SCHEDULE 1

MARKETING AUTHORISATIONS

PART 2

Derogations from some of the requirements in Part 1

Application for a product using a new combination of active substances

8. If an application is for a veterinary medicinal product containing active substances already used in an authorised veterinary medicinal product but not previously used in that combination in a veterinary medicinal product, he need not provide the safety and efficacy data for the individual active substances.