SCHEDULE 1

Regulation 4(5)

REQUIREMENTS IN RESPECT OF PRODUCTS OTHER THAN IMMUNOLOGICAL PRODUCTS

1. The applicant shall comply with all the requirements set out in Parts 1 and 4 of Title I of the Annex to Council Directive 81/852/EEC.

2.—(1) Subject to sub-paragraphs (2) and (3) below, the applicant shall comply with the requirements set out in Part 2 of Title I of the Annex to Council Directive 81/852/EEC.

(2) Where at the request of the applicant a manufacturer of an active ingredient of the product submits details concerning the method of manufacture, quality control during manufacture and process validation directly to the Ministers, the applicant shall obtain from the manufacturer—

(a) all the data necessary for him to take responsibility for the product,

(b) written confirmation that the manufacturer will ensure batch to batch consistency and inform the applicant before he modifies the manufacturing process, and

(c) written confirmation that the manufacturer will supply to the Ministers all documents and particulars which may be required by them relating to any such modification,

and shall submit the data and confirmation received to the Ministers.

(3) Where the applicant refers to a specification in a monograph in a pharmacopoeia but the Ministers consider that such specification is insufficient to ensure the quality of the product, the applicant shall submit to the Ministers on request a more appropriate specification.

3. The applicant shall comply with the requirements set out in Part 3 of Title I of the Annex to Council Directive 81/852/EEC, and shall supply a copy of any certificate issued by a laboratory which carried out any such test certifying that the test was carried out in conformity with the principles of good laboratory practice as referred to in the second paragraph of Part 3.

SCHEDULE 2

Regulation 4(6)

REQUIREMENTS IN RESPECT OF IMMUNOLOGICAL PRODUCTS

1. The applicant shall comply with the requirements set out in Part 5, 7, 8 and 9 of Title II of the Annex to Council Directive 81/852/EEC and shall supply a copy of any certificate issued by a laboratory which carried out a safety test certifying that the test was carried out in conformity with the principles of good laboratory practice as referred to in paragraph 3 of Section A of Part 7 of that Title.

2.—(1) Subject to sub-paragraphs (2) and (3) below, the applicant shall comply with the requirements set out in Part 6. Title II of the Annex to Council Directive 81/852/EEC.

(2) Where at the request of the applicant a manufacturer of an active ingredient of the product submits details concerning the method of manufacture, quality control during manufacture and process validation directly to the Ministers, the applicant shall obtain from the manufacturer—

(a) all the data necessary for him to take responsibility for the product,

(b) written confirmation that the manufacturer will ensure batch to batch consistency and inform the applicant before he modifies the manufacturing process or specifications, and

(c) written confirmation that the manufacturer will supply to the Ministers all documents and particulars which may be required by the authority relating to any such modification,

and shall submit the data and confirmations received to the Ministers.

(3) Where the applicant refers to a specification in a monograph in a pharmacopoeia but the Ministers consider that such specification is insufficient to ensure the quality of the product, the applicant shall submit to the Ministers on request a more appropriate specification.

SCHEDULE 3

Regulation 12

PROCEDURE ON REFERENCE TO APPROPRIATE COMMITTEE OR COMMISSION

1. Where the appropriate committee or the commission consulted under regulation 12 have reason to think that—

(a) they may be unable to advise the Ministers to grant an authorisation,

(b) they may be unable to advise the Ministers to grant it unless it contains provisions otherwise than in accordance with the application, or

(c) they may advise the Ministers to suspend or revoke an authorisation,

the committee or commission shall notify the applicant or authorisation holder accordingly, and, before giving their advice to the Ministers, shall afford to him an opportunity of appearing before and being heard by them, or of making representations in writing to them with respect to those grounds.

2. Whether the applicant or authorisation holder has been heard or has made representations under this Schedule or not, if the appropriate committee or the commission advise the Ministers that the authorisation ought to be refused, suspended or revoked, or ought, if granted, to contain provisions specified in their advice, the Ministers shall provisionally determine the issue taking account of that advice and shall notify the applicant or authorisation holder of such determination and of the advice taken into account, and including in the notification a time within which he can appeal against such determination.

3. If, within the time allowed in the notification of a provisional determination, in a case where the applicant or authorisation holder has not been heard by, or made representations to, the commission under this Schedule, he gives notice to the Ministers of his desire to be heard with respect to the provisional determination or advice given to the Ministers, or makes representations in writing to the Ministers with respect to that provisional determination or advice, then—

(a) if the applicant or authorisation holder has given notice of his desire to be heard, the Ministers shall arrange for him to have an opportunity of appearing before, and being heard by, the commission, or

(b) if he has made representations in writing, the Ministers shall refer those representations to the commission,

after which the commission shall report to the Ministers their findings and advice and the reasons for their advice.

