes available, to the appropriate authorities within the State, such quantities of a specified substance as may be necessary to carry out routine checks for the presence of residues of the animal remedy to which the authorisation relates in food producing animals or in the flesh or produce of such animals, if such specified substance is not readily available through normal commercial channels.
(7) The holder of a veterinary product authorisation shall up-date the documents and particulars relating to an animal remedy, as

necessary, in order to –
(a) comply with the requirements of Article 14 of the Council Directive;
(b) take account of technical and scientific progress;
(c) take account of any prohibitions or restrictions placed on the marketing of the animal remedy in any other State or jurisdiction;
(d) take account of any serious unexpected adverse reactions arising out of the use of the animal remedy.
(8) Any changes notified under paragraph (7) shall be subject to the approval of the Competent Authority.
(9) The holder of a veterinary product authorisation shall maintain records of all undesirable effects observed in animals or human beings arising out of the use of the animal remedy, which records shall be kept for at least five years and made available to the Competent Authority upon request.

REG 11

11 REFUSAL OF APPLICATION FOR VETERINARY PRODUCT AUTHORISATION
11. (1) The Competent Authority shall not grant a veterinary product authorisation where –
(a) the animal remedy is harmful under the conditions of use stated at the time of application for authorisation;
(b) the animal remedy has no therapeutic effect or the applicant has not provided sufficient proof of such effect as regards the species or class of animal which is 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 foodstuffs obtained from the treated animal do not contain residues which exceed those prescribed by Council Regulation 2377/90/EEC, any other instrument of Community Law, or any limit prescribed by Regulations made under the Act, or which might constitute a health hazard to the consumer of produce derived from the treated animal, or is insufficiently substantiated;
(e) the animal remedy is, or is to be, offered for sale or supply for a use prohibited under Community Law or the Act or Regulations made or deemed to have been made pursuant to the Act;
(f) the animal remedy is intended for administration to food producing animals whose flesh or products are intended for human consumption and the animal remedy consists of, or contains a substance, which is mentioned in Annex IV of Council Regulation (EEC) No. 2377/90;
(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 prohibited pursuant to Community Law or the Law of the State ;
(h) such action is necessary for the protection of public or animal health or the environment;
(j) the application documents do not comply with the requirements of the Council Directive;
(k) the animal remedy is not manufactured in accordance with the principles and guidelines of good manufacturing practice for veterinary medicinal products as prescribed by Commission # Directive 91/412/EEC;

(l) a request by the Competent Authority for further particulars, to enable compliance with the requirements of the Council Directive to be determined satisfactorily, has not been complied with within the time specified by the Competent Authority.
(2) For the purpose of these Regulations an animal remedy shall be deemed 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 or class of animal for which the treatment is intended.

REG 12

12 REFUSAL OF APPLICATION FOR VETERINARY PRODUCT AUTHORISATION IN RESPECT OF AN ANIMAL REMEDY FOR FOOD PRODUCING ANIMALS
12. Without prejudice to Regulation 11, the Competent Authority shall not grant a veterinary product authorisation in respect of an animal remedy intended for administration to a food producing animal unless
(1) (a) the active substance or substances capable of pharmacological action contained in the animal remedy were authorised for use in other animal remedies on the date of entry into force of Council Regulation (EEC) No 2377/90 laying down a Community procedure for the fixing of maximum levels of residues of veterinary medicinal products in foodstuffs of animal origin, and
(b) the time for obtaining a listing in the Annex of the said Council Regulation in respect of such substances has not expired, or
(2) the active substance or substances capable of pharmacological action is, or, are mentioned in Annex I, II or III of the aforementioned Council Regulation.

REG 13

13 ROUTES OF SALE OR SUPPLY OF ANIMAL REMEDIES
13. (1) For the purposes of these Regulations the following routes of sale or supply shall apply–
(a) veterinary surgeon only in respect of an animal remedy which may be administered only by
(i) a registered veterinary surgeon, or
(ii) under the direct supervision of a registered veterinary surgeon where such registered veterinary surgeon is present at the time of administration and in a position to render assistance if required;
(b) prescription only in respect of 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 surgeon, or
(ii) a registered veterinary surgeon in the course of his or her professional practice for the treatment of animals under his or her care and concerning which he or she has been consulted in a professional capacity;
(c) prescription only exempt in respect of an animal remedy which may be sold or supplied only by –
(i) a pharmacist, from a pharmacy, or
(ii) a registered veterinary surgeon in accordance with subparagraph (b)(ii);
(d) pharmacy only in respect of 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 surgeon in accordance with subparagraph (b) (ii);
(e) licensed merchant in respect of an animal remedy, to which subparagraphs (a), (b), (c) or (d) do not apply, and which may be sold or supplied from a pharmacy, a premises to which an Animal Remedies Merchant's Licence relates and which may be sold or supplied by a registered veterinary surgeon in accordance with subparagraph (b) (ii);
(f) companion animal medicine in respect of an animal remedy to which subparagraphs (a), (b), (c), (d) or (e) do not apply, which may be sold or supplied from a pharmacy, a premises to which an Animal Remedies Merchant's Licence or a Companion Animal Medicine Seller's Licence relates and which may be sold or supplied by a registered veterinary surgeon in accordance with subparagraph (b) (ii);
(2) The authorised routes of sale or supply for an animal remedy shall be stated on the container, label or package insert for which purpose the symbols set out in Part IV of the First Schedule may be used.
(3) In deciding the route of sale or supply for an animal remedy the Competent Authority shall have due regard to the need to protect public health, animal health, animal welfare and the environment and shall accordingly have 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.
(4) Where an animal remedy requires to be administered by, or, under the direct supervision of a registered veterinary surgeon, because,
(a) the method of administration is novel, or
(b) the professional skill of a registered veterinary surgeon 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 shall be restricted to administration by, or, as the case may be, under the direct supervision of, a registered veterinary surgeon.
(5) Without prejudice to stricter provisions pursuant to the law of the State, an animal remedy to which the following conditions apply shall be restricted to supply by, or in accordance with the prescription of, a registered veterinary surgeon –
(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 veterinary medicinal products

resulting from Community Law;
(b) an animal remedy in respect of which special precautions must be taken by a registered veterinary surgeon when supplying or 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 consumer of foodstuffs derived from the treated animal, or
(iv) the environment;
(c) an animal remedy intended for treatments or pathological processes which require a precise prior diagnosis or the use of which may cause effects which impede or interfere with subsequent diagnostic or therapeutic measures;
(d) magisterial formulae intended for animals;
(e) an animal remedy containing an active ingredient 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 Competent Authority is satisfied that None of the other criteria referred to in this paragraph apply.
(6) Notwithstanding paragraph (5) the Competent Authority, may, in the case of an animal remedy to which some or all of the provisions of paragraph (5), other than subparagraph (5) (c) or subparagraph (5) (d), apply, having regard to
(a) the purposes for which the animal remedy is intended, and
(b) the extent to which the container, label and package insert are specific to such purpose, and
(c) the strength of the active ingredient contained therein, and
(d) the maximum dose specified in the product authorisation, and
(e) the pharmaceutical form, and
(f) the potential for misuse, designate such animal remedy as prescription only exempt.
(7) Where the Competent Authority considers that the 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, or
(b) possible contra-indications with other commonly used animal remedies, or
(c) the method of administration or use or the handling or preparation prior to use, or
(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 shall be designated pharmacy only sale.

REG 14

14 RESTRICTION ON SALE OF CERTAIN ANIMAL REMEDIES
14. (1) This Regulation applies to an animal remedy which consists of, or, contains any substance, or any substance belonging to a class of substances, set out in the Second Schedule.
(2) Subject to paragraph (3) the sale or supply of an animal remedy to which this Regulation applies is prohibited save under

licence granted by the Minister.
(3) This Regulation shall not apply to an animal remedy which is—
(a) sold or supplied by a registered veterinary surgeon for the treatment of animals under his or her care and concerning which he or she has been consulted in a professional capacity, or
(b) sold or supplied by a pharmacist in accordance with the prescription of a registered veterinary surgeon, or
(c) an animal remedy which is designated prescription only exempt in accordance with the provisions of Regulation 13 (7) and is sold or supplied by a pharmacist.
(4) Paragraph (2) shall not apply to an animal remedy which—
(a) is sold or supplied (whether by being packaged in a particular manner or otherwise) as an intramammary preparation for the prevention or treatment of mastitis in bovine animals, and
(b) is intended for use exclusively as such a preparation, and
(c) whose container and any outer wrapper bears a notice clearly indicating that the animal remedy is so sold or supplied and is intended for such use only.

REG 15

15 LABELLING OF ANIMAL REMEDIES
15. (1) The holder of an animal remedies authorisation shall not sell or supply an animal remedy unless and until the package and label comply with the provisions and conditions attached to the animal remedies authorisation.
(2) No person shall remove, deface or otherwise alter a label or, package insert, prescribed by these Regulations prior to the sale or supply of an animal remedy.
(3) No person shall sell or supply an animal remedy where the label or package insert has been defaced or otherwise altered or where the label or package insert has been removed.

REG 16

16 LICENSING OF CERTAIN ANIMAL REMEDIES IN SPECIFIED CIRCUMSTANCE
16. (1) (a) Notwithstanding Regulation 6(2), the Minister may, by licence, where the animal health situation so requires—
(i) in particular to deal with a serious disease epidemic, or
(ii) for the treatment of minor or exotic species, or
(iii) in exceptional circumstances where issues of public or environmental health arise relating to the use of authorised animal remedies,
authorise the possession, sale or supply and the administration to an animal of an animal remedy, in respect of which there is not otherwise in force an animal remedies authorisation, which is authorised in another Member State in accordance with the provisions of the Council Directive.
(b) The Minister shall not grant a licence under this paragraph unless and until he or she is satisfied that the animal remedy subject of the application is authorised in another Member State and, for such purpose, may require confirmation of such authorisation to be furnished by the applicant.
(2) (a) For the purposes set out in paragraph (1)(a), in exceptional circumstances, where there is no appropriate animal remedy

authorised within the State or in another Member State, the Minister may, by licence, authorise the manufacture, import, sale, supply or use of an animal remedy, in respect of which there is not otherwise in force an animal remedies authorisation, pending the consideration of an application for such authorisation by the Competent Authority.
(b) The Minister shall not grant a licence under this paragraph for the administration of an animal remedy to a food producing animal unless he or she is satisfied that the administration, and the conditions attached thereto, of such animal remedy will not result in produce derived from treated animals containing residues harmful to the consumers of such produce.
(3) (a) The Minister may, if he or she thinks it appropriate to do so for the purposes of ensuring compliance with these Regulations or the law of the State and having regard to the provisions of this Regulation, attach conditions to a licence at the time of the grant of a licence or subsequently and may amend or revoke a condition attached to a licence
(b) A licence granted under this Regulation shall specify the route of sale or supply of the animal remedy to which it relates in accordance with Regulation 13.
(4) The Minister may make the granting of a licence under this Regulation conditional on application for a veterinary product authorisation being made to the Competent Authority.
(5) The Minister shall not grant a licence under this Regulation when, following consultation with the Competent Authority, he or she is satisfied that in the circumstances it is more appropriate that an application for a veterinary product authorisation should be made to, and determined by, the Competent Authority.

REG 17

17 VALIDITY OF VETERINARY PRODUCT AUTHORISATION
17. (1) A veterinary product authorisation shall, unless previously revoked be valid for a period, specified therein, not exceeding five years, commencing on the date of the grant of the authorisation.
(2) A veterinary product authorisation shall be renewable where application for renewal is made by the holder in accordance with the provisions of these Regulations and the Council Directives.
(3) Where application for renewal of a veterinary product authorisation is made by the holder, in accordance with the provisions of these Regulations and the Council Directives, at least 90 days before the expiry date, the veterinary product authorisation shall remain in force pending the decision of the Competent Authority.
(4) Where a veterinary product authorisation is renewed the period of validity of the authorisation shall commence immediately following the expiry of the authorisation which it replaces.
(5) In exceptional circumstances and following consultation with the applicant, a veterinary product authorisation may be granted subject to annual review or subject to certain specific obligations, including—
(a) the carrying out of further studies following the granting of authorisation, or
(b) the notification to the Competent Authority of all, or

specified, adverse reactions to the animal remedy.
(6) The applicant for the grant or renewal of a veterinary product authorisation must be established in the European Community.

REG 18

18 PHARMACOVIGILANCE
18. (1) The Competent Authority shall establish a pharmacovigilance system for the purpose of surveillance of animal remedies with particular reference to
(a) adverse reactions and to evaluate such information scientifically,
(b) to collate information on frequently observed misuse and serious abuse of animal remedies, and
(c) to collate information on the consumption and use of animal remedies.
(2) (a) The holder of an animal remedies authorisation shall have permanently and continuously at his or her disposal an appropriately trained person responsible for pharmacovigilance.
(b) The trained person referred to in subparagraph (a) shall be responsible for —
(i) the establishment and maintenance of a system which ensures that information about all suspected adverse reactions which are reported to the authorisation holder, his or her servants or agents is collected and collated at a single point;
(ii) the preparation for the Competent Authority of the reports referred to in paragraph (3) in such form as may be prescribed by the Competent Authority in accordance with the relevant national or Community guidelines;
(iii) responding to requests from the Competent Authority for the provision of additional information necessary for the evaluation of the benefits and risks affected by an animal remedy including provision of information concerning volume of sales for the particular animal remedy concerned.
(3) The holder of an animal remedies authorisation shall ensure that —
(a) all suspected serious adverse reactions (including unexpected serious adverse reactions) are recorded and reported to the Competent Authority at the earliest opportunity and not later than 15 days following receipt of a report;
(b) detailed records of all adverse reactions, (including unexpected adverse reaction), other than those to which subparagraph (a) refers, which are reported are recorded and reported to the Competent Authority at least every six months during the first two years following first authorisation and once a year for the following three years and thereafter at five yearly intervals together with the application for renewal of the veterinary product authorisation, unless other requirements have been laid down as a condition of the animal remedies authorisation;
(c) the reports referred to in subparagraph (a) and subparagraph (b) shall be accompanied by a scientific evaluation, and where it is not possible to furnish such evaluation in respect of a report to which subparagraph (a) applies with the initial report it shall be sufficient compliance to forward such evaluation at the earliest opportunity.

