

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;”;
 - (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.”.

(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.

(4) S.I. 1976/1726 to which there are amendments not relevant to these Regulations.

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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;”;

(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 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—

(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](#).

(11) [S.I. 1982/207](#).

(12) [S.I. 1982/234](#) to which there are amendments not relevant to these Regulations.

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- (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”.

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 Stuff and of Medicated Animal Feeding Stuff) Regulations 1988(**17**) shall be amended as follows—

- (a) in regulation 2—
 - (i) after the definition of “international non-proprietary name” and before the definition of “medicated feeding stuff” there shall be inserted the following—

(13) S.I. 1985/71.
(14) S.I. 1985/1542.
(15) S.I. 1986/228.
(16) S.I. 1986/1510.
(17) S.I. 1988/1009.

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““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 medicated feeding 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—

(18) S.I. 1988/1771.

(19) S.I. 1989/2325 to which there are amendments not relevant to these Regulations.

(20) S.I. 1990/566.

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

- (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;”;

- (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;”;

(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.

(24) S.I. 1992/33, as amended by S.I. 1992/3081 and S.I. 1994/599.

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- (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 Stuff) (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”;
- (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—

⁽²⁵⁾ S.R. 1992/39.

⁽²⁶⁾ S.I. 1992/1520, as amended by S.I. 1994/1531.

- (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—
 - ““marketing authorisation” means a marketing authorisation to which the Marketing Authorisations for Veterinary Medicinal Products Regulations 1994 apply;”;
- (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—

(27) S.I. [1993/3250](#).

(28) S.R. [1994/199](#).

(29) S.I. [1994/2328](#).

(30) S.I. [1994/2852](#).

(31) S.I. [1994/2986](#).

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“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 regulation 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”.