

SCHEDULE 2

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

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).

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(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).