(4) (a) A person licenced to sell or supply animal remedies pursuant to Regulations 30, 31 or 32, a registered veterinary surgeon or a pharmacist shall report all adverse reactions which are reported to him or her, or, which otherwise come to his or her attention, to the Competent Authority.
(b) In the case of a serious adverse reaction the report shall be made at the earliest opportunity and not later than 15 days following receipt of such information and other adverse reactions or any undesirable effects of animal remedies shall be reported within six months of the receipt of the report.
(c) The Competent Authority shall prescribe the form in which such reports shall be made.
(5) (a) Where as a result of evaluation of an adverse reaction report the Competent Authority considers that a veterinary product authorisation should be revoked, varied or suspended it shall inform the Agency and the holder of the veterinary product authorisation (who shall be afforded an opportunity to make representations within such period as may be fixed by the Competent Authority) forthwith.
(b) A veterinary product authorisation shall not be revoked, varied or suspended until the representations, if any, of the holder of the veterinary product authorisation have been considered.
(c) Notwithstanding sub paragraph (b), in case of urgency where public or animal health is threatened, the Competent Authority may temporarily suspend the distribution, sale and supply of an animal remedy.
(6) The Competent Authority shall immediately inform the Agency and the holder of an animal remedies authorisation of all reports of serious adverse reactions and unexpected serious adverse reactions received by the Authority and in any event not later than 15 days following receipt of the report.
(7) The person responsible for the sale or supply of an animal remedy shall notify the Competent Authority of any action taken by him to suspend the sale or supply of, or the recall of, an animal remedy together with the reasons for such action if it concerns the efficacy or safety (including the protection of public health) of the animal remedy.
(8) 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;
"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;
"unexpected adverse reaction" means an adverse reaction which is not mentioned in the summary of the product characteristics;
"serious unexpected adverse reaction" means an adverse reaction which is both serious and unexpected;
"appropriately trained person" means a person who, although not necessarily possessing the qualifications prescribed by the Third Schedule, as a result of professional qualification, and, or, education and training is competent to discharge the responsibilities prescribed by this Regulation.

19 SUSPENSION AND REVOCATION OF VETERINARY PRODUCT AUTHORISATION

19. The Competent Authority shall suspend or revoke a veterinary product authorisation where in the opinion of the Competent Authority —

(1) the animal remedy proves to be harmful under the conditions of use stated at the time of application for authorisation or subsequently, or where the animal remedy does not have any therapeutic effect or its qualitative and quantitative composition is not as stated;

(2) the recommended withdrawal period is inadequate to ensure that foodstuffs obtained from the treated animal do not contain residues which might constitute a health hazard to the consumer; or which exceed the maximum residue limits prescribed by Council Regulation (EEC) No. 2377/90 or under any other instrument of Community Law or the Law of the State;

(3) the animal remedy is sold or supplied for a use which is prohibited by other provisions of Community Law; however, pending Community rules, the Competent Authority may suspend or revoke a veterinary product authorisation for an animal remedy where such action is necessary for the protection of public, consumer or animal health;

(4) 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 prohibited pursuant to Community Law or the Law of the State;

(5) the information given in the application documents pursuant to Articles 5 and 14 of the Council Directive is incorrect;

(6) the control tests referred to in Article 35 of the Council Directive have not been carried out;

(7) a requirement to include a tracer or marker substance pursuant to Regulation 10 (2) or the second paragraph of Article 12 of the Council Directive has not been complied with;

(8) the particulars supporting the application, as provided for in Article 5 of the Council Directive, have not been amended in accordance with the first and third paragraphs of Article 14 of the Council Directive;

(9) any new information as referred to in the second paragraph of Article 14 of the Council Directive has not been communicated to the Competent Authority;

(10) the animal remedy is not manufactured in accordance with the principles and guidelines of good manufacturing practice for veterinary medicinal products as prescribed by Commission Directive 91/412/EEC; or

(11) the animal remedy is not labelled in accordance with the provisions of the veterinary product authorisation.

REG 20

20 RECALL OF ANIMAL REMEDIES

20. (1) The Competent Authority shall ensure that the distribution, sale or supply of an animal remedy is prohibited and that the animal remedy concerned is withdrawn and an animal remedy already sold or supplied is recalled where in the opinion of the Competent Authority —

(a) the animal remedy is harmful under the conditions of use stated at the time of the application for authorisation or subsequently, as a result of the report of undesirable effects observed in animals or humans pursuant to the third paragraph of Article 14 of the Council Directive; or
(b) the animal remedy has no therapeutic effect on the species of animal for which it is intended; or
(c) the qualitative and quantitative composition of the animal remedy is not as stated on the label or as specified in the veterinary product authorisation; or
(d) the recommended withdrawal period is inadequate to ensure that foodstuffs obtained from the treated animal do not contain residues which might constitute a health hazard to the consumer; or
(e) the control tests on the finished animal remedy referred to in Article 35 of the Council Directive have not been carried out, or any other requirement or obligation relating to the grant of the veterinary product authorisation referred to in Article 24 of the Council Directive has not been complied with; or
(f) the animal remedy is not manufactured in accordance with the principles and guidelines of good manufacturing practice for veterinary medicinal products as prescribed by Commission Directive 91/412/EEC; or
(g) the use of the animal remedy for the purpose for which it is authorised, or the use of a substance contained therein, is prohibited, whether in animals generally, or, to the particular class or classes of animals for which the animal remedy is authorised, pursuant to Community Law or the law of the State.
(2) The Competent Authority may confine the prohibition on distribution, sale or supply and the requirement to withdraw and recall an animal remedy already sold or supplied solely to specific production batches.

PART III

MANUFACTURE, IMPORT AND EXPORT OF ANIMAL REMEDIES

REG 21

21 MANUFACTURE OF ANIMAL REMEDIES
21. (1) A person shall not manufacture an animal remedy in the State or import an animal remedy from a country other than a Member State of the European Union save under and in accordance with a licence ('Manufacturer's licence') granted by the Competent Authority.
(2) A Manufacturer's Licence may relate to animal remedies generally, to animal remedies of a particular class or description specified in such licence or to one or more animal remedies specified in such licence.
(3) (a) A Manufacturer's Licence shall be required for both total and partial manufacture and for the various processes of dividing up, packaging or presentation.
(b) A Manufacturer's licence, shall not be required for dividing up, packaging or presenting an animal remedy where those processes are not carried out in advance and are carried out by —

(i) a pharmacist in respect of an animal remedy to be sold from a pharmacy, or
(ii) a registered veterinary surgeon in respect of an animal remedy supplied by him or her for the treatment of an animal under his or her care concerning which he or she has been consulted in a professional capacity,
and the quantity to be supplied is less than that available in the smallest proprietary pack size lawfully available within the State.
(c) Where an animal remedy is sold or supplied in accordance with paragraph (3) (b) it shall be labelled with, or bear a notice staling
(i) the proprietary name of the animal remedy,
(ii) for animal treatment only,
(iii) the species to be treated,
(iv) the route of administration,
(v) the dose rate,
(vi) the name of the person to whom supplied,
(vii) the name and adress of the supplier, and
(viii) where necessary, precautions regarding use and withdrawal period, if applicable, so as to ensure the safe use of the animal remedy so supplied.
(d) The provisions of this paragraph shall not apply to an animal remedy which is authorised in the form of a sterile preparation which animal remedy may only be sold or supplied in the authorised container or package.
(4) A Manufacturer's Licence shall not be required for the extemporaneous preparation of an animal remedy or magistral formula not prepared in advance in accordance with Regulation 40 by —
(a) a registered veterinary surgeon for the treatment of an animal under his or her care concerning which he or she has been consulted in a professional capacity, or
(b) a pharmacist, in accordance with the prescription of a registered veterinary surgeon issued for the treatment of an animal under his or her care concerning which he or she has been consulted in a professional capacity.
(5) The provisions of this Regulation shall not apply to the manufacture of an animal remedy in a laboratory which is engaged in recognised veterinary or pharmaceutical education, research or analysis and used for such purposes in such a laboratory.
(6) A licence granted under section 7 of the Therapeutic Substances Act, 1932 shall be deemed to be a Manufacturer's Licence in respect of the animal remedy or remedies named therein until the date of expiry of such licence.
(7) Save under and in accordance with a licence granted under Regulation 26, a person shall not manufacture or import a prohibited animal remedy.
(8) This Regulation shall 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).

REG 22

22 PROVISIONS RELATING TO IMPORT OF ANIMAL REMEDIES FOR EXPORT

22. (1) A Manufacturer's licence shall not be required for the import of an animal remedy from a country other than a Member State of the European Union where the animal remedy is imported for the purpose of trans-shipment to another Member State of the European Union and is not intended to be sold or supplied within the State.
(2) An animal remedy to which paragraph (1) applies must be accompanied by a copy of the authorisation granted for its importation duly certified by the appropriate authority of the Member State of destination.

REG 23

23 APPLICATION FOR MANUFACTURE'S LICENCE
23. (1) The Competent Authority may grant a Manufacturer's Licence to any person who applies in the form and manner required by the Competent Authority provided, in regard to the animal remedy which it is proposed to manufacture, the Competent Authority is satisfied that the applicant has suitable premises, equipment, staff and manufacturing operations and suitable arrangements for quality control, record keeping, handling, storage and distribution.
(2) An application for a Manufacturer's Licence shall meet at least the following requirements —
(a) the application shall specify the animal remedies and pharmaceutical forms which are to be manufactured or imported and also the place where they are to be manufactured and/or controlled;
(b) the application shall provide particulars to establish that the applicant has available suitable and sufficient premises, technical equipment and trained staff as regards both manufacture and control and the storage of animal remedies or ingredients thereof;
(c) the applicant shall satisfy the Competent Authority that all manufacturing shall be carried out in accordance with the criteria set out in Commission Directive 91/412/EEC laying down the principles and guidelines of good manufacturing practice for veterinary medicinal products; and
(d) the applicant shall satisfy the Competent Authority that the services of at least one qualified person within the meaning of the Third Schedule are available in relation to carrying out the necessary controls and functions as prescribed by the Council Directive.
(3) A Manufacturer's licence shall be subject to such conditions as the Competent Authority may specify and may, in particular, include the general conditions set out in the Fourth Schedule.
(4) The holder of a Manufacturer's licence may only sell or supply an animal remedy manufactured under such licence in accordance with these Regulations and the law of the State.
(5) The holder of a Manufacturer's licence shall allow an officer of the Competent Authority or an authorised officer access to the premises where the business of manufacture, control, storage, distribution and associated activities, in relation to the manufacture of animal remedies is carried out.
(6) (a) The holder of a Manufacturer's licence shall keep detailed records of each animal remedy manufactured, sold or supplied by him, including samples, in accordance with these Regulations, the Law of the State or, in the case of an animal remedy exported

from the State, the laws of the country of destination;
(b) The following information at least shall be recorded in respect of each transaction whether or not it is made for payment:
(i) date,
(ii) name of animal remedy,
(iii) batch numbers and expiry date,
(iv) quantity supplied and
(v) name and address of the recipient.
(c) The records required under this paragraph shall be available for inspection by an officer of the Competent Authority, an authorised officer, or an officer of the Minister 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 lodger period.
(7) A Manufacturer's licence shall remain in force for a period of three years, or such shorter period as may be specified in the licence, unless it is sooner revoked, suspended or varied by the Competent Authority.
(8) (a) The Competent Authority may grant, revoke, suspend or vary a Manufacturer's licence or refuse an application.
(b) Without prejudice to the generality of this paragraph the Competent Authority shall refuse an application or revoke, suspend or vary a Manufacturer's licence where —
(i) the manufacture, import, sale, supply or use of the animal remedy concerned is contrary to the Law of the State, or, in the opinion of the Competent Authority, the animal remedy concerned is being or would be sold, supplied or used in the State otherwise than for the purpose specified in the application for a licence or the veterinary product authorisation, or
(ii) in the opinion of the Competent Authority the staff, premises, equipment, machinery or plant used or to be used, by the applicant or licence holder, are not or cease to be, suitable for such manufacture, or
(iii) the applicant, or licence holder, does not have, or ceases to have, the services of a qualified person in relation to the animal remedy or substance concerned as required by the Council Directive, or
(iv) the applicant or licence holder, as the case may be, is incapable of complying with, ceases to, or has failed to comply with the requirements of Commission Directive 91/412/EEC laying down the principles and guidelines of good manufacturing practice for veterinary medicinal products, or
(v) in the course of routine inspections 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 said animal remedy, or
(vi) if in the opinion of the Competent Authority the person is not, for any other reason, (including conviction of an offence or for failure to comply with the conditions attached to a previous licence or animal remedies authorisation), a fit and proper person to hold a licence.

