

SCHEDULES

SCHEDULE 11

Advice and representations

PART 3

Referral to the ^{F1}appropriate committee for traditional herbal registrations]

F1 Words in Sch. 11 Pt. 3 heading substituted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **63(8)(a)**; 2020 c. 1, Sch. 5 para. 1(1)

Application of this Part

24.—(1) This Part applies if the licensing authority proposes to refer an application for a traditional herbal registration to the ^{F2}appropriate committee in accordance with regulation 130A(1)].

^{F3}(2) In relation to an application for a UKMA(NI) or THR(NI), this Part is subject to Part 4 of this Schedule.]

- F2** Words in Sch. 11 para. 24(1) substituted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **63(8)(b)(i)**; 2020 c. 1, Sch. 5 para. 1(1)
- F3** Sch. 11 para. 24(2) substituted (31.12.2020) by S.I. 2019/775, **reg. 63(8)(b)(ii)** (as substituted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 46(d)**)

Opportunity to make representations

25.—(1) The licensing authority must notify the applicant of the authority's proposal.

(2) The applicant may by notice in writing to the licensing authority request the opportunity to make written or oral representations to the appropriate committee.

(3) The applicant must make the request within the period of 28 days beginning with the day on which the notification is given or such longer period as the licensing authority may allow.

(4) The licensing authority must inform the appropriate committee of the applicant or holder's request.

Written representations

26.—(1) If the applicant requests the opportunity to make written representations, the applicant must provide the appropriate committee with those representations and any documents on which the applicant wishes to rely in support of them—

- (a) before the end of the period of six months beginning with the date of the request; or
 - (b) before the end of such shorter period as the licensing authority may specify in the notification under paragraph 25.
- (2) The appropriate committee may, at the request of the applicant, extend the period mentioned in sub-paragraph (1) up to a maximum of twelve months beginning with the date of the request under paragraph 25.
- (3) The applicant may submit additional representations or documents after the end of the period for doing so only with the permission of the appropriate committee.
- (4) The appropriate committee must—
- (a) take the representations made under this paragraph into account; and
 - (b) report its findings and advice to the licensing authority together with the reasons for that advice.

Oral representations

- 27.—**(1) If the applicant requests the opportunity to make oral representations, the applicant must provide the appropriate committee with a written summary of those representations and any documents on which the applicant wishes to rely in support of them—
- (a) before the end of the period of six months beginning with the date of the request; or
 - (b) before the end of such shorter period as the licensing authority may specify in the notification under paragraph 25.
- (2) The appropriate committee may, at the request of the applicant, extend the period mentioned in sub-paragraph (1) up to a maximum of twelve months beginning with the date of the request under paragraph 24.
- (3) The applicant may submit additional written representations or documents after the end of the period for doing so only with the permission of the appropriate committee.
- (4) After receiving the summary and any other documents provided under this paragraph, the appropriate committee must arrange for the applicant to make oral representations at a hearing before the appropriate committee.
- (5) The appropriate committee must—
- (a) take the representations made under this paragraph into account; and
 - (b) report its findings and advice to the licensing authority together with the reasons for that advice.

Other decisions of the appropriate committee

- 28.—**(1) This paragraph applies if the applicant—
- (a) requests the opportunity to make written representations, but fails to make those written representations within the period for doing so; or
 - (b) requests the opportunity to make oral representations, but—
 - (i) fails to provide a summary of those representations or the documents in support of them within the period for doing so, or
 - (ii) fails to make oral representations at a hearing before the appropriate committee.
- (2) The appropriate committee must notify the licensing authority of that fact.

Decision of licensing authority following report

29.—(1) After receiving the appropriate committee's report under paragraph 26 or 27 or notification under paragraph 28 the licensing authority must decide whether to [^{F4}grant or refuse the application].

(2) If the appropriate committee gives a report under paragraph 26 or 27, the licensing authority must take that into account in making its decision.

(3) The licensing authority must notify the applicant or holder of—

(a) its decision; and

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

F4 Words in [Sch. 11 para. 29\(1\)](#) substituted (31.12.2020) by [The Human Medicines \(Amendment etc.\) \(EU Exit\) Regulations 2019](#) (S.I. 2019/775), regs. 1, **63(8)(c)**; 2020 c. 1, Sch. 5 para. 1(1)

Right to review after paragraph 29 notification

30.—(1) This paragraph applies if the licensing authority notifies the applicant of its decision under paragraph 29 to refer the applicant to the Committee on Herbal Medicinal Products as proposed.

(2) The applicant may notify the licensing authority in writing that the person wishes the licensing authority to submit the decision to review upon oral representations.

(3) The applicant must give the notification within the period of 28 days beginning with the day on which the licensing authority's notification is given or such longer period as the licensing authority may allow.

(4) The review must be conducted in accordance with Schedule 5.

(5) This paragraph does not apply if the person has not made any representations in accordance with paragraph 26 or 27.

Changes to legislation:

There are currently no known outstanding effects for the The Human Medicines Regulations 2012, PART 3.