SCHEDULE 2 Regulations 6(2), 7(7)

PROCEDURAL PROVISIONS RELATING TO THE GRANT, RENEWAL, VARIATION, REVOCATION AND SUSPENSION OF TRADITIONAL HERBAL REGISTRATIONS

PART 1

INTERPRETATION AND APPLICATION

Interpretation

1. In this Schedule—

"active ingredient from a new source" means an active ingredient in respect of which the application names as manufacturer a manufacturer not previously named as the manufacturer of that active ingredient included in a medicinal product in respect of which a marketing authorization (other than a product licence of right) or a traditional herbal registration has previously been granted;

"complex variation application" means an application by a traditional herbal registration holder to vary a traditional herbal registration which relates to a change in the formulation of a medicinal product comprising one or more of the following changes—

(a) a change in that product's active ingredients which involves the addition of one or more active ingredients which are active ingredients from a new source;

(b) a change in that product's excipients which involves the addition of one or more TSE risk excipients from a new source; or

(c) a change which involves the addition of one or more vitamins or minerals which are vitamins or minerals from a new source where no European Pharmacopoeia certificate of suitability covering those vitamins or minerals has been submitted with the application;

"new excipient" means any ingredient of a medicinal product, other than an active ingredient, that has not previously been included in a medicinal product which is intended to be administered by the same route of administration as the product in question and in respect of which a marketing authorization (other than a product licence of right) or a traditional herbal registration has previously been granted, except that—

(a) in the case of a medicinal product intended to be administered orally, the expression does not include any ingredient specified in any enactment (including an enactment comprised in subordinate legislation or in any Directive, Regulation or Decision of the European Community) as an approved ingredient or additive in food or in a food product; and

(b) in the case of a medicinal product intended for external use only, the expression does not include any ingredient specified in any enactment (including an enactment comprised in subordinate legislation or in any Directive, Regulation or Decision of the European Community) as an approved ingredient or additive in a cosmetic product;

"new excipient variation application" means an application, other than a complex variation application, by a traditional herbal registration holder to vary a traditional herbal registration which relates to a change in the formulation of the medicinal product to add a new excipient;

"the time allowed" means the period of twenty-eight days beginning with the date of the relevant notification, or such longer period as the licensing authority may allow in any particular case;

"TSE risk excipient from a new source" means an excipient which has been manufactured from raw materials of ruminant origin or which has had raw materials of ruminant origin used in its manufacture and in respect of which—

(a) the application names as manufacturer a manufacturer not previously named as the manufacturer of that excipient included in a medicinal product in respect of which a marketing authorization (other than a product licence of right) or a traditional herbal registration has previously been granted; and

(b) no European Pharmacopoeia certificate of suitability covering the excipient has been submitted with the application;

"vitamin or mineral from a new source" means a vitamin or mineral in respect of which the application names as manufacturer a manufacturer not previously named as the manufacturer of that vitamin or mineral included in a medicinal product in respect of which a marketing authorization (other than a product licence of right) or a traditional herbal registration has previously been granted.

Scope and application of this Schedule

2. Subject to paragraphs 6 and 7, Part 2 applies to—

(a) any application for the grant of a traditional herbal registration for a traditional herbal medicinal product except one made pursuant to the procedure in Article 28 of the 2001 Directive;

(b) any application to renew a traditional herbal registration for a traditional herbal medicinal product; and

(c) any proposal to revoke, vary or suspend a traditional herbal registration for a traditional herbal medicinal product, other than a variation on the application of the holder of that traditional herbal registration.

3. Subject to paragraphs 6 and 7, Part 3 applies to any application to vary a traditional herbal registration for a traditional herbal medicinal product which is a complex or a new excipient variation application.

4. Subject to paragraphs 6 and 7, Part 4 applies where the licensing authority propose to refer an application for the grant of a traditional herbal registration for a traditional herbal medicinal product to the Committee for Herbal Medicinal Products in accordance with Article 16c(4) of the 2001 Directive.