24 Decision on application for manufacture's licence
24. (1) Subject to paragraph (4) the Competent Authority shall, within 90 days of the receipt of an application, notify an applicant for a Manufacturer's licence of a decision to grant a licence, or a proposal to refuse an application.
(2) If the Competent Authority proposes to refuse an application, the applicant shall be notified in writing of the reasons for such proposal and be invited to make representations to the Competent Authority, within 30 days of the giving of such notification.
(3) The Competent Authority having considered any representations made under paragraph (2) shall inform the applicant, in writing, of its decision within 60 days of the notification referred to in that paragraph.
(4) Where the Competent Authority requires further information from an applicant for the purpose of consideration of an application for a Manufacturer's licence, the time limit referred to in paragraph (1) shall be suspended until the information required has been supplied.
(5) The Competent Authority may revoke, suspend or vary the conditions of a licence granted under this Regulation.
(6) If the Competent Authority proposes to revoke or suspend a licence or vary the conditions of a licence, the holder of the licence shall be notified of the reasons for such proposal and invited to make representations in the matter to the Competent Authority within 30 days of the giving of such notification.
(7) The Competent Authority having considered any representation made under paragraph (6), shall inform the licence holder in writing of its decision regarding such proposed revocation, suspension or variation as mentioned in paragraph (6) within sixty days of the notice referred to in that paragraph.

REG 25

25 SUSPENSION OF MANUFACTURE'S LICENCE
25. (1) Notwithstanding Regulation 24, whenever in relation to a premises in respect of which there is for the time being in force a Manufacturer's licence, an officer of the Competent Authority, who is an authorised officer for the purposes of these Regulations, is of the opinion that there is a grave and immediate risk —
(a) to public or animal health arising from the manner in which such premises is managed, maintained or operated, or
(b) that an animal remedy, which is manufactured on such premises and is intended to be sold or supplied for administration to animals, is liable, if so used, to cause illness or injury to a treated animal or the consumer of the produce of such a treated animal, or
(c) that an animal remedy, which is on such 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 Council Directives,
then such authorised officer may serve on the holder of the Manufacturer's licence in relation to that premises or on the person who seems to him for the time being in charge of such premises, a notice in writing requiring that -

(i) the manufacture of animal remedies in such premises or part thereof cease forthwith, or
(ii) the manufacture of a particular animal remedy or a particular class of animal remedy cease forthwith, or
(iii) the distribution, sale or supply of a particular animal remedy or a particular class of animal remedy cease forthwith, and the notice, or a subsequent notice, may specify the steps which ought to be taken, or the things that ought to be done , before such premises or part thereof, as the case may be, is used for the manufacture of the animal remedy or remedies to which the said notice relates.
(2) A person upon whom a notice is served under paragraph (1) shall forthwith comply with the terms of the notice.
(3) Any person who fails to comply with the terms of a notice under paragraph (1) shall be guilty of an offence.
(4) An officer of the Competent Authority, who is an authorised officer for the purposes of these Regulations, may at any time, by a notice in writing, revoke or vary a notice served under paragraph (1).
(5) The service of a notice under paragraph (1) shall not be construed as in any way affecting any proceedings, whether instituted before or after such service, to revoke, vary or suspend a manufacturer's licence, or in which a contravention of any provision of the Act or of Regulations made thereunder is alleged.
(6) Any person aggrieved by a notice under paragraph (1) may, not later than 21 days after the service of the notice, make representations in the matter to the Competent Authority.
(7) The Competent Authority shall consider such representations and shall, as it thinks proper, affirm, vary or cancel the notice.

REG 26

26 POSSESSION ETC. OF A PROHIBITED ANIMAL REMEDY
26. (1) Notwithstanding Regulation 21, a person shall not have possession of, manufacture, import into the State, sell or supply a prohibited animal remedy save under and in accordance with a licence under this Regulation (referred to in this Regulation as "a licence").
(2) Subject to the subsequent provisions of this Regulation, on application to the Minister in that behalf by or on behalf of a person the Minister may grant a licence to the person authorising the possession, manufacture, import, sale or supply by that person of such quantity as may be specified in the licence of a prohibited animal remedy so specified or the Minister may refuse the application.
(3) The Minister may, if he or she thinks it appropriate to do so, for the purpose of ensuring compliance with these Regulations and the law of the State and having regard to the provisions of this Regulation, attach conditions to a licence at the time of the grant of the licence or subsequently and may amend or revoke a condition attached to a licence.
(4) Without prejudice to the generality of paragraph (2) the Minister shall refuse an application for a licence to manufacture a prohibited animal remedy if he or she is not satisfied that all of the prohibited animal remedy or substance is intended to, and will,

be —
(a) administered to animals in the course of a test or trial authorised by a licence granted pursuant to Regulation 41, or
(b) supplied to the Competent Authority or the Minister for the purpose of an application for an animal remedies authorisation, or
(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, or
(d) used for in vitro or other studies or analysis not involving administration to animals, or
(c) exported from the State.
(5) Without prejudice to the generality of paragraph (2) the Minister shall refuse an application for a licence authorising the possession, import, sale or supply of a prohibited animal remedy if he or she is not satisfied that all of the prohibited animal remedy or substance is intended to, and will, be -
(a) administered to animals in the course of a test or trial referred to in paragraph (4) (a), or
(b) supplied to the Competent Authority or the Minister for the purposes referred to in paragraph 4(b), or
(c) supplied to a University or other institution concerned with higher education or scientific research or analysis for the purposes for the purposes referred to in paragraph 4(c), or
(d) used for the purposes referred to in paragraph 4(d).
(6) The Minister shall refuse to grant a licence to a person or shall revoke a licence held by a person if —
(a) the person has been convicted of, or has committed, an offence, whether he or she has been convicted or not, under the Act or Regulations deemed to have been made thereunder, or for any other conviction, or failure to comply with the conditions attached to a previous licence or animal remedies authorisation, or, is not, in the opinion of the Minister, a fit and proper person to hold a licence; or
(b) in the opinion of the Minister, the possession, manufacture, import, sale or supply (as may be appropriate having regard to the particular class of licence applied for or held) of the prohibited animal remedy concerned prejudices, or would prejudice, public or animal health or trade in animals or animal products from the State; or
(c) in the opinion of the Minister, the prohibited animal remedy concerned is being or would be sold, supplied or used in the State otherwise than for a purpose specified in paragraph (4) or (5) of this Regulation; or
(d) in the case of a licence authorising the manufacture of a prohibited animal remedy, in the opinion of the Minister, the staff, premises, equipment, machinery or plant used, or to be used, are not suitable for the purpose of such manufacture.

REG 27

27 CERTIFICATES
27. (1) The Minister, or as the case may be, the Competent Authority, shall, at the request of the holder of a Manufacturer's licence, an exporter or the appropriate authority in an importing state, provide a certificate stating that

(a) the manufacturer is in possession of a valid Manufacturer's licence to manufacture a particular class of animal remedy, and
(b) there is for the time being in force an animal remedies authorisation relating to the animal remedy to be exported, or
(c) where there is no such animal remedies authorisation in force the animal remedy to be exported has been manufactured for such purpose pursuant to a licence granted under Regulation 26.
(2) In granting a certificate under paragraph (1) the Minister and the Competent Authority shall have regard to the prevailing administrative arrangements of the World Health Organisation regarding the issue of certification for animal remedies.
(3) Where there is for the time being in force an animal remedies authorisation the Minister or the Competent Authority shall, if requested, supply a copy of the approved summary of product characteristics and where such document is not available, an equivalent document.
(4) Where the manufacturer is not in possession of an animal remedies authorisation 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 such an authorisation has not been sought.

PART IV

SALE AND SUPPLY OF ANIMAL REMEDIES

REG 28

28 RESTRICTION ON SALE OF CERTAIN ANIMAL REMEDIES
28. (1) Subject to paragraphs (2) and (3) a person shall not sell or supply an animal remedy save under and in accordance with a licence granted for that purpose by the Minister.
(2) Paragraph (1) shall not apply to —
(a) the sale or supply of an animal remedy by, or under the supervision of, a pharmacist, subject to these Regulations, or
(b) the sale or supply of an animal remedy by a registered veterinary surgeon to a bona fide client in the course of the provision of a professional service, for the treatment of an animal under the care of, and concerning which, such registered veterinary surgeon (or group veterinary practice of which such registered veterinary surgeon is a member), has been consulted in a professional capacity in accordance with Regulation 44 or Regulation 46
(c) the sale by wholesale of an animal remedy by the holder of a Manufacturer's licence where the animal remedy is manufactured by the said licence holder under and in accordance with a Manufacturer's licence.
(3) The holder of a Manufacturer's licence or an Animal Remedies Wholesaler's licence shall not sell an animal remedy to a particular person unless —
(a) the person to whom the animal remedy is to be sold or supplied is lawfully entitled, by virtue of these Regulations or a licence granted thereunder, to sell or supply animal remedies, and
(b) the sale or supply of such animal remedy by the person to

whom the animal remedy is to be sold or supplied would not contravene these Regulations.
(4) No person shall publish or cause to be published an advertisement or other promotion for an animal remedy unless such animal remedy is an authorised animal remedy.

REG 29

29 RESTRICTION ON USE OF PREMISES
29. A person shall not use a premises for the sale or supply of an animal remedy unless such premises is —
(1) a premises in respect of which there is for the time being in force a Manufacturer's licence, or
(2) a premises in respect of which there is for the time being in force an Animal Remedies Wholesaler's licence, or
(3) a premises in respect of which there is for the time being in force an Animal Remedies Merchant's licence, or
(4) a premises in respect of which there is for the time being in force a Companion Animal Medicine Seller's licence, or
(5) a pharmacy, or
(6) such part of a premises, not being a shop, as is used by a registered veterinary surgeon in connection with carrying on the practice of veterinary medicine and surgery.

REG 30

30 WHOLESALE OF ANIMAL REMEDIES
30. (1) No person shall sell or supply an animal remedy by wholesale except under and in accordance with a licence ('Animal Remedies Wholesaler's licence').
(2) Following consideration of an application for an Animal Remedies Wholesaler's licence the Minister may grant a licence or refuse an 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 the animal remedies which it is proposed to sell.
(4) An Animal Remedies Wholesaler's licence may relate to animal remedies generally, to animal remedies of a particular class or description specified in such licence, or to one or more animal remedies specified in such 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 such premises may not be used for the purposes of Regulation 31 or Regulation 32.
(6) An Animal Remedies Wholesaler's licence shall be subject to such conditions as the Minister may specify and shall, in particular, require that the holder of the licence —
(a) shall sell or supply an animal remedy only to a person who is the holder of a valid Animal Remedies Wholesaler's licence, or, a valid Animal Remedies Merchant's licence, or, as the case may be, a valid Companion Animal Seller's licence, applicable to the class of animal remedy to be supplied, or to a pharmacist or a

registered veterinary surgeon;
(b) shall not sell or supply an animal remedy
(i) other than an animal remedy to which the licence relates,
(ii) which is not the subject of an animal remedies authorisation for the time being in force,
(iii) otherwise than in conformity with the provisions of the animal remedies authorisation, granted in respect of such animal remedy, as stated on the packaging or labelling in relation to the sale or supply of the animal remedy;
(c) shall provide and maintain such premises, equipment and staff, and have in operation such arrangements as are necessary to avoid deterioration of the animal remedy to which the licence relates and shall notify the Minister promptly of any material change in such premises, equipment, staff or arrangements;
(d) shall undertake procedures for storage, stock rotation and maintenance of records which are in compliance with the particulars furnished in connection with the application for the licence or with such other arrangements as may be approved by the Minister from time to time;
(e) shall, on being informed by the Minister or the Competent Authority or the manufacturer that
(i) any batch or part of a batch of an animal remedy to which the licence relates has been found not to conform as regards the provisions of the relevant product authorisation in force under these Regulations or as regards strength, quality or purity with the appropriate specification of that animal remedy, or
(ii) an animal remedy to which the licence relates has been found to give rise to unacceptable adverse reactions,
if so directed by the Minister or the Competent Authority, in relation such animal remedy or batch thereof, immediately withdraw from sale or supply any supplies held by him or her and, so far as is practicable, immediately recall all supplies already sold or supplied by him or her;
(f) shall keep records, of purchase/sales invoices in a machine readable or other form in respect of which the Minister has given prior approval, in respect of each incoming and outgoing transaction detailing at least the following information
(i) date of transaction;
(ii) precise identity of the animal remedy including name and pharmaceutical form and pack sizes;
(iii) manufacturer's batch number and expiry date;
(iv) quantity received or supplied;
(v) name and address of the supplier or consignee.
(g) shall keep available the records referred to in subparagraph (f) for inspection by an authorised officer or an officer of the Competent Authority for a period of three years from the date of receipt, sale or supply of the animal remedy;
(h) shall permit such inspections and make available such information as may be required to satisfy the Minister that the conditions of the licence are being complied with,
(i) shall give without payment, an adequate sample of an animal remedy to a person authorised to take such a sample; and
(j) shall furnish to the purchaser with each supply of an animal remedy information detailing:
(i) the date of supply,

(ii) precise identity of the animal remedy including proprietary name and pharmaceutical form and pack size,
(iii) the quantity supplied,
(iv) the name and address of the supplier and consignor and
(v) the manufacturer's batch number.
(7) An Animal Remedies Wholesaler's licence shall remain in force for a period of one year, or for such shorter period as may be specified by the Minister, unless it is sooner suspended, varied or revoked.
(8) The holder of an Animal Remedies Wholesaler's licence shall, at least once a year, carry out a detailed audit to compare 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 for inspection by an authorised officer for a period of not less that three years.
(9) Notwithstanding paragraph (1) a person who is
(a) engaged in the lawful wholesale of animal remedies, and
(b) who is lawfully carrying on such business on the date on which these Regulations come into force, and
(c) who is registered in accordance with the provisions of the Animal Remedies (Registration of Manufacturers, Importers and Wholesalers) Regulations, 1980 (S.I. No. 115 of 1980),
shall, within three calendar months, apply to be licenced by the Minister pursuant to this Regulation and may sell or supply animal remedies to a person referred to in paragraph (6) (a) in accordance with the provisions of these Regulations until such time as the application is determined.
(10) (a) This Regulation shall not apply to
(i) arrangements for the distribution of animal remedies amongst themselves by one member of a group of persons not exceeding three in number who cooperate in the purchase by wholesale of animal remedies, or,
(ii) the sale of an animal remedy by a person who manufactured it in accordance with a Manufacturer's licence.
(b) "Person" for the purposes of subparagraph (a) (i) means a pharmacist or a registered veterinary surgeon.
(c) Where an animal remedy is sold or supplied or received in accordance with the provisions of sub paragraph (i) details of each transaction shall be recorded in the manner prescribed by these Regulations for the retail sale or supply of animal remedies.

