SCHEDULE 1

Marketing authorisations

PART 4

Variations of marketing authorisations on the application of the holder

Variation of a marketing authorisation for a mutually recognised veterinary medicinal product

33. Where a veterinary medicinal product is authorised in more than one member State, the Secretary of State is the competent authority for the purposes of Commission Regulation (EC) No. 1084/2003 (concerning the examination of variations to the terms of a marketing authorisation for medicinal products for human use and veterinary medicinal products granted by a competent authority of a member State)(**1**).

Variation of a marketing authorisation not authorised in another member State

34.—(1) Where a veterinary medicinal product is not authorised in another member State, an application to vary it must be made by the holder to the Secretary of State.

(2) Paragraph 24 of this Schedule (refusal of a marketing authorisation) applies to an application for a variation in the same way as it applies to an application for a marketing authorisation.

(3) The Secretary of State, when granting a variation of a veterinary medicinal product must (unless there are exceptional circumstances necessary to protect human or animal health or the environment) specify transitional measures to enable products produced in accordance with the previous authorisation to continue to be marketed for the transitional period.

(4) The Secretary of State must give written reasons for refusing to grant a variation; and if those reasons are on the grounds of safety, quality or efficacy, the applicant may appeal to the Veterinary Products Committee.

Administrative variations

35.—(1) The holder of a marketing authorisation may apply for a minor change in a marketing authorisation to be made without the Secretary of State considering any scientific data (an "administrative variation").

(2) If the Secretary of State grants an administrative variation, and subsequently establishes that this should have been a variation requiring consideration of scientific data, the Secretary of State may notify the marketing authorisation holder, require the holder to submit an application for a variation enabling data to be assessed and revoke the administrative variation.

Changes after a marketing authorisation has been issued

36. After a marketing authorisation has been issued, the holder must take account of scientific and technical progress in manufacturing and control methods, and apply to the Secretary of State for any variation in the marketing authorisation that may be required to enable that veterinary medicinal product to be manufactured and checked by means of generally accepted scientific methods.

(**1**) OJ No. L 159, 27.6.2003, p. 1.

Compulsory variation

37.—(1) If the Secretary of State decides, for any of the reasons for suspending a marketing authorisation specified in paragraph 38, or because the classification of a veterinary medicinal product should be changed, that a variation to a marketing authorisation is necessary, the Secretary of State must notify the marketing authorisation holder in writing of the required variation, together with the reasons.

(2) The notification may specify a time limit within which the marketing authorisation holder must apply for the variation.

(3) If the variation is on the grounds of safety, quality or efficacy, the applicant may, within 28 days of the notification, appeal to the Veterinary Products Committee.

(4) If the marketing authorisation holder fails to apply for the variation within that time limit the Secretary of State may suspend or revoke the marketing authorisation.