SCHEDULE 4

Regulation 20

REVOCATIONS

Title of instrument	Reference
The Medicines (Leaflets for Veterinary Drugs) Regulations 1983	S.I.1983/1727

Title of instrument	Reference
The Medicines (Veterinary Medicinal Products) (Applications for Product Licences) Regulations 1993	S.I. 1993/2398
The Medicines (Veterinary Medicinal Products) (Applications for Product Licences) (Amendment) Regulations 1994	S.I. 1994/2157

SCHEDULE 5

Regulation 21

AMENDMENTS

1. Article 3 of the Sheep Scab Order (Northern Ireland) 1970(**1**), shall be amended as follows:

(a) in the definition of "approved sheep dip" after the words "product licence" there shall be inserted the words "or marketing authorisation";

(b) after the definition of "fat sheep" there shall be inserted the following—

> ""marketing authorisation" means a marketing authorisation valid in Northern Ireland to which the Marketing Authorisations for Veterinary Medicinal Products Regulations 1994 apply;".

2. In the Medicines (Importation of Medicinal Products for Re-exportation) Order 1971(**2**), there shall be inserted after article 3 the following article—

"**Marketing authorisations**

4. The restriction imposed by regulation 3 of the Marketing Authorisations for Veterinary Medicinal Products Regulations 1994 (which regulates the placing on the market and possession of veterinary medicinal products unless a marketing authorisation has been granted) shall not apply to veterinary medicinal products which have been imported in the circumstances set out in article 3 of this Order, subject to the conditions of that article and accordingly in the case of marketing authorisations references in that article to the "licensing authority" shall be construed as references to "the Ministers" as defined in the 1994 Regulations."

3. The Medicines (Data Sheet) Regulations 1972(**3**), shall be amended as follows—

(a) in regulation 1 after the definition of "mark" there shall be inserted the following—

> ""marketing authorisation" means a marketing authorisation to which the Marketing Authorisations for Veterinary Medicinal Products Regulations 1994 apply;";

(b) in regulation 2 after the words "product licence" and "product licences", in each place where they occur, there shall be inserted the words "or marketing authorisation" and "or market authorisations" respectively;

(c) in sub-paragraph (c) of regulation 2(5) after the words "the licensing authority" there shall be inserted the words "or, in the case of a marketing authorisation, the Ministers as defined in the Marketing Authorisations for Veterinary Medicinal Products Regulations 1994,";

(**1**) S.R. 1970/240; relevant amending instruments are S.R. 1978/247 and S.R. 1981/311.
(**2**) S.I. 1971/1326 to which there are amendments not relevant to these Regulations.
(**3**) S.I. 1972/2076 to which there are amendments not relevant to these Regulations.

(d) in regulation 4 after the words "product licence", in each place where they occur, there shall be inserted the words "or marketing authorisation"; and

(e) in Schedule 3 after the words "product licence", in each place where they occur, there shall be inserted the words "or marketing authorisation".

4. In the Medicines (Labelling) Regulations 1976(**4**) after regulation 3 there shall be inserted the following regulation—

"**3A.** Other than regulations 9 and 13 below, these Regulations shall not apply in relation to any product placed on the market in accordance with the Marketing Authorisations for Veterinary Medicinal Products Regulations 1994.".

5. In the Medicines (Prohibition of Importation and Possession of Veterinary Drugs) Order (Northern Ireland) 1977(**5**) in article 3(2) after the words "product licence" there shall be inserted the words "or a marketing authorisation to which the Marketing Authorisations for Veterinary Medicinal Products Regulations 1994 apply".

6. The Medicines (Fluted Bottles) Regulations 1978(**6**) shall be amended as follows—

(a) in regulation 1(2) after the definition of "external use" there shall be inserted the following—

""marketing authorisation"means a marketing authorisation to which the Marketing Authorisations for Veterinary Medicinal Products Regulations 1994 apply;"; and

(b) in regulation 3(g) after the words "a product licence," there shall be inserted the words "marketing authorisation," and after the words "any such licence" there shall be inserted the words "or authorisation".

7. In the Importation of Animal Products and Poultry Products Order 1980(**7**), in the Schedule, after the words "Medicines Act 1968" there shall be inserted the words "or the Marketing Authorisations for Veterinary Medicinal Products Regulations 1994".