REG 31

31 RETAIL SALE OF ANIMAL REMEDIES
31. (1) No person shall sell an animal remedy by retail except under and in accordance with a licence ('Animal Remedies Merchant's licence').
(2) Following consideration of an application for an Animal Remedies Merchant's licence the Minister may grant a licence or refuse an application.
(3) 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 each animal remedy or class of animal remedy to which the application relates.

(4) An Animal Remedies Merchant's licence may relate to animal remedies generally, to animal remedies of a particular class or description, or to one or more animal remedies specified in such licence.
(5) An Animal Remedies Merchant's licence shall specify the location and premises from which the business of retail sale of animal remedies is to be carried out and such premises may not be used for the purposes of Regulation 30.
(6) An Animal Remedies Merchant's licence shall be subject to such conditions as the Minister may specify and shall, in particular, require that the holder of the licence
(a) shall not sell or supply an animal remedy —
(i) other than an animal remedy to which the licence relates, or
(ii) which is not the subject of an animal remedies authorisation for the time being in force, or
(iii) otherwise than in conformity with the provisions of the animal remedies authorisation granted in respect of such animal remedy;
(iv) other than in accordance with the provisions of these Regulations and the law of the State;
(v) to a person to whom Regulation 30(6) (a) refers.
(b) shall provide and maintain such premises, equipment and staff, and have in operation such arrangements as are necessary to avoid deterioration of an animal remedy to which the licence relates and shall notify the Minister within seven days of any material change in such premises, equipment, staff or arrangements,
(c) shall undertake such procedures for storage, stock rotation and maintenance of records as may be specified in compliance with the particulars furnished in connection with the application for the licence or with such other arrangements as may be approved by the Minister from time to time.
(d) shall, on being informed by the Minister or the Competent Authority or the manufacturer that
(i) any batch or part of a batch of an animal remedy to which the licence relates has been found not to conform as regards the provisions of the relevant product authorisation or as regards strength, quality or purity with the appropriate specification of that animal remedy, or
(ii) an animal remedy to which the licence relates has been found to give rise to unacceptable adverse reactions,
if so directed by the Minister or the Competent Authority, in relation such animal remedy or batch thereof, immediately withdraw from sale or supply any supplies held by him, and, in so far as is practicable, immediately recall all such animal remedies already sold or supplied by him.
(e) without prejudice to Regulation 37, shall not possess, sell or supply an animal remedy which consists of or contains an organophosphorous substance unless and until a person has completed an appropriate training course approved by the Minister.
(7) An Animal Remedies Merchant's licence shall remain in force for a period of one year, or for such shorter period as may be specified by the Minister, unless it is sooner suspended, varied or revoked.
(8) The holder of an Animal Remedies Merchant's licence shall, at least once a year, carry out a detailed audit to compare 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 for inspection by an authorised officer for a period of not less that three years.
(9) The Minister shall not grant a licence in respect of a premises unless the premises conforms to the general conditions set out in the Fifth Schedule.

REG 32

32 SALE OF COMPANION ANIMAL REMEDIES
32. (1) (a) No person shall sell an animal remedy to which this Regulation applies except under and in accordance with a licence ('Companion Animal Medicine Seller's Licence') granted by the Minister.
(b) In this Regulation: "companion animal" means domestic dogs and cats, rabbits (which are not kept for human consumption) small rodents, cage birds, homing pigeons, terrarium animals and aquarium fish.
(c) The holder of a Companion Animal Medicine Seller's licence may only sell an animal remedy designated as a companion animal medicine.
(2) Following consideration of an application for a Companion Animal Medicine Seller's licence the Minister may grant a licence or refuse an application.
(3) A Companion Animal Medicine Seller's licence shall be subject to such conditions as the Minister may specify and, in particular, shall specify the location and premises from which the business of sale of animal remedies is to be carried out and that such premises may not be used for the purposes of Regulation 30 or Regulation 31.
(4) A person who is engaged in the lawful business of sale of companion animal medicines, who is not a person to whom Regulation 30 or Regulation 31 applies and who is lawfully carrying on such business on the date on which these Regulations come into force, shall, within twelve calendar months apply to be licenced by the Minister pursuant to this Regulation and may continue to carry out such business in accordance with this Regulation until such time as the application is determined.

REG 33

33 RECORDS
33. (1) This Regulation applies to:—
(a) an animal remedy which is designated veterinary surgeon only, prescription only, prescription only exempt or pharmacy only by virtue of these Regulations or the Law of the State, or
(b) an animal remedy intended for administration to food producing animals whose flesh or products may be used for human consumption and in respect of which a withdrawal period must be observed by virtue of these Regulations, Community Law or the Law of the State.
(2) A person who sells or supplies an animal remedy to which this Regulation applies in a retail sale or in the course of a professional service shall record the following information in relation to each incoming and outgoing transaction —
(a) date of receipt or, as the case may be, sale or supply,

(b) proprietary name or, where not applicable, the precise identity of the animal remedy,
(c) quantity received, sold or supplied.
(d) name and address of the supplier or, as the case may be, the recipient, and
(e) where relevant, the name and address of the prescribing veterinary surgeon and a copy of the prescription.
(3) (a) Where a veterinary surgeon sells or supplies an animal remedy to which subparagraph (1) (a) applies it shall be clearly labelled with a notice stating —
(i) proprietary name if this is not stated on the product label or, where not applicable, the precise identity of the animal remedy;
(ii) the active ingredient if this is not stated on the product label or, if applicable, on the package insert;
(iii) the manner and site of administration if this is not stated on the product label or, if applicable, the package insert;
(iv) the dose rate and withdrawal period to be observed if this is not stated on the product label or, if applicable, the package insert;
(v) a description of the animal or animals to which the animal remedy is to be administered;
(vi) the person or class of persons by whom the animal remedy is to be administered:
(vii) the name and address of the person to whom the animal remedy is being supplied;
(viii) the name and address of the registered veterinary surgeon supplying the animal remedy; and
(ix) the date of supply.
(b) In the case of an animal remedy in relation to which it is not possible to give the particulars specified in subparagraph (3)(a) it shall be sufficient compliance therewith if those particulars are attached to the animal remedy by a means other than by a label provided the name and address of the registered veterinary .surgeon selling or supplying the animal remedy, the name of the person to whom supplied, and the date of such sale or supply are specified on a label attached to the animal remedy.
(c) Where a registered veterinary surgeon sells or supplies an animal remedy to which this Regulation applies he or she shall, in addition to the particulars prescribed in paragraph (2) record the identity of the animal or animals to be treated.
(d) Where a label placed on an animal remedy pursuant to an animal remedies authorisation contains any of the information required by paragraph (3), such information need not be repeated on the notice required pursuant to subparagraph (a) provided the aforesaid label is not obscured in any material way.
(4) (a) A pharmacist who has dispensed in part a prescription issued under these Regulations shall immediately record on the prescription and on the copy thereof in a conspicuous and indelible manner the quantity of each animal remedy sold or supplied by him on foot of the prescription and the date on which each such sale or supply was made.
(b) A pharmacist who has completed the dispensing of a prescription issued under this Regulation shall write on the prescription and on the copy thereof in a conspicuous and indelible manner the word "dispensed" and the date on which the dispensing was completed.

(c) Where a pharmacist has duly completed the dispensing of a prescription he or she shall return a copy of the prescription to the person who presented it for dispensing and retain the original prescription for a period of three years, such copy to be made available on request to an authorised officer.
(d) A pharmacist, who sells or supplies an animal remedy to which paragraph (1) (a) applies shall affix (in such manner as not to obscure the information required by the animal remedies authorisation to be stated on the label or container) to such animal remedy a label indicating the name and address of the dispensing pharmacist, the name and address of the person to whom sold or supplied, the name of the prescribing registered veterinary surgeon and the date of sale or .supply.
(5) A person who sells or supplies an animal remedy, to which this Regulation applies, and who maintains the records prescribed by this Regulation in a machine readable form shall, in respect of each days transactions, make and sign a hard copy of that record which shall be kept on the premises and be made available on request to an authorised officer for a period of not less than three years.

REG 34

34 EMERGENCY SUPPLY OF CERTAIN ANIMAL REMEDIES BY PHARMACISTS
34. (1) It shall not be a contravention of the Regulations for a pharmacist to sell or supply an authorised animal remedy to which Regulation 14 applies or which is designated prescription only in accordance with Regulation 13 where —
(a) the pharmacist by whom the animal remedy is to be sold or supplied has been requested to sell or supply the animal remedy for the treatment of a particular animal by a registered veterinary surgeon who by reason of an emergency is unable to furnish a prescription immediately, and
(b) the registered veterinary surgeon concerned has undertaken to furnish a prescription within 72 hours, and
(c) the animal remedy is sold or supplied in accordance with the directions of the registered veterinary surgeon requesting it, and
(d) the animal remedy is not a controlled drug specified in Schedule 1 or 2 to the Misuse of Drugs Regulations, 1988, or an animal remedy consisting of or containing a substance specified in Part I of the Second Schedule, and
(e) the animal remedy is labelled in accordance with of Regulation 33 (4) and the pharmacist maintains the records prescribed by Regulation 33 (2).
(2) If a registered veterinary surgeon fails to comply with an undertaking under paragraph (1) (b), the pharmacist may not, in the future, sell or supply an animal remedy under this Regulation at the request of that registered veterinary surgeon.

REG 35

35 PROHIBITION ON SALE OF ANIMAL REMEDIES AFTER EXPIRY DATE
35. (1) A person shall not sell or supply an animal remedy after the date specified thereon as its expiry date.
(2) "Expiry date" in relation to an animal remedy means the date specified on the container, label or package insert of the animal

remedy by the manufacturer in accordance with the terms and conditions of the veterinary product authorisation.

REG 36

36 SALE OF ANIMAL REMEDIES RESTRICTED TO FIXED PREMISES

36. (1) Without prejudice to paragraph (2), notwithstanding that the Minister has granted a licence under Regulation 30 or Regulation 31 or Regulation 32 the sale or supply of an animal remedy otherwise than from a fixed premises is hereby prohibited.

(2) (a) Paragraph (1) shall not apply to the sale or supply of an animal remedy in the course of the provision of a professional service by a registered veterinary surgeon in respect of the treatment of animals under the care of such registered veterinary surgeon who has been consulted in a professional capacity and given care of the animals concerned.

(b) Subparagraph (a) shall only apply to such range and quantity of animal remedies as is generally required for the Daily needs of good veterinary' practice.

(3) There is hereby prohibited save under licence of the Minister —

(a) the sale or supply of an animal remedy from a travelling shop, vehicle or automatic vending machine or retail sale or supply by mail order, or

(b) the making of visits from house to house for the purpose of soliciting, collecting or obtaining orders, or

(c) the sale or supply of an animal remedy at trade fairs or any public or private place where animals are placed for exhibition or competition.

(4) Paragraph (3)(b) shall not apply where house to house visits are made to persons at their respective places of business and the persons so visited are lawfully entitled to sell or supply any such animal remedy from their respective places of business.

(5) In this Regulation:—

"house" includes land or other premises;

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

REG 37

37 TRAINING OF CERTAIN PERSONS

37. (1) For the purpose of ensuring that a person, other than a registered veterinary surgeon 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 shall approve appropriate training courses.

(2) A person who has successfully completed such a training course shall hereinafter be referred to as a responsible person.

(3) With effect from three years after the coming into force of these Regulations the Minister shall not grant or renew an Animal Remedies Merchant's licence unless the sale or supply of animal remedies on the premises to which the said licence relates is conducted by or under the personal supervision of such a responsible

person.
(4) Nothing in this Regulation shall entitle a responsible person to sell or supply animal remedies which are designated veterinary surgeon only prescription only, prescription only exempt or pharmacy only, or, to offer advice concerning the treatment of an animal that would contravene the Veterinary Surgeons Acts, 1931 to 1960.
(5) It shall be a condition of approval of a course that the person providing the course shall furnish the Minister with the names and addresses of persons who have successfully completed such course.
(6) The Minister may refuse to accept the nomination of a person to be a responsible person, if notwithstanding that the person has successfully completed an approved training course, the person has been convicted of an offence under the Act or Regulations made or deemed to have been made thereunder.

