SCHEDULES

SCHEDULE 5

Regulation 27; Schedule 11paragraphs 11(3), 13(3),23(4) and 30(4)

Review upon oral representations

Application of this Schedule

[F1 1.—(1) This Schedule applies if a person ("the applicant") mentioned in sub-paragraph (2) notifies the licensing authority that the applicant wishes the licensing authority to submit the proposal or as the case may be the decision to review upon oral representations under—

(a) regulation 27(3)(b);

(b) regulation 45H(3)(b);

(c) regulation 45R(3)(b);

(d) regulation 256J(4)(b); or

(e) Part 1, 2 or 3 of Schedule 11.

(2) Those persons are—

(a) in respect of notification under regulation 27(3)(b) the licence holder;

(b) in respect of a notification under regulation 45H(3)(b) the person registered as a broker;

(c) in respect of a notification under regulation 45R(3)(b) the person with an active substance registration;

(d) in respect of a notification under regulation 256J(4)(b) the person on the list in accordance with Part 12A; and

(e) in respect of a notification under Part 1, 2 or 3 of Schedule 11—

(i) an applicant for a UK marketing authorisation, **[**F2parallel import licence,**]** certificate of registration or traditional herbal registration,

(ii) an applicant for the renewal of an authorisation, **[**F3licence,**]** certificate or registration, and

(iii) the holder of an authorisation, **[**F3licence,**]** certificate or registration.**]**

Textual Amendments

F1 Sch. 5 para. 1 substituted (20.8.2013) by The Human Medicines (Amendment) Regulations 2013 (S.I. 2013/1855), regs. 1(1), **32(a)**

F2 Words in Sch. 5 para. 1(2)(e) inserted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **22(2)(a)**; 2020 c. 1, Sch. 5 para. 1(1)

F3 Words in Sch. 5 para. 1(2)(e) inserted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **22(2)(b)**; 2020 c. 1, Sch. 5 para. 1(1)

Appointment of reviewers

2.—(1) The licensing authority must—

(a) appoint a panel of at least two persons ("the reviewers") to conduct the review; and

(b) provide facilities for the applicant to have the opportunity to appear before the reviewers.

(2) A person must not be appointed under sub-paragraph (1) if within the period of one year immediately preceding that time the person has been a member of—

(a) the Commission;

(b) an expert committee appointed by the licensing authority;

(c) an expert advisory group;

(d) the British Pharmacopoeia Commission or any of its sub-committees;

(e) the Advisory Board on the Registration of Homoeopathic Products formerly established under section 4 of the Medicines Act 1968; or

(f) the Herbal Medicines Advisory Committee formerly established under section 4 of the Medicines Act 1968.

(3) A person appointed under sub-paragraph (1) must not be an officer or servant of a Minister of the Crown, the Scottish Ministers, the Welsh Ministers or a Northern Ireland Minister.

Procedure before hearing

3.—(1) The applicant must supply the reviewers with a written summary of the oral representations that the applicant wishes to make and any documents on which the applicant wishes to rely in support of them before the end of the period of three months beginning with the date of the notification mentioned in paragraph 1.

(2) The reviewers may, at the request of the applicant and after consulting the licensing authority, extend the period mentioned in sub-paragraph (1) up to a maximum of six months beginning with the date of that notification.

(3) The applicant may submit additional written representations or documents after the end of the periods for doing so only with the permission of the reviewers.

(4) In the case of a decision or a proposal by the licensing authority under Part 1, 2 or 3 of Schedule 11, the representations and documents referred to in paragraphs (1) and (3)—

(a) must not be based on any evidence or data that was not available to the licensing authority at the time that the decision or, as the case may be, the proposal that is the subject of the review was notified to the applicant by the licensing authority; unless

(b) the evidence or data is unfavourable in respect of the safety, quality or efficacy of the product concerned.