8. In the Medicines (Sale or Supply) (Miscellaneous Provisions) Regulations 1980(**8**), in regulation 5(1) in sub-paragraph (a) after the words "holder of a product licence" there shall be inserted the words "or a marketing authorisation to which the Marketing Authorisations for Veterinary Medicinal Products Regulations 1994 apply".

9. The Medicines (Pharmacy and General Sale — Exemption) Order 1980(**9**) shall be amended as follows—

(a) in article 5(3) after the words "product licence granted under Part II of the Act" there shall be inserted the words "or a marketing authorisation to which the Marketing Authorisations for Veterinary Medicinal Products Regulations 1994 apply"; and

(b) in Schedule I, Part I at point 11 after the words "product licences" in column 1 and after the words "licences" in column 2 there shall be inserted the words "or marketing authorisations to which the Marketing Authorisations for Veterinary Medicinal Products Regulations 1994 apply".

10. In the Health and Safety (Dangerous Pathogens) Regulations 1981(**10**), in regulation 2(1) after the words "any substance in respect of which there is in force a" there shall be inserted the

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(**4**) S.I. 1976/1726 to which there are amendments not relevant to these Regulations.
(**5**) S.R. 1977/359 as amended by S.R. 1981/182.
(**6**) S.I. 1978/40.
(**7**) S.I. 1980/14 as amended by S.I. 1994/2920.
(**8**) S.I. 1980/1923 to which there are amendments not relevant to these Regulations.
(**9**) S.I. 1980/1924 to which there are amendments not relevant to these Regulations.
(**10**) S.I. 1981/1011.

words "marketing authorisation to which the Marketing Authorisations for Veterinary Medicinal Products Regulations 1994 apply or".

11. The Warble Fly (Scotland) Order 1982(**11**) shall be amended as follows—

(a) in article 2 in the definition of "product" after the words "granted under the Medicines Act 1968" there shall be inserted the words "or a marketing authorisation to which the Marketing Authorisations for Veterinary Medicinal Products Regulations 1994 apply"; and

(b) in the Schedule in paragraph 1 of Form A after the words "product licensed" there shall be inserted the words "or authorised".

12. The Warble Fly (England and Wales) Order 1982(**12**), shall be amended as follows—

(a) in article 2 in the definition of "dressing" after the words "granted under the Medicines Act 1968" there shall be inserted the words "or a marketing authorisation to which the Marketing Authorisations for Veterinary Medicinal Products Regulations 1994 apply"; and

(b) in the Schedule in paragraph (a) of Form A after the words "by using a dressing licensed" there shall be inserted the words "or authorised".

13. In the Natural Mineral Waters Regulations 1985(**13**) in paragraph (c) of regulation 3 after the words "the Medicines Act 1968" there shall be inserted the words "or a marketing authorisation to which the Marketing Authorisations for Veterinary Medicinal Products Regulations apply".

14. In the Warble Fly (England and Wales) (Infected Areas) Order 1985(**14**), in article 2 in the definition of "product" after the words "granted under the Medicines Act 1968" there shall be inserted the words "or a marketing authorisation to which the Marketing Authorisations for Veterinary Medicinal Products Regulations 1994 apply".

15. The Medicines (Veterinary Drugs) (Exemption from Licences) (Importation) Order 1986(**15**) shall be amended as follows—

(a) there shall be inserted after article 3 the following article—

"**Exemption from marketing authorisations for certain imported veterinary drugs**

3A. Subject to the conditions in article 4 below, the restriction imposed by regulation 3 of the Marketing Authorisations for Veterinary Products Regulations 1994 (which regulates the placing on the market and possession of veterinary medicinal products unless a marketing authorisation has been granted) shall not apply to the importation of a veterinary medicinal drug (not being an immunological veterinary drug) or to the sale or supply of any such imported veterinary drug.";

(b) in article 4(1) for the words "Article 3" there shall be substituted the words "Article 3 or by Article 3A";

(c) in article 4(1) in sub-paragraph (a) after the words "section 7(2) of the Act" there shall be inserted the words "or a marketing authorisation to which the Marketing Authorisations for Veterinary Medicinal Products Regulations 1994 apply"; and

(d) in article 4(1) in sub-paragraphs (b) and (c) after the word "licence", in each place where it occurs, there shall be inserted the words "or marketing authorisation".