PART V

ADMINISTRATION OF ANIMAL REMEDIES AND PROVISIONS RELATING TO ANIMALS AND ANIMAL PRODUCTS

REG 38

38 Administration of animal remedies
38. (1) Without prejudice to Regulation 40 and subject to paragraph (2), a person shall not, except under and in accordance with a licence under Regulation 41, administer an animal remedy to an animal, or cause or permit any such administration.
(2) Paragraph (1) shall not apply to the administration of an authorised animal remedy to an animal of any particular kind where —
(a) the administration is carried out in accordance with the provisions of the conditions of use stated in the animal remedies authorisation, or other conditions of use pursuant to the Council Directives, Law of the State and Community Law, and
(b) the animal remedies authorisation concerned authorises the administration of the animal remedy to animals of that kind, and
(c) the animal remedies authorisation authorises the use of the animal remedy by that person, and
(d) the Act has been complied with in respect of the animal remedy.
(3) (a) A person, including a registered veterinary surgeon, who administers, or authorises, 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 that animal remedy (other than those relating to the treated animal that fall to be complied with after such administration), and
(ii) if the person is not the owner or the person in charge of the treated animal, inform the owner or person in charge of such animal
(I) of the conditions of use of the animal remedy relating to the treated animal that fall to be complied with after such administration, and
(II) that the treated 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, and
(III) that the produce of the treated animal may not be sold, supplied or used 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 treated animal that fall to be complied with after such administration, and
(ii) not slaughter the treated animal for human consumption, or export or sell such 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, the produce of the treated animal during the withdrawal period specified in the conditions of use of the animal remedy.
(4) In this Regulation "conditions of use", in relation to an animal remedy, means
(a) the information and directions that, pursuant to the relevant animal remedies authorisation are required to appear on containers and outer packages of, and package inserts for, the animal remedy, or
(b) where the animal remedy is sold or supplied by a registered veterinary surgeon in accordance with Regulation 40(1)(a) the conditions of use stated in the product authorisation granted in the State of origin.
(5) It shall be the duty of the owner or person in charge of an animal to take such care as will ensure that this Regulation is not contravened in relation to such animal.

REG 39

39 PROVISIONS RELATING TO CERTAIN ANIMALS TO WHICH AN ANIMAL REMEDY HAS BEEN ADMINISTERED
39. A person shall not —
(1) administer to a food producing animal, by any means whatsoever, an animal remedy or an ingredient for an animal remedy, which consists of or, or contains, a substance the administration of which to such animal, or species or class of animal, is prohibited under these Regulations, the law of the State or Community Law; or
(2) import, export, sell or supply, or, slaughter for human consumption, a food producing animal to which an animal remedy or an ingredient for an animal remedy has been administered in contravention of subparagraph (1); or
(3) import, export, sell or supply for human or animal consumption any meat, milk or egg derived from, or produced by, an animal to which an animal remedy has been administered in contravention of subparagraph (1); or
(4) process meat, milk or egg as referred to in subparagraph (3) or import, export or sell any meat, milk or egg product prepared from, or with, such meat, milk or egg; or
(5) 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 (1) or meat, milk or egg derived from, or produced by, such an animal.

REG 40

40 ADMINISTRATION OF ANIMAL REMEDIES

40. (1) Notwithstanding Regulation 38 and subject to the subsequent provisions of this Regulation, where there is no authorised animal remedy for the treatment of a condition in a particular species and, where it is necessary in order to avoid causing unacceptable suffering to the animal or animals concerned, a registered veterinary surgeon may administer, sell, supply or prescribe the use of—

(a) an animal remedy in respect of which there is for the time being in force an animal remedies authorisation authorising the use of such animal remedy in another animal species or for another condition in the same species, or

(b) if there is no animal remedy such as referred to in subparagraph (a), a medical preparation authorised for human use in accordance with the provisions of the Medical Preparations (Licensing, Advertisement and Sale) Regulations, 1984 and 1989 and the Medical Preparations (Licensing, Advertisement and Sale) (Amendment) Regulations, 1993 (S.I. No. 70 of 1993), or

(c) if there is no animal remedy or medical preparation as referred to at subparagraphs (a) or (b), an animal remedy prepared extemporaneously by —

(i) a pharmacist in accordance with the prescription of a registered veterinary surgeon, or

(ii) a registered veterinary surgeon, in respect of animals under his or her care concerning which he or she has been consulted in a professional capacity, or

(iii) a person licensed to manufacture such class of animal remedy in accordance with Regulation 21.

(2) Where it is necessary to treat a food producing animal in accordance with paragraph (1), the provisions of that paragraph shall only apply to the administration or prescription of substances which are to be found in animal remedies authorised by the Competent Authority or licensed by the Minister for administration to food producing animals.

(3) Where a registered veterinary surgeon administers or prescribes an animal remedy in accordance with paragraph (1) for administration to food producing animals such registered veterinary surgeon shall specify an appropriate withdrawal period so as to ensure that food produced from the treated animal does not contain residues which may be harmful for consumers of produce derived from treated animals.

(4) Where an animal remedy or medical preparation administered or prescribed in accordance with paragraph (1) does not indicate a withdrawal period for the species to be treated, the following withdrawal periods shall be mandatory unless a longer withdrawal period is specified in accordance with paragraph (3):—

-eggs from treated animals- 7 days-milk from treated animals- 7 days-meat, including fat & offal from poultry and mammals- 28 days-meat from fish- 500 degree days.

(5) Where a registered veterinary surgeon administers or prescribes

an animal remedy in accordance with paragraph (1) a record shall be kept detailing
(a) date of examination of animals,
(b) identification of animals,
(c) number of animals treated,
(d) name and address of owner or person in charge of the animals,
(e) diagnosis,
(f) details of the animal remedy or medicinal product administered or prescribed and reasons for such choice,
(g) the dosage administered or prescribed,
(h) the duration of treatment,
(i) the withdrawal period, if any, specified.
(6) The records specified in paragraph (5) shall be maintained for three years and be furnished on request for examination by an authorised officer.
(7) This Regulation applies to the treatment of an individual animal or a small number of animals on a particular holding or premises and shall not be construed so as to provide for the general manufacture, sale, supply or use as an animal remedy of a medical preparation or an animal remedy to which subparagraph (1)(b) or subparagraph (1)(c) applies.
(8) A registered veterinary surgeon who prescribes, sells or supplies an animal remedy under this Regulation (or a pharmacist who sells or supplies an animal remedy in accordance with the prescription of a registered veterinary surgeon) shall label the animal remedy with a notice in the form prescribed and containing the information specified by Regulation 33 (3).
(9) This Regulation shall not apply to the administration of an animal remedy to an animal or class of animal where the administration of such animal remedy to such animal or class of animal is specifically prohibited by the animal remedies authorisation or where the animal remedy consists of, or contains, a substance the administration of which to such an animal or class of animal is prohibited by the law of the State or any provision of Community Law.
(10) An animal remedy administered in accordance with, and for the purposes provided for by, this Regulation, shall for the purposes of such administration be deemed to be an authorised animal remedy.

REG 41

41 CLINICAL TRIALS
41. (1) Tests and trials of animal remedies for the purposes of Article 5.10 of the Council Directive shall not be performed other than under and in accordance with a license, granted by the Minister (referred to subsequently in this Regulation as "a license") under this Regulation and by persons authorised, at such premises and on such animals as may be specified, in that behalf by the license.
(2) A person engaged in scientific research or analysis may not administer an animal remedy, other than an authorised animal remedy in accordance with the provisions of the product authorisation, to an animal for the purpose of scientific research or analysis save under and in accordance with a license (referred to in this Regulation as "a license") under this Regulation.

(3) Subject to the subsequent provisions of this Regulation, on application to the Minister in that behalf by or on behalf of any person , the Minister may, after consultation with the Competent Authority, if he or she is satisfied that the person is qualified and competent to perform on animal remedies the tests, trials, scientific research or analysis aforesaid, grant a license to the person authorising the performance by the person, for the purposes of the said Council Directive or scientific research or analysis, of the said tests, trials, research or analysis on the animal remedy specified in the license.
(4) The Minister may, if he or she thinks it appropriate to do so for the purpose of ensuring compliance with these Regulations and the law of the State and having regard to the provisions of this Regulation, attach conditions to a license at the time of the grant of the license or subsequently and may amend or revoke a condition attached to a license.
(5) The Minister shall refuse to grant a license to a person and shall revoke a license held by a person if the person has been convicted of or committed, (whether or not he or she has been convicted), an offence under the Act or Regulations made or deemed to have been made thereunder, or is for other reasons (including conviction of another offence) not, in the opinion of the Minister, a fit and proper person to hold a license.
(6) From 1 January, 1997, no produce derived from animals which have been treated in the course of a test, trial or research to which this Regulation applies may be used for human consumption unless a Maximum Residue Limit has been established for the active ingredient concerned in accordance with the provisions of Council Regulation (EEC) No 2377/90, and the Minister is satisfied that an appropriate withdrawal period has been established to ensure that this maximum residue limit will not be exceeded in the produce.
(7) Notwithstanding Regulation 39, 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 license under this Regulation relates under and in accordance with such license.

REG 42

42 WITHDRAWAL PERIODS
42. (1) Where an animal remedy is administered to an animal or animals whose meat, offal or products, including milk, eggs and honey, are intended for human consumption, the owner or person in charge of the animal or animals concerned shall ensure that the treated animal or animals are 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 the produce obtained from such a treated animal before the end of such a withdrawal period is not disposed of with a view to their being offered for human consumption.
(2) (a) A person who administers an animal remedy in respect of which a withdrawal period must be observed, prior to the slaughter of or the taking of produce from that animal for the purpose of human consumption, shall enter, on each occasion when such an animal remedy is administered or otherwise used in relation to that animal, in a book kept solely, in chronological order, for that purpose by

the owner, or person in charge of the animal, and to be known as the "Animal Remedies Record" the particulars contained in the form set out in the Sixth Schedule.
(b) Notwithstanding that an animal remedy in respect of which a withdrawal period must be observed may have been administered to an animal by a person other than the owner or person in charge, such owner or person in charge shall be responsible for maintaining the Animal Remedies Record.
(3) An owner or person in charge of a food producing animal to which a prescription only animal remedy has been administered shall keep, for a period of three years, a copy of each prescription issued by a registered surgeon for the supply and use of such an animal remedy administered to animals under his or her control and make such copies and the records prescribed in paragraph (2) available for inspection on request by an authorised officer.
(4) Where an animal remedy to which this Regulation applies is administered by a registered veterinary surgeon the registered veterinary surgeon concerned shall give to the person referred to in paragraph (1) sufficient information to enable that person to comply with the provisions of paragraphs (1) and (2).

PART VI

VETERINARY MEDICINE AND SURGERY

REG 43

43 CROSS BORDER PRACTICE BY VETERINARY SURGEONS
43. (1) A veterinary surgeon established in another Member State of the European Union, who possesses a qualification mentioned in Council Directive 78/1026/EEC15, in the course of providing cross border veterinary services within the State in accordance with the provisions of the aforementioned Directive may, subject to the subsequent provisions of this Regulation, import and administer small quantities of proprietary animal remedies in respect of which there is not for the time being in force a veterinary product authorisation.
15 O.J. No. L 362 of 23.12.78 p.1
(2) Paragraph (1) shall only apply in respect of an animal remedy —
(a) which is authorised in accordance with the provisions of Council Directive 81/85 1/EEC in the Member State where the veterinary surgeon is established, and
(b) which is brought into the State and supplied in the original manufacturer's packaging, and
(c) in the case of an animal remedy intended for administration to a food producing animal the animal remedy has the same qualitative and quantitative composition in terms of active ingredients as one authorised for such purposes within the State.
(3) A veterinary surgeon administering an animal remedy in accordance with the provisions of this Regulation shall ensure that the owner or person in charge of the treated animal is made fully aware of any withdrawal period which must elapse before the taking of produce from such animal for human consumption.

(4) A veterinary surgeon selling or supplying an animal remedy in accordance with the provisions of this Regulation shall sell or supply the owner or person in charge of the animal or animals to be treated with such quantity of the animal remedy, as is necessary to complete the treatment of the animal or animals concerned having regard the condition to which the service relates and, in any event, no more than 31 days supply, and any animal remedy so supplied must, where applicable, be labelled with an appropriate withdrawal period.
(5) A veterinary surgeon to whom this Regulation applies may only administer, sell or supply an animal remedy in respect of animals under his or her care and concerning which he or she has been consulted in a professional capacity.
(6) For the purposes of this Regulation a veterinary surgeon may only carry such range and quantity of animal remedies to which this Regulation applies as is generally required for the daily needs of good veterinary practice.
(7) A veterinary surgeon to which this Regulation applies shall keep records of the following
(a) identity of the animal or animals treated,
(b) date of examination of the animal or animals,
(c) number of animals treated,
(d) name and address of the owner or person in charge of the animal or animals,
(f) diagnosis,
(g) details of the animal remedies administered, sold or supplied ,
(h) the dosage administered, sold or supplied,
(i) the duration of treatment, and
(j) the withdrawal period, if any, specified
(8) The records specified in paragraph (7) shall be maintained for three years and furnished on request for examination by an authorised officer
(9) An animal remedy administered, sold, supplied or held in possession in accordance with this Regulation, shall for the purposes of such administration, sale, supply or possession be deemed to be an authorised animal remedy.

REG 44

44 ANIMALS UNDER THE CARE OF A VETERINARY SURGEON
44. (1) Without prejudice to Regulation 45 and Regulation 46 an animal, or, as the case may be, herd or flock, is deemed to be under the care of a registered veterinary surgeon and he or she is deemed to have been consulted in a professional capacity regarding the care of such animal, herd or flock where —
(a) the registered veterinary surgeon, or as the case may be, another member of the group veterinary practice of which he or she is a member, has been consulted in a professional capacity and has been given responsibility for the professional care of the animal, herd or flock by the owner or person in charge of such animal, herd or flock, and
(b) the registered veterinary surgeon has sufficient knowledge of the animal, herd or flock to initiate at least a general or preliminary diagnosis of the medical condition of the animal and, for this purpose, he or she or another member of the group veterinary

practice, must have visited the farm or other premises on which the animal, herd or flock is kept sufficiently often and recently enough to have acquired an accurate picture of the current health, welfare and disease status of the animals on that farm or premises, and
(c) the registered veterinary surgeon (or other member of the group veterinary practice of which he or she is a member) is available to respond to requests to provide such services of veterinary medicine and surgery .and clinical procedures on the animal or in the herd or flock as are in accordance with ethical veterinary practice, and
(d) the registered veterinary surgeon 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 surgeon or group veterinary practice make evident that the professional responsibility for the animal, herd or flock in question is real and not merely nominal.

