

SCHEDULE 2

PROCEDURAL PROVISIONS RELATING TO THE GRANT, REVOCATION AND SUSPENSION OF UNITED KINGDOM MARKETING AUTHORIZATIONS

Licensing Authority's decision

7.—(1) In the case of an application for the grant of an authorization the licensing authority shall then (subject to the following provisions of this Schedule) either grant or refuse the application and may grant it with provisions otherwise than in accordance with the application.

(2) In the case of an application of the renewal of an authorization the licensing authority shall either renew the authorization (whether or not in accordance with the application) or decide that it is still minded to refuse it.

(3) In the case of a proposal to revoke, suspend or vary an authorization the licensing authority shall decide whether or not to proceed further with the proposal.

(4) The licensing authority shall give notice to the applicant or holder of the advice given to it by the appropriate committee or the Medicines Commission, of the reasons for that advice, and of its decision made in accordance with sub-paragraphs (1), (2) or (3) above.