(**11**) S.I. 1982/207.
(**12**) S.I. 1982/234 to which there are amendments not relevant to these Regulations.
(**13**) S.I. 1985/71.
(**14**) S.I. 1985/1542.
(**15**) S.I. 1986/228.

16. In the Control of Pesticides Regulations 1986(**16**) in Regulation 3(2)(b) after the words "under that enactment is exercised" there shall be inserted the words "or substances controlled by the Marketing Authorisations for Veterinary Medicinal Products Regulations 1994";

17. The Medicines (Labelling of Medicinal Products for Incorporation in Animal Feeding Stuffs and of Medicated Animal Feeding Stuffs) Regulations 1988(**17**) shall be amended as follows—

(a) in regulation 2—

(i) after the definition of "international non-proprietry name" and before the definition of "medicated feeding stuff" there shall be inserted the following—

""marketing authorisation" means a marketing authorisation to which the Marketing Authorisations for Veterinary Medicinal Products Regulations 1994 apply;"; and

(ii) after the words "product licence", in each place where they occur, there shall be inserted the words "or marketing authorisation";

(b) in regulation 9(6)—

(i) after the words "any licence or certificate granted or issued under the Act" there shall be inserted the words "or to any marketing authorisation"; and

(ii) for the words "or such regulations, orders, licence or certificate" there shall be substituted the words "or such regulations, orders, licence, certificate or marketing authorisation";

(c) Schedule 2 shall be amended as follows—

(i) after the words "product licence", in each place where they occur, there shall be inserted the words "or marketing authorisation"; and

(ii) in paragraph 2 after the words "the licensing authority" there shall be inserted the words "or, in the case of a marketing authorisation, the Ministers as defined in the Marketing Authorisations for Veterinary Medicinal Products Regulations 1994," and

(d) Schedule 3 shall be amended as follows—

(i) after the words "product licence", in each place where they occur, there shall be inserted the words "or marketing authorisation"; and

(ii) after the word "licence", in each place where it occurs, there shall be inserted the words "or marketing authorisation".

18. In the Trade Descriptions (Places of Production) (Marking) Order 1988(**18**) in article 1(2)(d) after the words "Medicines Act 1968" there shall be inserted the words "or to which the Marketing Authorisations for Veterinary Medicinal Products Regulations 1994".

19. In the Medicines (Exemptions from Licences) (Intermediate Medicated Feeding Stuffs) Order 1989(**19**) there shall be inserted after article 2 the following article—

"**Marketing authorisations**

3.—(1) The restriction imposed by regulation 3 of the Marketing Authorisations for Veterinary Medicinal Products Regulations 1994 (which regulates the placing on the market and possession of veterinary medicinal products unless a marketing authorisation has been granted) shall not apply to anything done in relation to an intermediate mediciated feeding

(**16**) S.I. 1986/1510.
(**17**) S.I. 1988/1009.
(**18**) S.I. 1988/1771.
(**19**) S.I. 1989/2325 to which there are amendments not relevant to these Regulations.

stuff in the circumstances set out in article 2 of this Order, subject to the conditions in that article.

(2) For the purposes of paragraph (1) above the reference in article 2 of this Order to a product licence shall be construed as a reference to a marketing authorisation to which the Marketing Authorisations for Veterinary Medicinal Products Regulations 1994 apply.".

20. The Medicines (Exemption from Licences) (Wholesale Dealing) Order 1990(**20**) shall be amended as follows—

(a) in article 1(2) after the definition of "intermediate feed" and before the definition of "medicinal product" there shall be inserted the following—

""marketing authorisation" means a marketing authorisation to which the Marketing Authorisations for Veterinary Medicinal Products Regulations 1994 apply;"; and

(b) in article 2(1) after the words "product licence", in each place where they occur, there shall be inserted the words "or marketing authorisation".

21. The Medicines (Veterinary Drugs) (Prescription Only) Order 1991(**21**) shall be amended as follows—

(a) in article 1(2) after the definition of "intermediate feed" and before the definition of "the Misuse of Drugs Regulations" there shall be inserted the following—

""marketing authorisation" means a marketing authorisation to which the Marketing Authorisations for Veterinary Medicinal Products Regulations 1994 apply;";

(b) in article 3(1) in sub-paragraph (d)(iii) after the words "product licence" there shall be inserted the words "or marketing authorisation";

(c) in article 4(1) after the words "product licence" there shall be inserted the words "or marketing authorisation";

(d) in Schedule 1 after the words "Product Licence", in each place where they occur, there shall be inserted the words "or marketing authorisation"; and

(e) in Schedule 3 in Part I at point 10, after the words "product licences" in column 1 and after the word "licences" in column 2 there shall be inserted the words "or marketing authorisations".