REG 45

45 PRESCRIPTION FOR ANIMAL REMEDIES
45. (1) This Regulation applies to the issue of a prescription for an animal remedy by a registered veterinary surgeon to a person.
(2) Without prejudice to Regulation 46 a registered veterinary surgeon shall not issue a prescription for an animal remedy unless —
(a) the animal or animals to which the prescription relates are under his or her professional care, and concerning which he or she has been consulted in a professional capacity, in accordance with Regulation 44, and
(b) he or she is satisfied that the prescription will be used (by the person to whom the prescription is issued) for such animal or animals, and
(c) (i) in the case of an initial prescription for the treatment of a particular condition in an animal, he or she has clinically examined the animal or animals in question for the purpose of diagnosis immediately prior to the issue of a prescription, or
(ii) where, following consultation with the owner or person in charge of an animal he or she is satisfied that the condition to be treated is the same disease episode, in cohort animals in the same herd or flock on the same farm or premises, as that to which a clinical examination of an animal in accordance with subparagraph (i) has taken place within the preceding 7 days, or
(iii) in the case of a repeat prescription, following consultation with the owner or person in charge of the animal to be treated where prior clinical examination has not taken place, at the professional discretion, and on the basis, of the registered veterinary surgeon's own knowledge of the health status of the animal and information obtained from the owner or person in charge of the animal provided a clinical examination in accordance with subparagraph (i) has taken place within the preceding 15 days, or
(iv) in the case of a repeat prescription for the treatment of a chronic disease or injury in an individual animal following consultation with the owner or person in charge provided the registered veterinary surgeon clinically examines the animal at least

every 90 days for the purpose of checking the condition of the animal, the efficacy of treatment, the necessity for further treatment and any evidence of adverse drug reaction, or

(v) where for the purpose of assisting in making a diagnosis the registered veterinary surgeon carried out or caused to have carried out tests or analyses on the animal or cohort animal, or samples taken from the animal or cohort animals in question and on receipt of the results of such test or analysis the registered veterinary surgeon considers that treatment with a different animal remedy is appropriate.

(4) A registered veterinary surgeon prior to issuing a prescription for an animal remedy, shall be satisfied that —

(a) the use of the animal remedy to be prescribed is justified for the species concerned,

(b) administration of the animal remedy to be prescribed is, to the best of his or her knowledge and belief not incompatible with a previous treatment, and

(c) there is no contra-indication or adverse interaction where other animal remedies have been, or, are to be administered or prescribed.

(5) A registered veterinary surgeon may prescribe an animal remedy only in such quantity as is necessary for the treatment of the condition in respect of which the animal remedy is prescribed subject, in the case of food producing animals, to a maximum quantity of 31 days supply.

(6) A prescription to which this Regulation applies shall be in writing and shall contain at least the following particulars —

(a) the name of the animal remedy to be administered;

(b) the manner and site of administration;

(c) the dose rate and withdrawal period to be observed, if applicable;

(d) a description of the animal or animals to which the prescription relates:

(e) the person or class of persons by whom the animal remedy is to be administered;

(f) the name and address of the person to whom the prescription has been granted',

(g) the name, address and signature of the veterinary surgeon granting the prescription:

(h) the period during which, and the number of administrations for which, the prescription is valid; and

(i) a declaration that the prescription is granted in respect of an animal or animals under his or her professional care.

(7) (a) A veterinary prescription shall be issued in triplicate. The original and one copy shall be given to the owner or person in charge of the animal or animals to be treated and a copy shall be retained by the registered veterinary surgeon.

(b) Copies of veterinary prescriptions are to be retained for 3 years by the registered veterinary surgeon and are to be made available for inspection on request by an authorised officer.

(8) A veterinary prescription shall be written in ink so as to be indelible and signed in ink by, and bear, in block capital letters the name and address of the issuing registered veterinary surgeon.

(9) In this Regulation "prescription" includes the supply of an animal remedy which by virtue of the animal remedies authorisation

or the Law of the State is designated "prescription only" and the administration to an animal of an animal remedy which is designated "veterinary surgeon use only".
(10) (a) This paragraph applies to an animal remedy for a food producing animal.
(b) A veterinary surgeon who, in accordance with this Regulation, supplies or administers an animal remedy shall, in lieu of issuing a prescription, enter in the Animal Remedies Record prescribed by Regulation 42 (2) the relevant details of such administration or supply and shall endorse such entry by his or her personal signature.
(11) This Regulation is in addition to the requirements of Regulations 38, 40 and 42.

REG 46

46 PRESCRIPTION FOR ANIMALS IN INTENSIVE PRODUCTION SYSTEM
46. (1) Notwithstanding Regulation 45 (2) this Regulation applies to the issue of a prescription for an animal remedy for the treatment of disease associated with the intensive production of pigs, poultry and fish where such pigs, poultry or fish are reared in intensive units or under other intensive systems and where a herd or flock health scheme is in operation in respect of such system.
(2) For the purpose of issuing a prescription for an animal remedy for an animal to which this Regulation applies the registered veterinary surgeon shall have been given responsibility for the overall herd or flock health scheme by the owner or person in charge of the animal and such registered veterinary surgeon shall,
(a) have either seen the animal or herd or flock for the purpose of making a diagnosis immediately prior to initiating the treatment or supplying the animal remedy for such treatment, or
(b) have carried out tests, or have had recourse to the results of tests or analyses carried out on samples taken from the animal or a representative animal from the herd or flock in question, and
(c) have visited the farm or other premises in which the animal or herd or flock are located within the preceding 60 days, and to have acquired from first hand personal knowledge, and, as necessary, recourse to results of laboratory tests or analyses, an accurate picture of the health and welfare status of animals on that farm or premises, and following consultation with the owner or person in charge of the animal sufficient information to make a diagnosis and prescribe or supply appropriate treatment, and
(d) shall, save where otherwise provided for by this Regulation, comply with the provisions of Regulation 45 in respect of such supply.
(3) In this Regulation
"intensive unit" means a building or structure in which animals are kept under a husbandry system relying, for the purpose of providing care for the animals, on automatic equipment to such extent that a failure of that equipment would, if it were not rectified or if some other suitable provision were not made for the care of the animals, cause the animals unnecessary suffering.
"intensive system" means a husbandry method in which animals are kept in such numbers or density or in such conditions or at such production levels that their health and welfare depend upon frequent

human attention and includes an intensive unit.
"herd or flock health scheme" means a documented and recorded programme agreed between a registered veterinary surgeon and the owner or person in charge of an intensive system for the purpose of the identification, monitoring and reduction of animal disease and welfare problems, the elimination of zoonoses, and the ensuring of quality livestock production, effected in a manner that reduces unnecessary reliance on animal remedies.

REG 47

47 SCHEMES FOR THE ERADICATION AND CONTROL OF ANIMAL DISEASES
47. (1) This Regulation applies to the administration of an animal remedy to an animal, for the purpose, or in the course, of an official or voluntary scheme or programme operated by, or on behalf of, the Minister, for the treatment, control, eradication, monitoring, or surveillance of disease in animals or for the determination of the health or disease status of animals.
(2) The provisions of these Regulations regarding animals under the care of a registered veterinary surgeon shall not apply to the administration of an animal remedy to an animal for the purposes set out in paragraph 1, where the administration is carried out by—
(a) a registered veterinary surgeon, or
(b) other person,
where such registered veterinary surgeon or other person is for such purpose authorised by, or acting on behalf of, the Minister.
(3) In this Regulation "disease" has the same meaning as in the Diseases of Animals Act, 1966 (No. 6 of 1966).

PART VII

MISCELLANEOUS

REG 48

48 ADAPTATION OF CERTAIN ENACTMENTS
48. (1) (a) This Regulation applies to the following provisions, namely
(i) the Food Hygiene Regulations, 1950 (S.I. No. 205 of 1950),
(ii) the Agricultural Produce (Fresh Meat) Acts, 1930 to 1988, and Regulations thereunder,
(iii) the Abattoirs Act, 1988 (No. 8 of 1988), and Regulations thereunder,
(iv) the Slaughter of Cattle and Sheep Acts, 1934 to 1936,
(v) orders under the Agricultural and Fishery Products (Regulation of Export) Act, 1947 (No. 18 of 1947),
(vi) the Pigs and Bacon Acts, 1935 to 1988, and Regulations thereunder.
(vii) the European Communities (Fresh Poultry Meat) Regulations, 1996 (S.I. No. 3 of 1996), and
(viii) the European Communities (Hygienic production and placing on the market of raw milk, heat treated milk and milk-based products) Regulations, 1996 (S.I. No. 9 of 1996).
(b) A food producing animal to which an animal remedy, which is

not an authorised animal remedy, has been administered and any meat or meat product derived from such animal shall, for the purposes of the provisions to which this paragraph applies, be deemed to be unfit for human consumption.
(2) Meat or a meat product, milk or a milk product, or as the case may be egg or an egg product 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 shall, be deemed to be unfit for human consumption.

REG 49

49 AUTHORISED OFFICERS
49. Without prejudice to the powers of an authorised officer appointed pursuant to the Act, the Minister may appoint such persons
(1) nominated by the Competent Authority to be authorised officers for the purposes of enforcing the provisions of these Regulations in relation to any function conferred on, or, duly exercisable by, the Competent Authority under these Regulations, or
(2) nominated by the Pharmaceutical Society of Ireland to be authorised officers for the purpose of enforcing the provisions of these Regulations in relation to a person and the premises of a person keeping shop for the dispensing and compounding of medical preparations or for the sale of poisons in accordance with the Pharmacy Acts, 1875 to 1977,
which persons may, at all reasonable times, exercise such and so many of the powers conferred on an authorised officer by section 11 of the Act as he or she may deem appropriate.

REG 50

50 PUBLICATION OF CERTAIN DECISIONS
50. (1) Where the Competent Authority grants or revokes a veterinary product authorisation, notice of such grant or revocation shall be published in Iris Oifigiúil.
(2) (a) Notwithstanding paragraph (1), the Competent Authority, may at the request of the holder of a veterinary product authorisation, defer publication of the notice required by that paragraph where it is not proposed to sell or supply the animal remedy.
(b) Where the Competent Authority accedes to a request under this paragraph, the animal remedy to which the request relates shall not be sold or supplied until the publication of the notice required by paragraph (1).

REG 51

51 INFORMATION TO BE FURNISHED TO THE COMMITTEE FOR VETERINARY MEDICINAL PRODUCTS
51. (1) The Competent Authority shall, through the Agency, inform the Committee for Veterinary Medicinal Products immediately of each decision to grant a veterinary product authorisation and of each

decision refusing, varying, suspending or revoking a veterinary product authorisation, or of prohibiting the sale or supply, or the recall of an animal remedy already sold or supplied together with the reasons on which such decisions are based.
(2) The Competent Authority shall inform the Agency of any notification received pursuant to Regulation 18(7) if it concerns the efficacy or safety (including the protection of public health) of the animal remedy concerned.
(3) The Competent Authority shall ensure that appropriate information about actions taken pursuant to paragraph (1), or, Regulation 18(5) which may affect the protection of health in third countries is forthwith brought to the attention of the relevant international organisations and a copy of any such notification shall be furnished to the Agency.

REG 52

52 Fees
52. An application for an animal remedies authorisation, licence or registration under these Regulations shall not be considered valid or processed unless the application is accompanied by the appropriate fee.

REG 53

53 PROVISIONS RELATING TO FORGERY ETC.
53. (1) A person shall not forge, or utter a document knowing it to be forged, purporting to be —
(a) a prescription granted under these Regulations by a registered veterinary surgeon, or
(b) an animal remedies authorisation, or
(c) a licence, or
(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 prescription issued under these Regulations by a registered veterinary surgeon, or
(b) an animal remedies authorisation, or
(c) a licence, or
(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 falsely endorsed document or an altered document knowing it to be such.

(5) A person shall not have in his or her possession a forged document, a falsely endorsed document or an altered document.
(6) Paragraph (5) of this Regulation shall not apply in relation to any of the following persons —
(a) a member of the Garda Síochána when acting in the course of his or her duty as such;
(b) an authorised officer for the purposes of executing and enforcing these Regulations:
(c) an officer of the Competent Authority for the purposes of executing and enforcing these Regulations;
(d) a person who has taken into his or her possession such document for the purpose of —
(i) preventing another from committing or continuing to commit an offence under the Act, or
(ii) delivering it into the custody of a person specified in paragraph (a), (b) or (c) of this sub-paragraph.

REG 54

54 LICENCES AND REGISTRATIONS
54. (1) An application to the Minister for a licene or registration under a specified Regulation shall be made in such form and contain such information as the Minister may specify.
(2) An application may be refused if, in relation to the application, information required has not been furnished or information that is, in the opinion of the Minister, false or misleading in a material particular has been furnished.
(3) The Minister may refuse an application for a licence or registration under a specified Regulation or may revoke a licence or registration held by a person if the applicant or person has been convicted of, or committed, an offence, whether he or she has been convicted or not, under the Act or Regulations deemed to have been made thereunder, or for any other conviction, or failure to comply with the conditions attached to a previous licence or animal remedies authorisation, or, is not, in the opinion of the Minister, a fit and proper person to hold a licence;
(4) The Minister shall refuse an application for a licence or registration under a specified Regulation and shall revoke a licence or registration held by a person if the applicant or person has been convicted, on indictment, of an offence under the Act or regulations made or deemed to have been made thereunder.
(5) (a) Where the Minister proposes to refuse an application or to revoke a licence or registration under a specified Regulation or to attach a condition to, or amend or revoke a condition attached to, such a licence or registration, he or she shall notify in writing the person who made the application for or, holds the licence or registration of the proposal and the reasons for it.
(b) A person who has been notified of a proposal under subparagraph (a) may, within 21 days of the receipt of the notification, make representations in writing to the Minister and the Minister shall —
(i) before deciding the matter, take into consideration any representation duly made in relation to the proposal, and
(ii) notify the person in writing of his or her decision and the reasons therefor.

