

## SCHEDULE 2

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

#### 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.

*Status: This is the original version (as it was originally made). This item of legislation is currently only available in its original format.*

**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.