5. Subject to paragraphs 6 and 7, Part 5 applies where—

(a) an applicant for a traditional herbal registration for a traditional herbal medicinal product, or for the variation or renewal of such a traditional herbal registration; or

(b) the holder of a traditional herbal registration for a traditional herbal medicinal product,

gives notice under paragraphs 12, 17 or 20 of his wish to appear before or be heard by a person appointed by the licensing authority.

6. This Schedule shall cease to apply if at any time the relevant matter is, by virtue of any relevant Community provision, referred to the Committee for Herbal Medicinal Products for the application of the procedure laid down in Articles 32 to 34 of the 2001 Directive.

7. This Schedule does not apply—

(a) if an application relates to a traditional herbal medicinal product in respect of which either of the conditions set out in Article 16d(1) are fulfilled and—

(i) the licensing authority declines to assess the application because an application for an EC traditional herbal registration in another EEA State is being examined in

that State and the application to the licensing authority has not been submitted in accordance with Article 28(1) and (3) of the 2001 Directive; or

(ii) the licensing authority rejects the application where the traditional herbal medicinal product in question has an EC traditional herbal registration in another EEA State and the application has not been submitted in accordance with Article 28(1) and (2) of the 2001 Directive;

(b) if the application or proposal relates to the renewal, revocation, suspension or variation of a traditional herbal registration which has been granted—

(i) in accordance with the provisions of Title III, Chapter 4 of the Directive; or

(ii) which has not been so granted, but which has been subject to the procedure laid down in Articles 32 to 34 of the Directive following a referral under Article 30 or 31 of that Directive, unless the procedure was limited to certain specific parts of the traditional herbal registration; or

(c) if the licensing authority refuse to grant the traditional herbal registration applied for following a referral to the Committee for Herbal Medicinal Products in accordance with Article 16c(4) where the Committee for Herbal Medicinal Products has not supported the grant of the application.

PART 2

PROCEDURES RELATING TO GRANT, RENEWAL, COMPULSORY VARIATION, REVOCATION OR SUSPENSION OF TRADITIONAL HERBAL REGISTRATIONS

Requirement to consult the appropriate committee

8. The licensing authority shall not, at any time while this Schedule applies—

(a) refuse to grant or renew the traditional herbal registration applied for; or

(b) revoke, vary or (subject to paragraph 13 of this Schedule) suspend a traditional herbal registration,

on grounds relating to safety, quality or efficacy, except after consultation with the appropriate committee.

Provisional opinion against traditional herbal registration

9.—(1) Where the appropriate committee are consulted under the preceding paragraph 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 traditional herbal registration; 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 traditional herbal registration ought to be revoked, varied or suspended,

the appropriate committee shall notify the applicant or holder accordingly.

(2) A person who has been so notified may, within the time allowed, give notice of his wish to make written or oral representations to the appropriate committee.

(3) The appropriate committee shall give the applicant or holder an opportunity to make such representations in accordance with sub-paragraphs (4) to (7).

(4) Subject to sub-paragraph (5), the applicant or holder shall provide the appropriate committee with—

(a) his written representations or a written summary of the oral representations he intends to make; and

(b) any documents on which he wishes to rely in support of those representations,

before the end of the period of six months beginning with the date of the notice referred to in sub-paragraph (2), or within such shorter period as the appropriate committee may specify in the notification under sub-paragraph (1).

(5) If the applicant or holder so requests, the appropriate committee may extend the time limit referred to in sub-paragraph (4), up to a maximum period of twelve months beginning with the date of the notice referred to in sub-paragraph (2).

(6) The applicant or holder may not submit any additional written representations or documents once the time limit referred to in sub-paragraphs (4) and (5) has expired, except with the permission of the appropriate committee.

(7) If the applicant or holder gave notice of his wish to make oral representations, the appropriate committee shall, after receiving a written summary and any other documents in accordance with sub-paragraph (4), arrange for the applicant or holder to make such representations at a hearing before the committee.

(8) The appropriate committee shall—

(a) take into account such representations as are made in accordance with this paragraph; and

(b) report their findings and advice to the licensing authority, together with the reasons for their advice.