(c) A notification under subparagraph (a) shall include a statement that the person concerned may make representations to the Minister within 21 days of the receipt by him of the notification.
(6) In this Regulation "a specified Regulation" means either Regulation 3 or Regulation 30 or Regulation 31 or Regulation 32.

REG 55

55 REGISTER
55. (1) The Minister shall establish and maintain a register of licences and registrations granted by him for the purposes of these Regulations, ('the Register').
(2) There shall be entered in the Register —
(a) the full name, address and description of the holder of the licence or registration,
(b) an exact description of the location and, if relevant, the limits and extent of the premises and activity to which the licence or registration relates,
(c) the date on which the licence or registration was granted and the expiry date thereof,
(d) such particulars as the Minister may, from time to time, direct of an animal remedy or substance to which the licence or registration relates, and
(e) such other particulars as the Minister may, from time to time, direct.
(3) Whenever a licence or registration to which this Regulation applies is altered or revoked, there shall be entered in the Register such particulars of the alteration or revocation, as the case may be, as the Minister may, from time to time, direct.
(4) A certificate purporting to be under the hand of an officer, authorised by the Minister in that behalf, that the name of the person, premises or animal remedy specified in the certificate is not entered in the register shall, until the contrary is proved, be evidence of the matters so certified and it shall not be necessary to prove the signature of such officer, or that he or she was such an officer, or that he or she was in fact so authorised.
(5) Where in proceedings for an offence under these Regulations there is produced a certificate which —
(1) (a) purports to be signed by the Secretary of the competent authority for that purpose, and
(b) states that the certificate is given for the purposes of these Regulations, and
(c) certifies that in the case of a particular substance or person, a manufacturer's licence or veterinary product authorisation, as the case may be has not been granted by the competent authority.
or
(2) (a) purports to be signed by a person authorised by the Minister for that purpose, and
(b) states that the certificate is given for the purposes of these Regulations, and
(c) certifies that in the case of a particular substance or person
(i) a manufacturer's licence, or
(ii) an animal remedies wholesaler's licence, or

(iii) an animal remedies merchants licence, or
(iv) companion animal remedies licence, or
(v) an animal remedies authorisation, or
(vi) any other licence required by these Regulations, or
(vii) registration required by these Regulations.
has not been granted by the Minister, then such certificate shall, without proof of the signature of the person purporting to sign it, or, in case the certificate purports to be signed by a person appointed by the competent authority or authorised by the Minister, proof that at time at which the certificate purports to have been given, such person stood so appointed or authorised, be evidence for all purposes that such license, authorisation or registration was not granted unless the defendant requires the person who issued the certificate to be called as a witness.

REG 56

56 LICENSES NON-TRANSFERRABLE
56. (1) The holder of a licence granted under these Regulations shall not transfer the licence to any other person and any such purported transfer shall be void and of no effect.
(2) A licence granted under these Regulations shall have no effect if the holder of the licence —
(a) ceases trading or operation, or
(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, on dissolution, or
(c) sells or otherwise ceases to occupy the premises to which the licence relates.

REG 57

57 PROSECUTIONS
57. In a prosecution for an offence under these Regulations in relation to an animal remedy which is also an additive, premixture or feedingstuff within the meaning, in each case, of the European Communities (Additives in Feedingstuffs) Regulations, 1989 and 1991, it shall be a good defence to show —
(a) that either —
(i) where the animal remedy is such an additive, it is an additive specified in the First or Second Schedule to the European Communities (Additives in Feedingstuffs) Regulations, 1979 (S.I. No. 49 of 1989), as amended by the European Communities (Additives in Feedingstuffs) (Amendment) Regulations, 1991 (S.I. No. 124 of 1991), or it is a medicinal additive manufactured or imported in pursuance of an additive licence under those Regulations,
or,
(ii) where the animal remedy is such a premixture or feedingstuff, it contains an additive that complies with subparagraph (i) of this paragraph,
and
(b) that the European Communities (Additives in Feedingstuffs) Regulations, 1989 to 1993, were complied with in relation to the additive.

REG 58

58 IMPORT OF ANIMALS
58. (1) This Regulation applies to an animal which is lawfully imported into the State and to which
(a) an animal remedy was administered prior to such import, and
(b) the animal remedy was administered in accordance with the law of the State where such 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 to which the animal belongs is prohibited pursuant to Community law or the Law of the State.
(2) An animal to which paragraph (1) relates shall, in respect of such administration, be deemed to have been treated with an authorised animal remedy.

REG 59

59 RECORD KEEPING
59. Where a record required by these Regulations or a registration or a licence or animal remedies authorisation is maintained in machine readable form, the person responsible for maintaining such record shall, in respect of each day's transactions, make a hard copy of the record and attest to the accuracy of such copy by his or her signature and retain such copy for the period specified in these Regulations or such registration or licence or animal remedies authorisation aforesaid and make it available on request to an authorised officer.

REG 60

60 SERVICE OF NOTICE
60. (1) Subject to paragraph (2), a notification or notice under these Regulations shall be served on the person to be affected thereby, either by delivering it to him or her personally or by leaving it addressed to the person to be affected at his or her last known place of business or abode or by sending it through the post in a prepaid envelope addressed to the person there.
(2) Service of a notification or notice, in the manner prescribed in paragraph (1), on a person's legal representative shall be deemed to be service on that person.
(3) This Regulation shall apply to service of a notification or notice by, or on behalf of, the competent authority and service of a notification or notice by, or on behalf of, the Minister.

REG 61

61 REPEALS AND CONTINUANCE OF CERTAIN DOCUMENTS
61. (1) Subject to the subsequent provisions of this Regulation, these Regulations are in addition to and not in substitution for
(a) the Poisons Regulations, 1982 to 1986,
(b) the European Communities (Control of Veterinary Medicinal Products and Their Residues) Regulations, 1988 and 1990, and
(c) the European Communities (Animal Remedies and Medicated Feedingstuffs) Regulations, 1994 (S.I. No. 176 of 1994)

(2) (a) The following Regulations are hereby revoked
(i) the Animal Remedies (Registration of Manufacturers, Importers and Wholesalers) Regulations, 1980 (S.I. No. 115 of 1980);
(ii) the Poisons (Control of Residues in Food of Animal Origin) Regulations, 1985 and 1986;
(iii) the Animal Remedies (Control of Sale) Regulations, 1985 and 1986;
(iv) the European Communities (Veterinary Medicinal Products) Regulations, 1986 (S.I. No. 22 of 1986);
(v) Regulations 5 and 7 of the European Communities (Control of Veterinary Medicinal Products and Their Residues) Regulations, 1990 (S.I. No. 171 of 1990); and,
(vi) the Animal Remedies (Prohibition of Certain Sales) Regulations, 1991 (S.I. No. 244 of 1991).
(b) A veterinary product authorisation or a licence granted by the Competent Authority and in force immediately before the revocation of the aforementioned European Communities (Veterinary Medicinal Products) Regulations, 1986, shall continue in force upon such revocation as if granted under these Regulations.
(c) All licences granted by the Minister and in force immediately before the revocation of the aforementioned Regulations 5 and 7 of the European Communities (Control of Veterinary Medicinal Products and Their Residues) Regulations, 1990 shall continue in force upon such revocation as if granted under these Regulations.
(d) All licences granted by the Minister and in force immediately before the revocation of the aforementioned Animal Remedies (Prohibition of Certain Sales) Regulations, 1991 shall continue in force upon such revocation as if granted under these Regulations.
(4) Nothing in these Regulations shall be construed as affecting any provision of the European Communities (Additives in Feedingstuffs) Regulations, 1989 to 1993.
(5) An animal remedy which would but for the making of these Regulations be a therapeutic substance to which the Therapeutic Substances Act, 1932 applies, shall no longer be a therapeutic substance to which the said Therapeutic Substances Act, 1932 applies.

FIRST SCHEDULE

A label insert for an animal remedy shall contain at least the following

PART I

The following information, which shall conform with the particulars and documents provided pursuant to Article 5 of the Council Directive and be approved by the Competent Authorities, shall appear in legible characters on containers and outer packages of animal remedies.

1. Name of the animal remedy which may be a brand name accompanied by a trade mark or the name of the manufacturer, or a scientific name or formula, with or without a trade mark, or the name of the manufacturer.

Where the special name of an animal remedy containing only one active ingredient is a brand name, this name must be accompanied in legible characters by the international non-propriety name recommended by the World Health Organisation, where such name exists, or where no such name exists, by the usual non-proprietary name.

2. A statement of the active ingredients expressed qualitatively and quantitatively per dosage unit or according to the form of

administration for a particular volume or weight, using the international non-proprietary names recommended by the World Health Organisation, where such names exist or, where no such names exist, the usual non-proprietary names'.
3. reference number for production identification (manufacturer's batch number);
4. veterinary product authorisation, or, where applicable, marketing authorisation number;
5. name or corporate name and permanent address or registered place of business of the person responsible for marketing and of the manufacturer, if different;
6. the species of animal for which the animal remedy is intended; the method and route of administration;
7. The withdrawal period, even if nil, in the case of animal remedies administered to food-producing animals.
8. Expiry date, in plain language'.
9. special storage precautions, if any;
10. Special precautions for disposal of unused product or waste material, if any.
11. particulars required to be indicated pursuant to the first paragraph of Article 12 of the Council Directive if any;
12. the words 'For animal treatment only'.
The pharmaceutical form and the contents by weight, volume or number of dose-units need only be shown on the outer package.
The provisions of Part 2 A of the Annex to Commission Directive 92/18/EEC, in so far as they concern the qualitative and quantitative composition of veterinary medicinal products in respect of active ingredients, shall apply to the particulars provided for in point 2.
PART II
1. As regards ampoules, the particulars listed in Part I shall be given on the outer package. On the containers, however, only the following particulars shall be necessary:
— name of the animal remedy,
— quantity of the active ingredients,
— route of administration,
— reference number for production identification (manufacturer's batch number),
— date of expiry,
— the words 'For animal treatment only'.
2. As regards small single-dose containers, other than ampoules, on which it is impossible to give the particulars mentioned in Part I, those requirements shall apply only to the outer package and the container shall be labelled in a manner which satisfies the competent authority that its contents can be clearly and easily identified.
3. Where there is no outer package, all the particulars which should feature on such package pursuant to Part I shall be shown on the container.
4. The particulars mentioned in points 6, 7, 8, 9, 11 and 12 of Part I and the third and sixth indents of paragraph 1 of Part II shall appear on the outer package or container in the English or Irish Language.
PART III
The inclusion of a package insert in the packaging of an animal

remedy shall be obligatory unless all the information required by this part can be conveyed on the container and the external packaging. Information on the insert shall solely relate to the animal remedy with which it is included. The insert shall be in the English or Irish language and shall include at least the following information and conform with the particulars and documents provided in accordance with the application for the product authorisation.

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

(b) name of the animal remedy and a statement of its active ingredients expressed qualitatively and quantitatively.
The international non-proprietary names recommended by the World Health Organisation shall be used wherever they exist;

(c) the main therapeutic indications, contra-indications and side-effects in so far as these particulars are necessary for the use of the animal remedy;

(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 animal remedies administered to food-producing animals;

(f) special storage precautions, if any;

(g) particulars required to be indicated pursuant to the first paragraph of Article 12 of the Council Directive, if any.

(h) special precautions for the disposal of unused product or waste materials, if any.

Part IV

1. An animal remedy designated for veterinary surgeon use only may be designated by the following symbol:
VSO

2. An animal remedy designated for prescription only sale may be designated by the following symbol:
POM

3. An animal remedy designated for prescription only exempt sale may be designated by the following symbol:
POM (E)

4. An animal remedy designated for pharmacy only sale may be designated by the following symbol:
PS

5. An animal remedy designated for sale by a licensed merchant may be designated by the following symbol:
LM

6. An animal remedy designated for sale by a companion animal medicines seller may be designated by the following symbol:
CAM

SECOND SCHEDULE

PART I

Substances with oestrogenic, androgenic or gestagenic action within the meaning of Council Directive 81/602/EEC of the 31st July 198116 (which relates to the prohibition of certain substances having a hormonal action and of any substance having a thyrostatic action) or any enactment amending or replacing the said Council Directive and in particular the following substances their esters and derivatives—

Oestradiol 17B
Progesterone
Testosterone
Trenbolone and its acetate
Zeranol
PART II
1. Antibiotic substances generally and in particular the following substances, their salts, esters and derivatives, salts of their esters and salts of their derivatives:—
16 O.J. L.222 of 7.8.81
Actinomycins
Amikacin
Aminoglycocides (other than those specifically set out in this Part)
Amoxycillin
Amphomycin
Amphotericins
Ampicillin
Apramycin
Avoparcin
Azidamfenciol
Bacitracin
Bambermycin
Benzylpencillin
Bleomycin
Candicidin
Capreomycin
Carbenicillin
Cefaclor
Cefamandole
Cefoxitin
Cefuroxime
Cephacetrile
Cephalexin
Cephalonium
Cephalosporins (other than those specifically set out in this Part)
Cephaloridine
Cepalothin
Cephamycins (other than those specifically set out in this Part)
Cephapirin
Cephazolin
Cephoxazole
Cephradine
Chloramphenicol
Chlortetracyllines
Ciclacillin
Clavulanic Acid
Clindamycin
Clomocycline
Cloxacillin
Colistin
Cycloserine
Daunorubicin
Demeclocycline
Dicloxacillin
Dihydrostreptomycin

