SCHEDULE 8 Regulation 44

Revocations and amendments.

PART 1

The following instruments are revoked—

The Medicines (Veterinary Products Committee) Order 1970 (S. I. 1970/1304)

The Medicines (Exportation of Specified Veterinary Products) Order 1971 (S. I. 1971/1309)

The Medicines (Exemption from Licences) (Medicinal Tests on Animals) Order 1977 (S. I. 1977/161)

The Medicines (Veterinary Drugs) (Exemption from Licences) (Importation) Order 1986 (S. I. 1986/228)

The Medicines (Chemical Sterilants) Order 1986 (S. I. 1986/2177)

The Medicines (Exemptions from Licences) (Carbadox and Olaquindox) Order 1987 (S. I. 1987/2217)

The Medicines (Labelling of Medicinal Products for Incorporation in Animal Feeding Stuffs and of Medicated Animal Feeding Stuffs) Regulations 1988 (S. I. 1988/1009)

The Medicines (Veterinary Medicinal Products) (Renewal Applications for Product Licences Subject to Review) Regulations 1993 (S. I. 1993/2399)

The Medicines (Standard Provisions for Manufacturer's Licences for Veterinary Medicinal Products) Regulations 1994 (S. I. 1994/2852)

The Medicines (Veterinary Medicinal Products) (Veterinary Surgeons From Other EEA States) Regulations 1994 (S. I. 1994/2986)

The Medicines (Restrictions on the Administration of Veterinary Medicinal Products) Regulations 1994 (S. I. 1994/2987)

The Marketing Authorisations for Veterinary Medicinal Products Regulations 1994 (S. I. 1994/3142)

The Registration of Homoeopathic Veterinary Medicinal Products Regulations 1997 (S. I. 1997/322)

The Medicines (Registered Homoeopathic Veterinary Medicinal Products) (General Sale List) Order 1997 (S. I. 1997/1349)

The Medicines (Restrictions on the Administration of Veterinary Medicinal Products) Amendment Regulations 1997 (S. I. 1997/2884)

The Medicines (Exemptions for Merchants in Veterinary Drugs) Order 1998 (S. I. 1998/1044)

The Medicines (Sale or Supply) (Miscellaneous Provisions) Amendment Regulations 1998 (S. I. 1998/1045)

The Retailers' Records for Veterinary Medicinal Products Regulations 2000 (S. I. 2000/7)

The Marketing Authorisations for Veterinary Medicinal Products Amendment Regulations 2000 (S. I. 2000/776)

The Medicines (Data Sheets for Veterinary Drugs) Regulations 2000 (S. I. 2000/2386)

The Medicines (Exemptions for Merchants in Veterinary Drugs) (Amendment) Order 2000 (S. I. 2000/2686)

The Medicines (Veterinary Drugs) (General Sale List) Order 2001 (S. I. 2001/1645)

The Medicines (Veterinary Drugs) (Prescription Only) Order 2001 (S. I. 2001/1646)

The Marketing Authorisations for Veterinary Medicinal Products Regulations (Amendment) Regulations 2002 (S. I. 2002/269)

The Animal Test Certificates (Revocation) Regulations 2003 (S. I. 2003/3309)

The Medicines (Products for Animal Use – Fees) Regulations 2004 (2004/2750)

The Medicines (Vaccination against Foot-and-Mouth Disease) Order 2004 (2004/2779)

The Medicines (Products for Animal Use – Fees) (Amendment) Regulations 2004 (S. I. 2004/3081)

The Marketing Authorisations for Veterinary Medicinal Products (Revocation of Confidentiality Provision) Regulations 2004 (S. I. 2004/3193)

PART 2

Instruments revoked on 1st January 2006

The Medicated Feedingstuffs Regulations 1998 (S. I. 1998/1046)

The Medicated Feedingstuffs and Feedingstuffs (Zootechnical Products) (Consequential Provisions) Regulations 1998 (S. I. 1998/1048)

The Feedingstuffs (Zootechnical Products) Regulations 1999 (S. I. 1999 /1871)

The Feedingstuffs (Zootechnical Products) and Medicated Feedingstuffs (Amendment) Regulations 2000 (S. I. 2000/1686)

The Feedingstuffs (Zootechnical Products) (Amendment) (England, Scotland and Wales) Regulations 2002 (S. I. 2002/696)

The Medicated Feedingstuffs (Amendment) (England, Scotland and Wales) Regulations 2002 (S. I. 2002/697)