Licensing authority's decision after appropriate committee report

10.—(1) After receiving the report of the appropriate committee pursuant to paragraph 9(8) the licensing authority shall—

(a) decide whether to refuse to grant or renew the traditional herbal registration, or to grant or renew it otherwise than in accordance with the application, or to proceed further with their proposal to revoke, vary or suspend the traditional herbal registration; and

(b) take the report into account when making their decision.

(2) The licensing authority shall then notify the applicant or holder of—-

(a) the decision made pursuant to sub-paragraph (1); and

(b) the advice given to them by the appropriate committee and the reasons for that advice.

Licensing authority proposals in other cases

11.—(1) If—

(a) the appropriate committee was consulted pursuant to paragraph 8;

(b) the committee did not give a provisional opinion under paragraph 9(1); and

(c) the licensing authority propose—

(i) to determine the application in a way which differs from the advice of the committee,

(ii) to revoke, vary or suspend a traditional herbal registration against such advice, or

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

(aa) not to grant or renew a traditional herbal registration,

(bb) to grant or renew a traditional herbal registration otherwise than in accordance with an application, or

(cc) to revoke, vary or suspend a traditional herbal registration,

the licensing authority shall notify the applicant or holder accordingly.

(2) If—

(a) the appropriate committee has not been consulted pursuant to paragraph 8; and

(b) the licensing authority propose, on grounds not relating to safety, quality or efficacy—

(i) not to grant or renew a traditional herbal registration,

(ii) to grant or renew a traditional herbal registration otherwise than in accordance with an application, or

(iii) to revoke, vary or suspend a traditional herbal registration,

the licensing authority shall notify the applicant or holder accordingly.

(3) A notification given under sub-paragraph (1) or (2) shall state—

(a) the advice of the appropriate committee, if any, and the reasons stated by the committee for any such advice; and

(b) the proposals of the licensing authority and the reasons for them.

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

12.—(1) Subject to sub-paragraph (4), a person to whom a notification has been given under paragraph 10(2) may, within the time allowed, notify the licensing authority that he wishes to appear before and be heard by a person appointed by the licensing authority with respect to the decision.

(2) A person to whom a notification has been given under paragraph 11(1) or (2) may, within the time allowed—

(a) notify the licensing authority that he wishes to appear before and be heard by a person appointed for the purpose by the licensing authority, or

(b) make representations in writing to the licensing authority with respect to the proposal referred to in the notification.

(3) If the applicant makes written representations in accordance with sub-paragraph (2)(b) of this paragraph, the licensing authority shall take those representations into account before determining the matter.

(4) Sub-paragraph (1) shall not apply where—

(a) the person has not made any representations in accordance with paragraph 9(4) to (7); and

(b) the decision of the licensing authority was in accordance with the advice of the appropriate committee.

Cases where suspension is to have immediate effect

13.—(1) Paragraph 8 shall not apply to the suspension of a traditional herbal registration (whether or not it applies to any existing proposal to suspend or revoke the traditional herbal registration) where it appears to the licensing authority that, in the interests of safety, it is necessary to suspend the traditional herbal registration with immediate effect for a period not exceeding three months.

(2) Where the licensing authority so suspend a traditional herbal registration they shall report the suspension forthwith to the appropriate committee.

14. If, after suspending a traditional herbal registration with immediate effect by virtue of paragraph 13—

(a) it appears to the licensing authority; or

(b) the appropriate committee advise,

that the traditional herbal registration ought to be further suspended, or ought to be varied or revoked, the licensing authority shall proceed in accordance with the applicable provisions of this Schedule (including paragraph 13).

PART 3

VARIATION OF TRADITIONAL HERBAL REGISTRATION ON APPLICATION OF HOLDER

Hearing before appropriate committee

15.—(1) If the licensing authority decide, on grounds relating to safety, quality or efficacy—

(a) to refuse to grant a complex variation application or a new excipient variation application; or

(b) to grant it otherwise than in accordance with the application,

they shall notify the applicant accordingly.

