SCHEDULE 1

MARKETING AUTHORISATIONS

PART 2

Derogations from some of the requirements in Part 1

Application for a pharmacologically equivalent medicinal product

10.—(1) An applicant need not provide the results of safety tests, residue tests, pre-clinical trials or clinical trials if he can demonstrate that the veterinary medicinal product is pharmacologically equivalent to a veterinary medicinal product already authorised in the Community.

(2) For the purposes of this paragraph a product is pharmacologically equivalent to an existing product if—

(a) it has the same qualitative and quantitative composition in active substances;

(b) it has the same pharmaceutical form; and

(c) bioequivalence has been demonstrated by means of appropriate bioavailability studies.

(3) For the purposes of this paragraph—

(a) the different salts, esters, ethers, isomers, mixtures of isomers, complexes or derivatives of an active substance shall be considered to be the same active substance, unless they differ significantly in properties with regard to safety or efficacy; and

(b) if they do differ significantly in properties with regard to efficacy or safety, additional information intended to provide proof of the safety or efficacy of the various salts, esters or derivatives of an authorised active substance must be supplied by the applicant.

(4) Different immediate-release oral pharmaceutical forms are regarded as the same pharmaceutical form.

(5) Bioavailability studies are not required if the bioequivalence guidelines produced by the Agency exempt the product.

(6) In the case of a reference product authorised in another member State but not in the United Kingdom, the Secretary of State must be satisfied that the risk-benefit balance of the original product is appropriate for the product to be placed on the market in the United Kingdom, and if the data provided under Article 13, third paragraph of Directive 2001/82/EC by the member State in which the product is authorised are insufficient for him to be satisfied of this, he may notify the applicant and require the applicant to provide further data.