The Feedingstuffs (Zootechnical Products) (Amendment) Regulations 2003 (S. I. 2003/545)

The Medicated Feedingstuffs (Amendment) (Scotland, England and Wales) Regulations 2003 (S. I. 2003/752)

The Feedingstuffs (Zootechnical Products) and Medicated Feedingstuffs (Amendment) (England, Scotland and Wales) Regulations 2004 (S. I. 2004/1036)

The Feedingstuffs (Zootechnical Products) and Medicated Feedingstuffs (Amendment) (England, Scotland and Wales) Regulations 2005 (S. I. 2005/1033)

The Medicated Feedingstuffs (Amendment) Regulations (Northern Ireland) S.R. (NI) 2002 No.161

The Feedingstuffs (Zootechnical Products)(Amendment) Regulations (Northern Ireland) S.R. (NI) 2002 No. 162

The Medicated Feedingstuffs (Amendment) Regulations (Northern Ireland) S.R. (NI) 2004 No. 154

The Feedingstuffs (Zootechnical Products)(Amendment) Regulations (Northern Ireland) S.R. (NI) 2004 No. 155

The Feedingstuffs (Zootechnical Products)(Amendment) Regulations (Northern Ireland) S.R. (NI) 2005 No. 183

The Medicated Feedingstuffs (Amendment) Regulations (Northern Ireland) S.R. (NI) 2005 No. 184

PART 3

Consequential amendments

The following instruments shall be amended as follows—

The Medicines (Standard Provisions for Licences and Certificates) Regulations 1971

1. After regulation 1 of the Medicines (Standard Provisions for Licences and Certificates) Regulations 1971 (S.I.1971/972) there shall be inserted the following—

"**Veterinary medicinal products**

1A. These Regulations shall not apply in relation to veterinary medicinal products."

The Medicines (Applications for Manufacturer's and Wholesale Dealer's Licences) Regulations 1971

2. After regulation 1 of the Medicines (Applications for Manufacturer's and Wholesale Dealer's Licences) Regulations 1971 (S.I. 1971/974) there shall be inserted the following—

"**Veterinary medicinal products**

1A. These Regulations shall not apply in relation to veterinary medicinal products."

The Medicines (Control of Substances for Manufacture) Order 1971

3. After article 1 of the Medicines (Control of Substances for Manufacture) Order 1971 (S.I. 1971/1200) there shall be inserted the following—

"**Veterinary medicinal products**

1A. This Order shall not apply in relation to veterinary medicinal products."

The Medicines (Importation of Medicinal Products for Re-exportation) Order 1971

4. After article 1 of the Medicines (Importation of Medicinal Products for Re-exportation) Order 1971 (S.I. 1971/1326) there shall be inserted the following—

"**Veterinary medicinal products**

1A. This Order shall not apply in relation to veterinary medicinal products."

The Medicines (Exemption from Licences) (Special and Transitional Cases) Order 1971

5.—(1) In article 1(2) of the Medicines (Exemption from Licences) (Special and Transitional Cases) Order 1971 (S.I. 1971/1450) —

(a) the definition of "intermediate feed" shall be deleted;

(b) sub-paragraph (c) of the definition of "medicinal product" shall be deleted.

(2) After article 1 there shall be inserted the following—

"**Veterinary medicinal products**

1A. This Order shall not apply in relation to veterinary medicinal products."

(3) Article 2(2)(i)(b) shall be deleted.

The Medicines (Exemption from Licences) (Special Cases and Miscellaneous Provisions) Order 1972

6.—(1) In article 1(2) of the Medicines (Exemption from Licences) (Special Cases and Miscellaneous Provisions) Order 1972 (S.I. 1972/1200)—

(a) the definition of "intermediate feed" shall be deleted;

(b) paragraph (b) in the definition of "medicinal product" shall be deleted.

(2) After article 1 there shall be inserted the following—

"**Veterinary medicinal products**

1A. This Order shall not apply in relation to veterinary medicinal products."

(3) Article 2(1)(b) shall be deleted.

(4) Article 2(1)(c)(ii) shall be deleted.

(5) Article 2(4) shall be deleted.

(6) Article 2(7) shall be deleted.

(7) Article 4 shall be deleted.

The Medicines (Extension to Antimicrobial Substances) Order 1973

7. After article 1 of the Medicines (Extension to Antimicrobial Substances) Order 1973 (S.I. 1973/367) there shall be inserted the following—

"**Veterinary medicinal products**

1A. This Order shall not apply in relation to veterinary medicinal products."