(2) A person who has been notified in accordance with sub-paragraph (1) may, within the time allowed, give notice to the licensing authority of his wish to make written or oral representations to the appropriate committee.

(3) On receipt of a notice under sub-paragraph (2), the licensing authority shall inform the appropriate committee and the committee shall give the applicant an opportunity to make such representations in accordance with sub-paragraphs (4) to (7).

(4) Subject to sub-paragraph (5), the applicant shall provide the appropriate committee with—

(a) his written representations or a written summary of the oral representations he intends to make; and

(b) any documents on which he wishes to rely in support of those representations,

before the end of the period of six months beginning with the date of the notice referred to in sub-paragraph (1), or within such shorter period as the licensing authority may specify in the notification referred to in sub-paragraph (1).

(5) If the applicant so requests, the appropriate committee may extend the time limit referred to in sub-paragraph (4), up to a maximum period of twelve months beginning with the date of the notice referred to in sub-paragraph (2).

(6) The applicant may not submit any additional written representations or documents once the time limit referred to in sub-paragraphs (4) and (5) has expired, except with the permission of the appropriate committee.

(7) If the applicant gave notice of his wish to make oral representations, the appropriate committee shall, after receiving a written summary and any other documents in accordance with sub-paragraph (4), arrange for the applicant to make such representations at a hearing before the committee.

(8) The appropriate committee shall—

(a) take into account such representations as are made in accordance with this section; and

(b) report their findings and advice to the licensing authority, together with the reasons for their advice.

Licensing authority decision

16.—(1) After receiving the report of the appropriate committee, the licensing authority shall—

(a) confirm or alter their decision; and

(b) take the report into account before doing so.

(2) The licensing authority shall notify the applicant of—

(a) the decision made pursuant to sub-paragraph (1); and

(b) the advice given to them by the appropriate committee and the reasons for that advice.

Right to be heard by a person appointed

17.—(1) Subject to sub-paragraph (2), if the licensing authority notify the applicant of the authority's decision—

(a) to refuse the application; or

(b) to grant it otherwise than in accordance with the application,

the applicant may, within the time allowed, notify the licensing authority that he wishes to appear before and be heard by a person appointed by the licensing authority with respect to the decision.

(2) Sub-paragraph (1) shall not apply where—

(a) the person had not made any representations in accordance with paragraph 15(4) to (7); and

(b) the decision of the licensing authority was in accordance with the advice of the appropriate committee.

PART 4

REFERRAL TO THE COMMITTEE FOR HERBAL MEDICINAL PRODUCTS IN ACCORDANCE WITH ARTICLE 16C(4) OF THE 2001 DIRECTIVE

Hearing before appropriate committee

18.—(1) If the licensing authority propose to refer an application for a traditional herbal registration to the Committee for Herbal Medicinal Products in accordance with Article 16c(4) of the 2001 Directive they shall notify the applicant accordingly.

(2) A person who has been notified in accordance with sub-paragraph (1) may, within the time allowed, give notice to the licensing authority of his wish to make written or oral representations to the appropriate committee.

(3) On receipt of a notice under sub-paragraph (2), the licensing authority shall inform the appropriate committee and the committee shall give the applicant an opportunity to make such representations in accordance with sub-paragraphs (4) to (7).

(4) Subject to sub-paragraph (5), the applicant shall provide the appropriate committee with—

(a) his written representations or a written summary of the oral representations he intends to make; and

(b) any documents on which he wishes to rely in support of those representations,

before the end of the period of six months beginning with the date of the notice referred to in sub-paragraph (1), or within such shorter period as the licensing authority may specify in the notification referred to in sub-paragraph (1).

(5) If the applicant so requests, the appropriate committee may extend the time limit referred to in sub-paragraph (4), up to a maximum period of twelve months beginning with the date of the notice referred to in sub-paragraph (2).

(6) The applicant may not submit any additional written representations or documents once the time limit referred to in sub-paragraphs (4) and (5) has expired, except with the permission of the appropriate committee.

