SCHEDULE 2 Regulations 5(3) and 6(7)

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

Interpretation

1. In this Schedule—

"appropriate committee" has the meaning assigned to it by section 4(6) of the Act;

"authorization" means a United Kingdom marketing authorization; and

"the time allowed" means the period of twenty-eight days or such extended period as the licensing authority may in any particular case allow.

Scope and application of the procedural provisions

2.—(1) Subject to paragraphs 3 and 4 below, this Schedule applies to any application for the grant or renewal of a marketing authorization for a relevant medicinal product where, throughout the period beginning with the date on which the application is made and ending with the date on which the licensing authority give a decision on the application, either—

(a) there is no other marketing authorization in force in respect of the product anywhere in the Community; or

(b) any day in that period falls within the period beginning with 1st January 1995, and ending with 31st December 1997.

(2) Subject to paragraphs 3 and 4 below, this Schedule also applies to every proposal to revoke, vary or suspend an authorization for a relevant medicinal product where there is no such other authorization in force at the time of the proposal.

3. This Schedule shall cease to apply if at any time the matter is, by virtue of any relevant Community provision, referred to the Committee for Proprietary Medicinal Products for the application of the procedure laid down in Article 13 of Council Directive 75/319/EEC.

4. This Schedule does not apply—

(a) if the licensing authority make a decision in relation to the application in accordance with Article 7.2 of the 1965 Directive (suspension of detailed examination of an application under active examination in another Member State); or

(b) the application or proposal relates to the renewal or variation of a marketing authorization which has been granted in accordance with the provisions of Chapter III of Council Directive 75/319 EEC or which has been granted by Member States in accordance with Article 4 of Council Directive 87/22/EEC before 1st January 1995; or

(c) to the variation of an authorization on the application of holder.

Requirement to consult the appropriate committee or the Medicines Commission

5. The licensing authority shall not, at any time while this Schedule applies, refuse to grant or renew the authorization applied for, or revoke, vary (other than on the application of the holder) or (subject to paragraph 13 below) suspend the relevant authorization on grounds other than those relating to the accuracy or completeness of an application, except after consultation with the appropriate committee or, if for the time being there is no such committee, the Medicines Commission.

Provisional opinion against authorization

6.—(1) Where the appropriate committee or the Medicines Commission are consulted under paragraph 5 and are of the provisional opinion that, on grounds relating to safety, quality or efficacy, they—

(a) may be unable to advise the licensing authority to grant or renew the authorization; or

(b) may be unable to advise the licensing authority to grant it unless it contains provisions otherwise than in accordance with the application; or

(c) may have to advise the licensing authority that the authorization ought to be revoked, varied or suspended,

the committee or Medicines Commission shall notify the applicant or holder accordingly.

(2) A person who has been notified in accordance with sub-paragraph (1) above may within the time allowed after the giving of the notification give notice of his wish to make written or oral representations to the appropriate committee or the Medicines Commission, as the case may be, and the committee or Medicines Commission, having given him an opportunity to make written or oral representations, shall take into acount such representations as are made.

(3) The appropriate committee or the Medicines Commission shall report their findings and advice to the licensing authority together with the reasons for their advice and the licensing authority shall take the report into account in deciding whether to grant the authorization, or to continue with the proposal to refuse to renew or to revoke, vary or suspend it.

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.

Confirmation or alteration of the decision after taking into account the advice of the Medicines Commission

8.—(1) If a person is dissatisfied with the decision as notified to him under paragraph 7, and he has not made representations to the Medicines Commission under paragraph 6, he may give notice to the licensing authority of his wish to make written or oral representations to the Medicines Commission.

(2) On receipt of a notice under sub-paragraph (1) above the licensing authority shall arrange for the person who gave it to be heard by the Medicines Commission or, as the case may be, for his written representations to be considered by them.

(3) After considering the representations (oral or written) the Medicines Commission shall report their findings and advice, and the reasons for their advice, to the licensing authority who shall take it into account in deciding whether to confirm or alter its decision under paragraph 7.

(4) The licensing authority shall give notice to the applicant or holder of the Medicines Commission's advice and of the reasons for it, and of the confirmation or alteration of its decision under paragraph 7.

Person appointed to hear representations

9. If the licensing authority—

(a) determine an application in a way which differs from the advice of the Medicines Commission under paragraph 6, or propose to refuse to renew or propose to revoke, vary or suspend a marketing authorization against such advice, or propose not to alter their decision or propose to continue with their proposal following the advice of the Medicines Commission under paragraph 8; or

(b) where there has been no hearing before, and no representations have been made or referred to, the Medicines Commission, determine an application, or propose to refuse to renew or propose to revoke, vary or suspend a marketing authorization, in a way which differs from the advice of the appropriate committee under paragraph 6; or

(c) in the absence of any such advice as is mentioned in either of the preceding sub-paragraphs, determine an application, or propose to refuse to renew or to revoke, vary or suspend a marketing authorization, in a way which differs from the advice given by the appropriate committee or the Medicines Commission; or

(d) propose, on grounds not relating to safety, quality or efficacy—

(i) not to grant or renew an authorization;

(ii) to grant or renew an authorization otherwise than in accordance with the application; or

(iii) to revoke, vary or suspend an authorization,

the licensing authority (in any case where a decision on the application has not already been made, before determining the application) shall notify the applicant or holder accordingly.

10. Any notification given under paragraph 9—

(a) in a case falling within sub-paragraph (a), (b) or (c) of that paragraph, shall state the advice of the Medicines Commission or of the appropriate committee and the reasons stated by the Medicines Commission or the committee for giving that advice;

(b) in a case falling within sub-paragraph (d) of that paragraph (whether it also falls within any of the other sub-paragraphs of that paragraph or not), shall include a statement of the proposals of the licensing authority and of the reasons for them.

Right to be heard by a person appointed or to make further representations

11. A person to whom notification has been given under paragraph 9 may, within the time allowed after the notification was given, give notice of his wish to appear before and be heard by a person appointed for the purpose by the licensing authority, or of making representations in writing to the licensing authority with respect to the decision or proposal referred to in the notification.

12.—(1) Where the applicant or holder gives notice under paragraph 11 of his wish to appear before and be heard by a person appointed for the purpose by the licensing authority, the licensing authority shall make that appointment and—

(a) the person so appointed shall not, except with the consent of the applicant or holder, be an officer or servant of any of the Ministers specified in paragraphs (a) and (b) of section 1(1) of the Act;

(b) if the applicant or holder so requests, the hearing shall be in public; and

(c) if the applicant or holder so requests, the licensing authority shall furnish to him a copy of the report of the person so appointed.

(2) The licensing authority shall take into account the report of the person appointed and decide whether to renew the authorization, revoke, vary or suspend the authorization or confirm or alter its decision, as the case may be.

Cases where suspension is to have immediate effect

13. Paragraph 5 shall not apply to the suspension of an authorization (whether or not it applies to any existing proposal to suspend or revoke the authorization) where it appears to the licensing authority that, in the interests of safety, it is necessary to suspend the authorization with immediate effect for a period not exceeding three months, but where the licensing authority, by virtue of this paragraph, so suspends an authorization it shall report the suspension forthwith to the appropriate committee or, if for the time being there is no such committee, the Medicines Commission.

14. If after suspending an authorization with immediate effect by virtue of paragraph 13, it appears to the licensing authority that, or the appropriate committee or the Medicines Commission advise that, the authorization ought to be further suspended or revoked the licensing authority shall proceed in accordance with the applicable provisions of this Schedule (including paragraph 13).