The Medicines (Exemptions from Licences) (Emergency Importation) Order 1974

8. After article 1 of the Medicines (Exemptions from Licences) (Emergency Importation) Order 1974 (S.I. 1974/316) there shall be inserted the following—

"**Veterinary medicinal products**

1A. This Order shall not apply in relation to veterinary medicinal products."

The Medicines (Exemption from Licences) (Ingredients) Order 1974

9. In the Medicines (Exemption from Licences) (Ingredients) Order 1974 (S.I. 1974/1150) after article 1 there shall be inserted the following—

"**Veterinary medicinal products**

1A. This Order shall not apply in relation to veterinary medicinal products."

The Medicines (Labelling) Regulations 1976

10.—(1) The Medicines (Labelling) Regulations 1976 (S.I. 1976/1726) shall be amended as follows.

(2) For regulation 3A there shall be substituted—

"**Veterinary medicinal products**

3A. These Regulations shall not apply in relation to veterinary medicinal products."

(3) Regulation 7 (medicinal tests on animals) shall be deleted.

(4) Regulation 9(1)(b) (dispensed medicinal products for animal use) shall be deleted.

(5) Regulation 12(1)(a) (importation and exportation of medicinal products for animal use) shall be deleted.

(6) Regulation 14D (veterinary drugs) shall be deleted.

(7) In regulation 16—

(a) in paragraph (1) the following shall be omitted—

(i) the words "or in an animal test certificate";

(ii) the words "or certificate";

(iii) the words "or, as the case may be, certificate".

(b) in paragraph (2) the words "or animal test certificate" shall be omitted.

(8) Regulation 17(7) and (8) shall be deleted.

(9) In Schedule 1 —

(a) in paragraph 3 the words "and, where the medicinal product is for use by being administered to animals, the purposes for which the medicinal product is to be used," shall be omitted;

(b) paragraph 5 shall be deleted;

(c) paragraph 5A shall be deleted;

(d) paragraph 11A shall be deleted;

(e) paragraph 13 shall be deleted.

(10) Schedule 3 (particulars required in the labelling of containers and packages of medicinal products for medicinal tests on animals) shall be deleted.

(11) In Schedule 5 paragraphs 6, 7 and 8 shall be deleted.

(12) In Schedule 6 paragraphs 6 and 7 shall be deleted.

The Medicines (Manufacturer's Undertakings for Imported Products) Regulations 1977

11. In the Medicines (Manufacturer's Undertakings for Imported Products) Regulations 1977 (S.I. 1977/1038) after regulation 1 there shall be inserted the following—

"**Veterinary medicinal products**

1A. These Regulations shall not apply in relation to veterinary medicinal products."

The Medicines (Certificates of Analysis) Regulations 1977

12. In the Medicines (Certificates of Analysis) Regulations 1977 (S.I. 1977/1399) after regulation 1 there shall be inserted the following—

"**Veterinary medicinal products**

1A. These Regulations shall not apply in relation to veterinary medicinal products."

The Medicines (Retail Sale or Supply of Herbal Remedies) Order 1977

13.—(1) In article 1(2) of the Medicines (Retail Sale or Supply of Herbal Remedies) Order 1977 (S.I. 1977/2130) paragraph (b) of the definition of "external use" shall be deleted.

(2) After article 1 there shall be inserted the following—

"**Veterinary medicinal products**

1A. This Order shall not apply in relation to veterinary medicinal products."

The Medicines (Prohibition of Non-medicinal Antimicrobial Substances) Order 1977

14. After article 1 of the Medicines (Prohibition of Non-medicinal Antimicrobial Substances) Order 1977 (S.I. 1977/2131) there shall be inserted the following—

"**Veterinary medicinal products**

1A. This Order shall not apply in relation to veterinary medicinal products."

The Medicines (Fluted Bottles) Regulations 1978

15.—(1) In regulation 1(2) of the Medicines (Fluted Bottles) Regulations 1978 (S.I. 1978/40)—

(a) paragraph (b) in the definition of "external use" shall be deleted; and

(b) the definition of "marketing authorisation" shall be deleted.

(2) After regulation 1 there shall be inserted the following—

"**Veterinary medicinal products**

1A. These Regulations shall not apply in relation to veterinary medicinal products."

(3) For regulation 3(g) there shall be substituted—

"(g) where a product licence, a marketing authorisation within the meaning of the Medicines for Human Use (Marketing Authorisations Etc) Regulations 1994, or any variation of any such licence or authorisation, enables medicinal products to be contained in a bottle otherwise than in accordance with the requirements set out in regulation 2 above."

