SCHEDULE 1

Marketing authorisations

PART 4

Variations of marketing authorisations on the application of the holder

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.