SCHEDULE 8

Revocations and amendments.

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.