The Medicines (Sale or Supply) (Miscellaneous Provisions) Regulations 1980

16.—(1) In regulation 1(2)(a) of the Medicines (Sale or Supply) (Miscellaneous Provisions) Regulations 1980 (S.I. 1980/1923) the definition of "the Veterinary Drugs Exemption Order" shall be deleted.

(2) After regulation 1 of there shall be inserted the following—

"**Veterinary medicinal products**

1A. These Regulations shall not apply in relation to veterinary medicinal products."

(3) In regulation 2(1) and regulation 2(2) for the words "neither registered pharmacies nor premises on which there are sold or supplied medicinal products to which the Veterinary Drugs Exemption Order applies" there shall be substituted "not registered pharmacies".

(4) In regulation 2(3), sub-paragraph (b) shall be deleted.

(5) In regulation 5(1)(a) the words "or a marketing authorisation to which the Marketing Authorisations for Veterinary Medicinal Products Regulations 1994 apply" shall be deleted.

(6) Regulation 8(3) shall be deleted.

(7) Schedule 3 shall be deleted.

The Medicines (Pharmacy and General Sale – Exemption) Order 1980

17.—(1) In article 1(2) of the Medicines (Pharmacy and General Sale – Exemption) Order 1980 (S.I. 1980/1924) —

(a) paragraph (ii) in the definition of "external use" shall be deleted;

(b) the definition of "person responsible for marketing" shall be deleted; and

(c) the definition of "registered homoeopathic veterinary medicinal product" shall be deleted.

(2) After article 1 there shall be inserted the following—

"**Veterinary medicinal products**

1A. This Order shall not apply in relation to veterinary medicinal products."

(3) Article 4A(3)(c) shall be deleted.

(4) Article 4B(3)(c) shall be deleted.

(5) Article 4C(3) shall be deleted.

(6) Article 4D(3) shall be deleted.

(7) In article 5(3)(a) the words from "or a marketing authorisation" to "veterinary drug in question" shall be deleted.

(8) Article 5(3)(b) shall be deleted.

The Medicines (Control of Substances for Manufacture) Order 1985

18. After article 1 of the Medicines (Control of Substances for Manufacture) Order 1985 (S.I. 1985/1403) there shall be inserted the following—

"**Veterinary medicinal products**

1A. This Order shall not apply in relation to veterinary medicinal products."

The Medicines Act 1968 (Hearings by Persons Appointed)(Scotland) Rules 1986

19. After rule 1 of The Medicines Act 1968 (Hearings by Persons Appointed) (Scotland) Rules 1986 (S.I. 1986/1700) there shall be inserted the following—

"**Veterinary medicinal products**

1A. These Rules shall not apply in relation to veterinary medicinal products."

The Medicines Act 1968 (Hearings by Persons Appointed) Rules 1986

20. After rule 1 of the Medicines Act 1968 (Hearings by Persons Appointed) Rules 1986 (S.I. 1986/1761) there shall be inserted the following—

"**Veterinary medicinal products**

1A. These Rules shall not apply in relation to veterinary medicinal products."

The Medicines (Exemption from Licences) (Wholesale Dealing) Order 1990

21.—(1) In article 1(2) of the Medicines (Exemption from Licences) (Wholesale Dealing) Order 1990 (S.I. 1990/566)—

(a) the definition of "intermediate feed" is deleted;

(b) the definition ""marketing authorisation" means a marketing authorisation to which the Marketing Authorisations for Veterinary Medicinal Products Regulations 1994 apply" shall be deleted.

(c) in the definition of "medicinal product" paragraph (c) shall be deleted.

(2) After article 1 there shall be inserted the following—

"**Veterinary medicinal products**

1A. This Order shall not apply in relation to veterinary medicinal products."

(3) In article 2(3) the words "or a ready-made veterinary drug" shall be deleted.

The Medicines (Advisory Board On The Registration Of Homoeopathic Products) Order 1995

22. Article 2(1)(b) of the Medicines (Advisory Board on the Registration of Homoeopathic Products) Order 1995 (S. I. 1995/309) shall be deleted.

PART 4

Transitional provisions

Conversions of authorisations, etc.

1.—(1) A marketing authorisation granted under the Marketing Authorisations for Veterinary Medicinal Products Regulations 1994(**1**) and extant when these Regulations come into force becomes a marketing authorisation under these Regulations with the retail classification notified to the marketing authorisation holder by the Secretary of State.