22. In the Children's Homes Regulations 1991(**22**) in regulation 2(1) in the definition of "medicinal product" after the words "the Medicines Act 1968" there shall be inserted the words "or a marketing authorisation to which the Marketing Authorisations for Veterinary Medicinal Products Regulations 1994 apply".

23. In the Animals, Meat and Meat Products (Examination for Residues and Maximum Residue Limits) Regulations 1991(**23**), regulation 2 shall be amended as follows—

(a) in the definition of "unlicensed substance" in sub-paragraph (a)(i) after the words "product licence" there shall be inserted the words "or marketing authorisation";

(b) after the definition of "unlicensed substance" and before the definition of "veterinary medicinal product" there shall be inserted the following—

""veterinary medicinal marketing authorisation" means a marketing authorisation to which the Marketing Authorisations for Veterinary Medicinal Products Regulations 1994 apply;"; and

(**20**) S.I. 1990/566.
(**21**) S.I. 1991/1392, as amended by S.I. 1991/2568.
(**22**) S.I. 1991/1506.
(**23**) S.I. 1991/2843 as amended by S.I. 1993/990.

(c) in the definition of "withdrawal period" after the words "current veterinary medicinal product licence" there shall be inserted the words "or marketing authorisation".

24. The Medicines (Veterinary Drugs) (Pharmacy and Merchants' List) Order 1992(**24**) shall be amended as follows—

(a) in article 2(1) in the definition of "a specially authorised person" for (b) there shall be substituted the following—

"(b) a person specially authorised by the product licence or by the marketing authorisation to which the Marketing Authorisations for Veterinary Medicinal Products Regulations 1994 apply in respect of that drug to sell the drug under the alternative product name specified in the licence or marketing authorisation;";

(b) in article 2(1) in the definition of "veterinary drug" after the words "in respect of which a product licence" there shall be inserted the words "or a marketing authorisation";

(c) in article 3 after the words "holder of the product licence", in each place where they occur, there shall be inserted the words "or marketing authorisation";

(d) in article 6(1) after the words "holder of a product licence" there shall be inserted the words "or marketing authorisation";

(e) in article 9 after the words "product licence", in each place where they occur, there shall be inserted the words "or marketing authorisation";

(f) in article 11(1) after the words "product licence" there shall be inserted the words "or marketing authorisation"; and

(g) in Schedules 1, 2, 3 and 4 for the words "product licence no.", in each place where they occur, there shall be substituted the words "product licence/marketing authorisation no.".

25. In the Animals, Meat and Meat Products (Examination for Residues and Maximum Residue Limits) Regulations (Northern Ireland) 1992(**25**) article 2(2) shall be amended as follows—

(a) in the definition of "unlicensed substance" after the words "product licence" there shall be inserted the words "or marketing authorisation";

(b) after the definition of "unlicensed substance" and before the definition of "veterinary medicinal product" there shall be inserted the following—

""veterinary medicinal marketing authorisation" means a marketing authorisation valid in Northern Ireland to which the Marketing Authorisations for Veterinary Medicinal Products Regulations 1994 apply;"; and

(c) in the definition of "withdrawal period" after the words "product licence" there shall be inserted the words "or marketing authorisation".

26. The Medicines (Medicated Feeding Stuffs) (No. 2) Regulations 1992(**26**) shall be amended as follows—

(a) in regulation 2(1)—

(i) after the definition of "licensed medicinal product" and before the definition of "medicinal product" the following definition shall be inserted:

""marketing authorisation" means an authorisation to place on the market a veterinary medicinal product to which the Marketing Authorisations for Veterinary Medicinal Products Regulations 1994 apply;"; and

(ii) in the definition of "withdrawal period" after the words "current product licenced" there shall be inserted the words "or marketing authorisation";

(**24**) S.I. 1992/33, as amended by S.I. 1992/3081 and S.I. 1994/599.
(**25**) S.R. 1992/39.
(**26**) S.I. 1992/1520, as amended by S.I. 1994/1531.

(b) in regulation 4—

(i) after the words "product licence", in each place where they occur, there shall be inserted the words "or marketing authorisation"; and

(ii) in paragraph (4) after the words "no effective licensed medicinal product" there shall be inserted the words "or medicinal product for which a marketing authorisation has been granted";

(c) in regulation 6 after the words "product licence", in each place where they occur, there shall be inserted the words "or marketing authorisation"; and

(d) in Schedule 2—

(i) in section I(1) for the words "product licence number(s)" there shall be substituted the words "product licence/marketing authorisation number(s)"; and

(ii) in section IV(2) for the words "unlicensed combination of medicinal products" there shall be substituted the words "unlicensed or unauthorised combination of medicinal products".

