

SCHEDULE 1

Marketing authorisations

PART 9

Homeopathic remedies

Meaning of “homeopathic remedy”

62. For the purposes of these Regulations, a homeopathic remedy is a veterinary medicinal product (which may contain a number of principles) prepared from homeopathic 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.

Placing a homeopathic remedy on the market in accordance with a registration

63.—(1) By way of derogation from the provisions of these Regulations requiring a marketing authorisation for a veterinary medicinal product, a homeopathic remedy may be placed on the market in accordance with a registration by the Secretary of State instead of in accordance with 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.

(5) All other provisions relating to marketing authorisations apply in the same way to registrations of a homeopathic remedy.

Application for registration

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

- (a) the scientific name or other name of the homeopathic 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 homeopathic stock is obtained and controlled, and justifying its homeopathic 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 potentiation;
- (e) a copy of the manufacturing authorisation for the product;
- (f) copies of any registrations or authorisations obtained for the same homeopathic remedy in other member States;
- (g) a mock-up of the outer packaging and immediate packaging;

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- (h) stability data;
 - (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 the pharmaceutical quality and the batch-to-batch homogeneity of the products concerned.
- (3) In the case of a food-producing animal, if the applicant states in the application that the homeopathic remedy contains an active substance, or has been manufactured using an active substance, that substance must be one that appears in Annex II to Regulation (EEC) No. 2377/90 and complies with any requirements in that Annex relating to that substance.
- (4) 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 he is satisfied that it is reasonable to do so.

Procedure for registration

- 65.—(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 efficacy;
 - (b) the product is not required to have a summary of product characteristics;
 - (c) the Secretary of State is not required to 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

66. A homeopathic remedy that was on the market before 1st January 1994 may be placed on the market without being registered.

Classification

67. The registration must specify the classification of the homeopathic remedy, which must be one of the classifications specified for a veterinary medicinal product in Schedule 3.