(2) A registration of a homoeopathic veterinary medicine under the Registration of Homoeopathic Veterinary Medicinal Products Regulations 1997(**2**) becomes a registration under these Regulations.

(**1**) S.I. 1994/3142, amended by S.I. 1997/1729, 2884, 1998/1048, 1999/1540, 2000/776, 2002/269, 2004/3193.
(**2**) S.I. 1997/322, amended by S.I. 1997/2884, 1999/342.

(3) A manufacturer's licence as described in section 8(2) of the Medicines Act 1968(**3**) becomes a manufacturing authorisation under these Regulations and the expiry provisions in section 24 of the Medicines Act 1968 do not apply and the Certificate of Good Manufacturing Practice remains valid as issued.

(4) A wholesale dealer's licence as described in section 8(8) of the Medicines Act 1968 becomes a wholesale dealer's authorisation under these Regulations and expiry provisions in section 24 of the Medicines Act 1968 do not apply.

(5) An approval of premises under Part II of the Medicated Feedingstuffs Regulations 1998 becomes an establishment approval under Article 10(2) of Regulation (EC) No. 183/2005.

(6) An approval of a distributor under Part III of the Medicated Feedingstuffs Regulations 1998 becomes an approval referred to in Article 10(2) of Regulation (EC) No. 183/2005.

(7) An approval of an establishment under Part III of the Feedingstuffs (Zootechnical Products) Regulations 1999 becomes an approval referred to in Article 10(1) of Regulation (EC) No. 183/2005.

(8) An approval of an intermediary under Part IV of the Feedingstuffs (Zootechnical Products) Regulations 1999 becomes an approval referred to in Article 10(1) of Regulation (EC) No. 183/2005.

(9) An approval of a third country establishment under Part V of the Feedingstuffs (Zootechincal Products) Regulations 1999 becomes an authorisation under Article 24 of Regulation (EC) No. 183/2005.

(10) An animal test certificate granted under the Medicines Act 1968 becomes an animal test certificate under these Regulations.

(11) A special treatment authorisation granted by the Secretary of State becomes an import certificate granted under regulation 25 of these Regulations and a treatment certificate granted under paragraph 7 of Schedule 4, as appropriate.

(12) An exemption under section 9(2) of the Medicines Act 1968 and issued as an emergency product licence becomes an authorisation to manufacture an autogenous vaccine under these Regulations.

(13) A specific batch control certificate granted by the Secretary of State becomes an authorisation under specific batch control granted under these Regulations.

Suitably qualified persons

2. Each person who is a suitably qualified person in relation to the supply of a veterinary medicinal product for the purposes of the Medicines (Exemption for Merchants in Veterinary Drugs) Order 1998 becomes a suitably qualified person for the purposes of Schedule 3, paragraph 9.

Existing applications

3. An application pending when these Regulations come into force shall follow the procedure in these Regulations but the data requirements remain as they were before the Regulations come into force.

Existing procedures

4. A revocation or suspension procedure pending when these Regulations come into force shall follow the procedure in these Regulations.

(**3**) 1968 c. 67; section 8(8) was added by the Medicines Act 1968 (Amendment) Regulations 1993 (S.I. 1993/834), regulation 2; section 24 was amended by the Medicines (Medicines Act 1968 Amendment) Regulations 1977 (S.I. 1997/1050), regulation 4(4), and by the Medicines Act 1968 (Amendment) (No.2) Regulations 1994 (S.I. 1994/276), regulation 5.

Records

5. Any record being kept under any revoked provision when these Regulations come into force must be kept for the time specified in these Regulations, and failure to do so is an offence.

Labels

6. Existing labels may be used for three years from the coming into force of these Regulations unless there is a variation to the marketing authorisation requiring a change to the label.

Fees

7.—(1) Schedule 7 shall not apply to any application made before the coming into force of these Regulations in relation to which the fee payable under legislation revoked by this Schedule has been paid before the coming into force of these Regulations.

(2) Paragraph (1) does not apply where —

(a) an inspection is made after the coming into force of these Regulations in connection with such an application, in which case the inspection fee payable is that due under these Regulations; or

(b) such an application is a renewal application in relation to a permission due to expire after the coming into force of these Regulations, in which case the fee payable is that due under these Regulations.

References to "coming into force"

8. In the Part, references to "coming into force" are to 1st January 2006 in the case of feedingstuffs, and 30th October 2005 in any other case.