Dimethylchlortetracycline
Doxorubicin
Doxycycline
Epicilline
Erythromycin esters
Erythromycin
Flucloxacillin
Framycetin
Fumagillin
Fusafungine
Fusidic Acid
Gentamicins
Gramacidin
Griseofulvin
Hachimycin
Kanamycin
Lincomycins
Macrolide antibiotics (other than those specifically set out in this Part)
Mecillinam
Methacycline
Minocycline
Mithramycin
Mitomycins
Nafcillin
Natamycin
Neomycin
Novobiocin
Nystatin
Oleandomycin
Oxacillin
Oxytetracycline
Paromomycin
Penethamate
Penicillins (other than those specifically set out in this Part)
Pivampicillin
Pivmicillinam
Polymyxins
Polymyixin B
Procaine Benzyl penicillin
Rifamycins
Ristocetins
Spectinomycin
Talampicillin
Tetracyclines (other than those specifically set out in this Part)
Thiamphenicol
Tetracycline hydrochloride
Tiamulin
Tobramycin
Tylosin
Vancomycin
Viomycin
Virginiamycin

2. The following antibacterial substances and their salts:—

p - Aminobenzenesulphonamide and its derivatives (where such

derivatives have any of the hydrogen atoms of the p - amino group or of the sulphonamide group substituted by another radical) other than those specifically set out in this Part.
Carbadox
Dimetridazole
Dapsone
Furaltadone
Furazolidone
Metronidazole
Nitrofurantoin
Nitrofurazone
Nitroxoline
Olaquindox
Phtalylsulphacetamide
Phthalylsulphathiazole
Ronidazole
Succinylsulphathiazole
Sulfadoxine
Sulfametopyrazine
Sulfanitran
Sulfapyrazole
Sulfatroxazole
Sulphacetamide
Sulphachlorpyridazine
Sulphadiazine
Sulphadimethoxine
Sulphadimidine
Sulphaethidole
Sulphafurazole
Sulphaguanidine
Sulphaloxic acid
Sulphamerazine
Sulphamethizole
Sulphamethoxazole
Sulphamethoxydiazine
Sulphamethoxypyridazine
Sulphamopine
Sulphamoxole
Sulphanilamide
Sulphaphenazole
Sulphaproxyline
Sulphapyridine
Sulphaquinoxaline
Sulphasalazine
Sulphasamidine
Sulphasomizole
Sulphathiazole
Sulphormethoxine
Tinidazole
3. Corticosteroid substances generally and in particular the following substances and their esters:—
Alcometasone
Aldosterone
Beclometasone
Betamethasone

Clobetasol
Cortisone
Cortivasol
Deoxycorticosterone
Desonisde
Desoxymethasone
Dexamethasone
Diflucortolone
Fluclorolone acetonide
Fludrocortisone
Flumethasone
Flunisolide
Fluocinolone acetonide
Fluocinonide
Fluocortolone
Flurometholone
Fluperolone
Fluprednidine
Flurandrenolone
Formocortal
Halcinonide
Hydrocortisone
Isoflupredone acetate
Medrysone
Medprednisone
Methylprednisolone
Paramethasone
Prednisolone
Prednylidene
Triamcinolone
Triamcinolone acetonide
Triamcinolone hexacetonide
4. Prostaglandins generally and in particular the following substances and their salts,
Alfaprostol
Arbaprostil
Carboprost
Clopostenol
Delprostenate
Dinoprost
Fluprostenol
Gemeprost
Luprostiol
Prostalene
5. Beta-agonists generally and in particular the following and their salts:—
Cimaterol
Clenbuterol
Dobutamine
Fenoterol
Isoprenaline
Isoxuprine
Mabuterol
Prenalterol
Ractopamine

Ritodrine
Salbutamol
Terbutaline

THIRD SCHEDULE

QUALIFIED PERSON

A qualified person is a person who fulfils the following minimum conditions of qualification: —

(a) 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 Minister, 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:

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

—- where two university course or two courses recognised by the State in question as equivalent co-exist in a Member State of the European Union and where 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 in this sub-paragraph in so far 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.

The course shall include theoretical and practical study bearing upon at least the following basic subjects and shall be so balanced as to enable the person concerned to fulfil the obligations specified in paragraph 7(3) of the First Schedule

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 act ive principles of natural substances of plant and animal origin).

In so far as certain diplomas, certificates or other evidence of formal qualifications mentioned in the first paragraph do not fulfil the criteria laid down above the person concerned shall provide evidence to the Competent Authority of adequate knowledge of the subjects involved;

(b) practical experience for at least two years, in one or more undertakings which are authorised to manufacture medical preparations

or animal remedies, in the act ivities of qualitative analysis of medical preparations or animal remedies of quantitative analysis of active substances and of the testing and checking necessary to ensure the quality of medical preparations or animal remedies provided that the duration of practical experience may be reduced by one year where a university course lasts for at least five years and by a year and a half where the course lasts for at least six years.

(c) A person qualified by virtue of Article 32 of Council Directive 81/851/EEC

FOURTH SCHEDULE

GENERAL CONDITIONS SUBJECT TO WHICH MANUFACTURER'S LICENCES ARE GRANTED

1. The licence holder shall not, without the prior approval of the Competent Authority, manufacture an animal remedy other than one which has been specified in the application for a licence to the Competent Authority or which has subsequently been notified in writing to the Competent Authority and which has been specified in the licence either as such or as a class of animal remedy which may be manufactured by him or her.

2. The licence holder shall provide and maintain such premises, equipment and staff as are necessary for the carrying out, in accordance with their licence and any relevant product authorisation in force, of such stages of the manufacture of the animal remedy as are undertaken by the licence holder and the said holder shall not carry out any such manufacture except at the premises specified in the licence or such other premises as may be approved in writing from time to time by the Competent Authority.

3. The licence holder shall provide and maintain such premises, equipment facilities, and staff for the handling, storage and distribution of the animal remedies which he or she handles, stores or distributes under his or her licence as are necessary to avoid deterioration of such products and he or she shall not use for such purposes premises other than those specified in the licence or such other premises which may be approved in writing from time to time by the Competent Authority.

4. The licence holder shall conduct all manufacturing operations in such a way as to ensure that the animal remedies conform with the standards of strength, quality and purity applicable to them whether under the relevant product authorisations, or under any pharmacopoeial standard or other specification to which they may be manufactured. The licence holder shall conduct all manufacturing in accordance with the principles and guidelines of good manufacturing practice laid down by Commission Directive 91/412/EEC.

5. The licence holder shall either:—

(a) provide and maintain such premises, equipment, facilities and staff as are necessary for carrying out any tests of strength, quality or purity of the medical preparations that he or she manufactures as requires by the relevant product authorisation and in accordance with the requirements as laid down by Commission Directive 91/412/-EEC as may be specified by the Competent Authority, or

(b) make arrangements with a person approved in writing by the Competent Authority for such tests to be carried out on his or her behalf by that person.

6. The licence holder shall notify the Competent Authority in

writing before making any material alteration in the premises or equipment used under his or her licence, or in the operations in which they are used and he or she shall notify the Competent Authority in writing of any change that he or she proposes to make in any personnel named in his or her licence as respectively being:—

(a) responsible for the quality control of the animal remedies being manufactured including the person named as the qualified person for the purposes of paragraph 7 of this Part of this Schedule, or

(b) responsible for supervising the production operations, or

(c) responsible for biological or microbiological controls used in the manufacture or testing of the animal remedies being manufactured.

7. (1) If the licence holder is not a qualified person who as respects qualifications and experience satisfies the provisions of the Third Schedule to carry out the functions specified in paragraph (3) below, he or she shall at all times have at his or her disposal the services of such a person (hereinafter referred to as the qualified person).

(2) The licence holder shall at all times provide and maintain such staff, premises and facilities as will enable the qualified person to carry out the said functions.

(3) The functions to be carried out by the qualified person shall be as follows:

(a) to ensure that every batch of animal remedy to which the licence relates has been manufactured and checked in compliance with:—

(i) the laws in force in the State in respect of such animal remedy

(ii) the provisions of this manufacturer's licence, and

(iii) the provisions of the product authorisation or other standard which relates to the said animal remedy.

(b) to certify in a register, or other equivalent document appropriate for the purpose, whether each production batch of the animal remedy to which the licence relates satisfies the requirements set out in sub-paragraph (a) above and to ensure that such register or other document is regularly maintained and in particular that the appropriate entries in such register or other document are made as soon as practicable after each such batch has been manufactured.

(c) in the case of an animal remedy coming from a country which is not a Member State of the European Union to ensure that each particular batch imported has undergone within the State or another Member State a full quantitative analysis of at least all the active ingredients and all the other tests or checks necessary to ensure the quality of the animal remedy in accordance with the requirements of the product authorisation.

(4) Where, after giving the licence holder and the person acting as the qualified person the opportunity of making representations to it (either orally or in writing), the Competent Authority is of the opinion that the person so acting is failing to carry out the functions specified in paragraph (3) above and has notified the licence holder accordingly in writing, the licence 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 Competent Authority.

(5) The Competent Authority may require the licence holder

temporarily to suspend the person acting as such qualified person upon the commencement of administrative or disciplinary proceedings against him or her for failure to fulfil his or her functions in accordance with paragraph (3) above and the licence holder shall not permit that person to act as the qualified person pending the determination of such proceedings.

8. The licence holder shall keep readily available for inspection by an authorised officer durable records of the details of manufacture of each batch of every animal remedy being manufactured under his or her licence and of the tests carried out thereon, including any register or other document referred to in paragraph 7(3) (b), in such form that the records will be easily identifiable from the number of the batch as shown on each container in which the animal remedy is sold, supplied or exported and he or she shall permit such officer to take copies or make extracts from such records. Such records shall be retained for not less than five years from the date of manufacture or for the period which ends one year after the labelled expiry date of the animal remedy whichever is the longer period.

9. The license holder shall keep such documents as will facilitate the withdrawal or recall from sale, supply or exportation of any animal remedy to which the license related. Such documents shall be available for inspection by an authorised officer.

10. The license holder shall keep an adequate sample of each batch and of each active constituent used in the manufacture of an animal remedy to which the license relates for the period which ends one year after the labelled expiry date of the animal remedy, and shall furnish on request by the Competent Authority a sufficient sample of each such batch for the purpose of any test, examination or analysis which may be required by the Competent Authority.

11. Where the licence holder has been informed by the Competent Authority that any part of a batch of an animal remedy to which his or her license 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 Competent Authority 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.

12. Where the licence holder has been informed by the Competent Authority 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 Competent Authority, immediately withhold that remedy from sale, supply or exportation and, insofar as may be practicable, immediately recall all supplies of such remedy already sold, supplied or exported.

13. The licence holder shall ensure that any tests for determining conformity with the standards and specifications applying to any animal remedy to which the license relates, shall, except insofar as the conditions of the relevant product authorisation may otherwise permit or require, be 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 Competent Authority.

14. The licence holder, who is not the holder of an animal

remedies authorisation in respect of an animal remedy to which the license relates, shall comply with any provisions of such authorisation which relate to the sale or supply of that animal remedy and shall, by means of a label or otherwise, communicate the particulars of such provisions as they relate to mode of sale or supply or restriction as to sale or supply to any person to whom the licence holder sells or supplies that animal remedy.

15. The licence holder shall not dispose of an animal remedy to which his or her licence relates except in accordance with the law of the State.

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

17. The licence holder, for the purpose of enabling the Competent Authority to ascertain whether there are any grounds for suspending, revoking or varying any licence or authorisation granted under these Regulations shall permit and provide all necessary facilities to enable any officer responsible for the enforcement or execution of the said Regulations to carry out such inspection, to take such samples or to take copies of any documents in relation to any business carried on by the license holder, for the purpose of verifying any statement contained in an application for a licence or authorisation.

FIFTH SCHEDULE

General conditions for licensed retail 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. Where a premises is attached to such a dwelling the limits of the premises to be used as a retail premises shall be clearly defined and it must be possible to access the premises directly without trespass into the dwelling and animal remedies shall not be stored or kept for sale 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, display and storage of animal remedies shall take place in a separate designated area.

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

6. Animal remedies shall be stored in such 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 must be adequate to ensure that

animal remedies do not become contaminated by other animal remedies or stock on the premises or cause such contamination.

10. The use of such premises for the carrying out of a business of sale of animal remedies shall not contravene the Local Government Planning and Development Acts.

SIXTH SCHEDULE

Form of record to be kept in accordance with paragraph (2) of Regulation 42

Date of AdministrationName and quantity of animal remedy administeredIdentity of animal to which animal remedy administered including Ear Tag No. where appropriateDate of expiry of withdrawal period (if any)Name of person who administered the Animal RemedyName of prescribing Veterinary Surgeon (if applicable)Name of supplier of animal remedy

GIVEN under my Official Seal, this 13 day of June, 1996

Ivan Yates TD

Minister for Agriculture, Food and Forestry

EXPLANATORY NOTE

The effect of these is to transpose into national law Council Directive 81/851/EEC, Council Directive 81/852/EEC, Council Directive 87/20/EEC, Council Directive 87/22/EEC, Council Directive 90/676/EEC, Council Directive 90/677/EEC, Commission Directive 91/412/EEC, Commission Directive 92/18/EEC, Commission Directive 92/74/EEC, Council Directive 93/40/EEC and Council Directive 93/41/EEC and give further effect to Council Regulation (EEC) 2377/90 and Council Regulation (EEC) 2309/93.

The Regulations lay down detailed rules regarding the authorisation of animal remedies and the manufacture, wholesale and retail sale of animal remedies. The Regulations also lay down rules for the administration of animal remedies and certain matters relating to veterinary practice in relation to animal remedies.