SCHEDULE 8

Revocations and amendments.

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.

(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.

(**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**) 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.

(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.

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.