SCHEDULE 1

Marketing authorisations

PART 2

Derogations from some of the requirements in Part 1

Bibliographic application

7.—(1) An applicant for a marketing authorisation need not provide the results of safety tests, residue tests, pre-clinical trials or clinical trials if the active substance of the veterinary medicinal product has been in an authorised veterinary medicinal product for that species in the Community for at least ten years, and the applicant provides appropriate scientific literature to demonstrate this.

(2) He may use any publicly available document.

(3) If an applicant makes use of scientific literature to obtain authorisation for a food-producing species, and submits, in respect of the same medicinal product and with a view to obtaining authorisation for another food-producing species, new residue studies, together with further clinical trials, a third party may not use those studies or trials in an application for a pharmacologically equivalent product for a period of three years from the grant of the authorisation for the additional species.