27. In the Specified Animal Pathogens Order 1993(**27**) in article 5(2) for sub-paragraphs (a) and (b) there shall be substituted the following—

"(a) a marketing authorisation to which the Marketing Authorisations for Veterinary Medicinal Products Regulations 1994 apply, or

(b) a product licence has been granted in accordance with the provisions of section 7(2) of the Medicines Act 1968, or

(c) an animal test certificate has been issued in accordance with the provisions of section 32 of that Act.".

28. In the Aujeszky's Disease Scheme Order (Northern Ireland) 1994(**28**) the Schedule shall be amended as follows—

(a) in paragraph 2(1) after the definition of "holding number" and before the definition of "Officially Aujeszky's Disease free holding" there shall be inserted the following—

""marketing authorisation" means a marketing authorisation valid in Northern Ireland to which the Marketing Authorisations for Veterinary Medicinal Products Regulations 1994 apply;";

(b) in paragraph 2(1) in the definition of "vaccine" after the words "valid product licence" there shall be inserted the words "or marketing authorisation"; and

(c) in paragraph 8(1) after the words "product licence" there shall be inserted the words "or marketing authorisation".

29. In the General Product Safety Regulations 1994(**29**) in regulation 11(c)(ii)(aa) after the words "licensed in accordance with the provisions of the 1968 Act" there shall be inserted the words "or authorised in accordance with the provisions of the Marketing Authorisations for Veterinary Medicinal Products Regulations 1994".

30. The Medicines (Standard Provisions for Manufacturer's Licences for Veterinary Medicinal Products) Regulations 1994(**30**) shall be amended as follows—

(a) in regulation 2(1) after the definition of "Directive 91/412/EEC" and before the definition of "veterinary medicinal product" there shall be inserted the following—

(**27**) S.I. 1993/3250.
(**28**) S.R. 1994/199.
(**29**) S.I. 1994/2328.
(**30**) S.I. 1994/2852.

""marketing authorisation" means a marketing authorisation to which the Marketing Authorisations for Veterinary Medicinal Products Regulations 1994 apply;"; and

(b) in regulation 6 for the words "product licence" there shall be substituted the words "marketing authorisation".

31. In the Medicines (Veterinary Medicinal Products) (Veterinary Surgeons from Other EEA States) Regulations 1994(**31**) for article 3(1) there shall be substituted the following—

"**Exemption from marketing authorisations for certain veterinary medicinal products**

3.—(1) Subject to the conditions in paragraph (2) below, the restrictions imposed by regulation 3 of the Marketing Authorisations for Veterinary Medicinal Products Regulations 1994 (which regulates the placing on the market and possession of veterinary medicinal products unless a marketing authorisation has been granted) shall not apply to the importation of a ready-made veterinary medicinal product from another member State, or to its subsequent sale or supply.".

32. The Medicines (Restrictions on the Administration of Veterinary Medicinal Products) Regulations 1994(**32**) shall be amended as follows—

(a) in regulation 2(1)—

(i) after the definition of "the Act" and before the definition of "homeopathic medicinal product" there shall be inserted the following—

""authorised veterinary medicinal product" means a veterinary medicinal product which has been granted a marketing authorisation;"; and

(ii) after the definition of "homeopathic medicinal product" and before the definition of "ready-made veterinary medicinal product" there shall be inserted the following—

""marketing authorisation" means a marketing authorisation to which the Marketing Authorisations for Veterinary Medicinal Products Regulations 1994 apply;";

(b) in regulation 3 after the words "product licence has been granted under the Act" there shall be inserted the words "or marketing authorisation has been granted"; and

(c) in reguation 5—

(i) in paragraph (1) after the words "licensed veterinary medicinal product" there shall be inserted the words "or authorised veterinary medicinal product";

(ii) in sub-paragraph (a) of paragraph (1) and in sub-paragraph (a) of paragraph (2) after the word "licensed", in each place where it occurs, there shall be substituted the word "authorised"; and

(iii) in sub-paragraph (b) of paragraph (1) for the word "licensed" there shall be inserted the words "or authorised".

(**31**) S.I. 1994/2986.
(**32**) S.I. 1994/2987.