(7) If the applicant gave notice of his wish to make oral representations, the appropriate committee shall, after receiving a written summary and any other documents in accordance with sub-paragraph (4), arrange for the applicant to make such representations at a hearing before the committee.

(8) The appropriate committee shall—

(a) take into account such representations as are made in accordance with this section; and

(b) report their findings and advice to the licensing authority, together with the reasons for their advice.

Licensing authority decision

19.—(1) After receiving the report of the appropriate committee, the licensing authority shall—

(a) decide whether to proceed with their proposal; and

(b) take the report into account before doing so.

(2) The licensing authority shall notify the applicant of—

(a) the decision made pursuant to sub-paragraph (1); and

(b) the advice given to them by the appropriate committee and the reasons for that advice.

Right to be heard by a person appointed

20.—(1) Subject to sub-paragraph (2), if the licensing authority notify the applicant of the authority's decision to refer the application to the Committee for Herbal Medicinal Products as proposed, the applicant may, within the time allowed, notify the licensing authority that he wishes to appear before and be heard by a person appointed by the licensing authority with respect to the decision.

(2) Sub-paragraph (1) shall not apply where—

(a) the person had not made any representations in accordance with paragraph 18(4) to (7); and

(b) the decision of the licensing authority was in accordance with the advice of the appropriate committee.

PART 5

HEARING BEFORE PERSON APPOINTED

Hearing before person appointed

21.—(1) If an applicant or holder of a traditional herbal registration gives notice under paragraphs 12, 17 or 20 of his wish to appear before or be heard by a person appointed by the licensing authority, the authority shall—

(a) make that appointment; and

(b) arrange for the applicant or holder to have an opportunity of appearing before that person.

(2) The person appointed—

(a) shall not be, or at any time have been, a member of—

(i) the Commission on Human Medicines or any of its Expert Advisory Groups,

(ii) the Medicines Commission formerly established under section 2 of the Act or any of its committees, or

(iii) a committee established under section 4 of the Act, or any sub-committee of such a committee; and

(b) shall not be an officer or servant of a Minister of the Crown.

(3) Subject to sub-paragraph (4), the applicant or holder shall provide the person appointed with—

(a) a written summary of the oral representations he intends to make; and

(b) any documents on which he wishes to rely in support of those representations,

before the end of the period of three months beginning with the date of the notice referred to in sub-paragraph (1).

(4) If the applicant or holder so requests, the person appointed may, after consulting the licensing authority, extend the time limit referred to in sub-paragraph (3), up to a maximum period of six months beginning with the date of the notice referred to in sub-paragraph (1).

(5) If the applicant or holder fails to comply with the time limit in sub-paragraph (3) or, where he has been granted an extended time limit under sub-paragraph (4), that time limit—

(a) he may not appear before or by heard by the person appointed; and

(b) the licensing authority shall decide whether—

(i) to confirm or alter their decision,

(ii) to refer the application to the Committee for Herbal Medicinal Products,

(iii) to grant or renew the traditional herbal registration,

(iv) to grant or renew the traditional herbal registration otherwise than in accordance with the application, or

(v) to revoke, vary or suspend the traditional herbal registration,

as the case may be.

(6) The applicant or holder may not submit any additional written representations or documents once the time limit has expired, except with the permission of the person appointed.

(7) At the hearing before the person appointed, both the applicant or holder and the licensing authority may make representations.

(8) If the applicant or holder so requests the hearing shall be in public.

(9) After the hearing—

(a) the person appointed shall provide a report to the licensing authority; and

(b) the licensing authority shall take this report into account and decide whether—

(i) to confirm or alter their decision,

(ii) to refer the application to the Committee for Herbal Medicinal Products,

(iii) to grant or renew the traditional herbal registration,

(iv) to grant or renew the traditional herbal registration otherwise than in accordance with the application, or

(v) to revoke, vary or suspend the traditional herbal registration,

as the case may be.

(10) The licensing authority shall then—

(a) notify the applicant or holder of their decision;

(b) if the applicant or holder so requests, provide the applicant or holder with a copy of the report of the person appointed.