

SCHEDULE 5

TRANSITIONAL PROVISIONS

PART 3

TRANSITIONAL PROVISIONS IN RELATION TO THE GRANT, RENEWAL, REVOCATION, SUSPENSION OR VARIATION OF MARKETING AUTHORIZATIONS UNDER THE MARKETING AUTHORIZATION REGULATIONS

Marketing authorisation applications or proposals where appropriate committee has given advice to the licensing authority before 30th October 2005

9.—(1) This paragraph applies where, before 30th October 2005, the licensing authority have given notice to the applicant or holder of—

- (a) the advice referred to in paragraph 7 of this Schedule; and
- (b) of its decision made under paragraph 7 of Schedule 2 to the Marketing Authorization Regulations.

(2) If, before 30th October 2005—

- (a) the applicant or holder has not given notice of his desire to be heard by, or to make written representations to, the Medicines Commission; and
- (b) the period of 28 days after the service of the notice referred to in sub-paragraph (1), or such longer period as the licensing authority has allowed in the particular case, has not expired,

the applicant or holder may, by 30th November 2005, give notice to the licensing authority of his wish to make written or oral representations to the Commission.

(3) If, before 30th October 2005—

- (a) the applicant or holder made written representations in relation to a decision of the licensing authority which was made after the advice referred to in paragraph 7 had been given; and

(b) those representations were made within—

- (i) the period of 28 days after the service of the licensing authority's notice referred to in sub-paragraph (1), or
- (ii) such longer period as the licensing authority had allowed,

the applicant or holder may, by 30th November 2005, give notice of his wish to make oral representations, or additional written representations, to the Commission.