SCHEDULE 1

Marketing authorisations

PART 9

Homoeopathic veterinary medicinal products

Meaning of "homoeopathic veterinary medicinal product"

61. For the purposes of this Part, a homoeopathic veterinary medicinal product is a veterinary medicinal product (which may contain a number of principles) prepared from substances called homoeopathic stocks in accordance with a homeopathic manufacturing procedure described in the European Pharmacopoeia(**1**) or, if it is not described there, in a pharmacopoeia published by the British Pharmacopoeial Commission or by the competent authority of any member State.

Registration of a homoeopathic veterinary medicinal product

62.—(1) By way of derogation from the provisions of these Regulations requiring a marketing authorisation, a homoeopathic medicinal product may be placed on the market in accordance with a registration by the Secretary of State instead of a marketing authorisation if it complies with this paragraph.

(2) It must not be an immunological product.

(3) The route of administration must be as described in the European Pharmacopoeia or, if it is not described there, by a pharmacopoeia currently used officially in any member State.

(4) There must be a sufficient degree of dilution to guarantee the safety of the product, and in any event it must not contain more than one part in 10,000 of the mother tincture.

Application for registration

63.—(1) An applicant for registration must submit the following to the Secretary of State—

(a) the scientific name or other name of the homoeopathic stock given in a pharmacopoeia, together with a statement of the various routes of administration, pharmaceutical forms and degree of dilution;

(b) a dossier describing how the homoeopathic stock is obtained and controlled, and justifying its homoeopathic nature, on the basis of an adequate bibliography;

(c) in the case of a product containing biological substances, a description of the measures taken to ensure the absence of pathogens;

(d) the manufacturing and control file for each pharmaceutical form and a description of the method of dilution and potentisation;

(e) a copy of the manufacturing authorisation for the product;

(f) copies of any registrations or authorisations obtained for the same medicinal product in other member States;

(g) a mock-up of the outer packaging and immediate packaging;

(h) stability data;

(**1**) ISBN 9287145873

(i) the proposed withdrawal period necessary to ensure that the provisions of Council Regulation (EEC) No. 2377/90 are complied with together with all necessary justification.

(2) These documents must demonstrate, in particular, the pharmaceutical quality and the batch-to-batch homogeneity of the products concerned.

(3) If a product is registered in another member State, the Secretary of State may waive some or all of the requirements of this paragraph if she is satisfied that it is reasonable to do so.

Procedure for registration

64.—(1) The procedure for registration is the same as the procedure for granting a marketing authorisation in accordance with Part 3, except—

(a) the applicant is not required to provide proof of therapeutic effect;

(b) the product shall not have a summary of product characteristics;

(c) the Secretary of State shall not publish an assessment report.

(2) The procedure for variation, suspension and revocation is the same as for a marketing authorisation.

Products on the market before 1994

65. The requirement to register does not apply in relation to a product that was on the market as a veterinary medicinal product before 1st January 1994.

Administration

66. The registration must specify that a homoeopathic veterinary medicinal product may only be administered under the responsibility of a veterinary surgeon.