SCHEDULE 4 Regulation 8

ADMINISTRATION OF A VETERINARY MEDICINAL PRODUCT OUTSIDE THE TERMS OF A MARKETING AUTHORISATION

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Signature

Explanatory Note

Administration under the cascade

1.—(1) A veterinary surgeon acting under this paragraph may either administer a veterinary medicinal product prescribed by him personally or may direct another person to do so under his responsibility.

(2) If there is no authorised veterinary medicinal product in the United Kingdom for a condition the veterinary surgeon responsible for the animal may, in particular to avoid unacceptable suffering, treat the animal concerned with the following ("the cascade"), cascaded in the following order—

(a) a veterinary medicinal product authorised in the United Kingdom for use with another animal species, or for another condition in the same species; or

(b) if and only if there is no such product that is suitable, either—

(i) a medicinal product authorised in the United Kingdom for human use; or

(ii) a veterinary medicinal product not authorised in the United Kingdom but authorised in another member State for use with any animal species (in the case of a food-producing animal, it must be a food-producing species); or

(c) if and only if there is no such product that is suitable, a veterinary medicinal product prepared extemporaneously by a pharmacist, a veterinary surgeon or a person holding a manufacturing authorisation authorising the manufacture of that type of product.

(3) In the case of a veterinary medicinal product imported from another member State, if the veterinary surgeon has not obtained a certificate from the Secretary of State under regulation 25(5) permitting him to import it, he must obtain a certificate from the Secretary of State before he administers it.

(4) For the purposes of this paragraph a food-producing animal includes an animal belonging to the equidae family unless it has been declared, as not being intended for slaughter for human consumption in accordance with—

(a) the Horse Passports (England) Regulations 2004(**1**);

(**1**) S.I.2004/1397.

(b) the Horse Passports Regulations (Northern Ireland) 2004(**2**);

(c) the Horse Passports (Scotland) Regulations 2005(**3**); or

(d) the Horse Passports (Wales) Regulations 2005(**4**).

(5) Any pharmacologically active substances included in a medicinal product administered to a food-producing animal under the cascade must be listed in Annex I, II or III to Council Regulation (EEC) No. 2377/90.

Withdrawal periods

2.—(1) A veterinary surgeon administering a veterinary medicinal product to a food-producing animal under the cascade must specify an appropriate withdrawal period.

(2) The withdrawal period must ensure that, if there is a maximum residue limit specified for the active substance in Council Regulation (EEC) No. 2377/90, the level of residue of the active substance does not exceed that limit.

(3) In any event, unless the Secretary of State has specified in writing a different withdrawal period for a particular veterinary medicinal product, the withdrawal period (irrespective of whether or not a maximum residue limit is specified in Council Regulation (EEC) No. 2377/90) must not be less than—

(a) 7 days for eggs;

(b) 7 days for milk;

(c) 28 days for meat from poultry and mammals including fat and offal;

(d) 500 degree days(**5**) for fish meat.

(4) In the case of a homeopathic remedy in which active principles figure in Annex II to Council Regulation (EEC) No. 2377/90, the withdrawal period is zero.

Immunological products for serious epizootic disease

3.—(1) In the event of serious epizootic diseases, the Secretary of State may permit in writing the administration of immunological veterinary medicinal products without a marketing authorisation, in the absence of a suitable medicinal product and after informing the Commission of the detailed conditions of use.

(2) He shall publicise any permit as he sees fit.

Immunological products for an imported or exported animal

4. If an animal is imported from, or exported to, a third country, the Secretary of State may permit the administration to that animal of an immunological veterinary medicinal product that is not covered by a marketing authorisation in the United Kingdom but is authorised under the legislation of the third country.

Administration by veterinary surgeons from other member States

5.—(1) Veterinary surgeons practising in another member State may bring into the United Kingdom and administer to animals small quantities of veterinary medicinal products that are not authorised for use in the United Kingdom if—

(**2**) S.R. (NI) 2004 No. 497.
(**3**) S.S.I. 2005/223.
(**4**) S.I. 2005/231 (W. 21).
(**5**) The number of days of the withdrawal period is calculated by dividing 500 by the mean temperature of the water in degrees Celsius.

(a) the quantity does not exceed the requirements for the treatment of specific animals;

(b) the product is authorised in the member State in which the veterinary surgeon is established;

(c) the product is transported by the veterinary surgeon in the original manufacturer's packaging;

(d) in the case of administration to food-producing animals, there is a veterinary medicinal product authorised in the United Kingdom that has the same qualitative and quantitative composition in terms of active substances;

(e) the veterinary surgeon has acquainted himself with the Guide to Professional Conduct issued by the Royal College of Veterinary Surgeons(**6**).

(2) The veterinary surgeon must only supply to the owner or keeper enough veterinary medicinal product to complete the treatment of animals concerned.

(3) He must—

(a) ensure that the withdrawal period specified on the label of the product is complied with, or the United Kingdom withdrawal period for the equivalent product authorised in the United Kingdom if this is longer than the one on the label; and

(b) keep detailed records of the animals treated, the diagnosis, the products administered, the dosage administered, the duration of treatment and the withdrawal period applied, and shall keep them in the United Kingdom for at least three years, and failure to comply with this sub-paragraph is an offence.

(4) The overall range and quantity of veterinary medicinal products carried by the veterinary surgeon must not exceed that generally required for the daily needs of good veterinary practice.

(5) This paragraph does not apply in relation to immunological veterinary medicinal products.

Treatment in exceptional circumstances

6.—(1) the health situation so requires, and where there is no suitable veterinary medicinal product available either as an authorised product or under the cascade, a veterinary surgeon may treat an animal with a medicinal product authorised in a third country; but if the veterinary surgeon has not obtained a certificate from the Secretary of State under regulation 25(5) permitting him to import it, he must obtain a certificate from the Secretary of State before he treats the animal.

(2) The certificate may be granted subject to any condition the Secretary of State thinks fit.

Administration of a homeopathic remedy

7.—(1) A registered homeopathic remedy or a homeopathic remedy prepared and supplied by a pharmacist under paragraph 8 of Schedule 3 may be administered to an animal by anyone, subject to any restrictions specified in its registration.

(2) A homeopathic remedy that was on the market before 1st January 1994 may be administered by anyone.

(3) A veterinary surgeon may administer, either himself or under his responsibility—

(a) a homeopathic remedy authorised for human use, or

(b) a homeopathic remedy prepared extemporaneously by a veterinary surgeon or a person holding a manufacturing authorisation authorising the manufacture of that type of product.

(**6**) Published at www.rcvs.org.uk/PrintFullArticle.asp?NodeID=89642