(5) The reviewers must notify the applicant and the licensing authority of the date of the hearing at least 28 days before that date, unless the applicant and the licensing authority agree to a shorter period of notice.

(6) The reviewers may establish at any stage of the procedures described in this Schedule a date by which all of those procedures, except for the hearing, must be completed, and notify this date to the applicant and to the licensing authority.

(7) The date established under sub-paragraph (6) must not be earlier than whichever is the earlier of—

(a) the first day after the end of the period of three months beginning with the date of the notification mentioned in paragraph 1; or

(b) the first day after the end of the period of 28 days beginning with the date on which the reviewers receive the written summary of the oral representations and supporting documents submitted in accordance with sub-paragraphs (1) and (3) of this paragraph,

and in any case not earlier than the first day after the period of seven days beginning on the day after the notification under sub-paragraph (6).

(8) A date established under sub-paragraph (6) may be varied or withdrawn on the application of the applicant or of the licensing authority.

(9) In the case of a decision or a proposal by the licensing authority under Part 1, 2 or 3 of Schedule 11, the reviewers must not take into account any documents or other evidence, or any representations based on such documents or evidence, in the conduct of the hearing if it thinks that the data or evidence on which the documents or representations are based, or the evidence that is presented, were not available to the licensing authority at the time when the decision or, as the case may be, the proposal that is the subject of the review was notified to the applicant by the licensing authority, unless the evidence or data is unfavourable in respect of the safety, quality or efficacy of the product concerned.

(10) The reviewers may give such other directions as they think fit for the conduct of the hearing, including—

(a) the postponing or adjournment of the hearing for such period as it may decide; and

(b) establishing a list of documents that will be taken into account in the conduct of the hearing.

(11) If the applicant fails to comply with a time limit under sub-paragraph (1), (2) or (6)—

(a) the applicant may not appear before the reviewers; and

(b) the licensing authority must decide whether—

(i) to proceed with its proposal to revoke, vary or suspend the licence,

(ii) to confirm or alter its decision,

F4(iii) . . . . . .

(iv) to grant or renew the UK marketing authorisation, **[**F5parallel import licence,**]** certificate of registration or traditional herbal registration or to do so otherwise than in accordance with the application, F6...

(v) to revoke, vary or suspend the authorisation, **[**F7licence,**]** certificate or registration,

[F8(vi) to proceed to suspend, vary or remove the person's broker registration,

(vii) ro proceed to suspend, vary or remove the person's active substance registration, or

(viii) to proceed to suspend, vary or remove the person's entry on the list,**]**

as the case may be.

(12) The licensing authority must notify the applicant of its decision.

Textual Amendments

F4 Sch. 5 para. 3(11)(b)(iii) omitted (31.12.2020) by virtue of The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **22(3)**; 2020 c. 1, Sch. 5 para. 1(1)

F5 Words in Sch. 5 para. 3(11)(b) inserted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **22(2)(a)**; 2020 c. 1, Sch. 5 para. 1(1)

F6 Word in Sch. 5 para. 3(11)(b)(iv) omitted (20.8.2013) by virtue of The Human Medicines (Amendment) Regulations 2013 (S.I. 2013/1855), regs. 1(1), **32(b)(i)**

F7 Words in Sch. 5 para. 3(11)(b) inserted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **22(2)(b)**; 2020 c. 1, Sch. 5 para. 1(1)

F8 Sch. 5 para. 3(11)(b)(vi)-(viii) inserted (20.8.2013) by The Human Medicines (Amendment) Regulations 2013 (S.I. 2013/1855), regs. 1(1), **32(b)(ii)**

Procedure at hearing

4.—(1) Both the applicant and the licensing authority may make representations at the hearing.

(2) The hearing must be in public if the applicant so requests.

(3) If the applicant fails to appear at the hearing, the reviewers may conduct the review on the basis of the applicant's written summary of the oral representations and supporting documents submitted in accordance with sub-paragraphs (1), (2) and (3) of paragraph 3.

Procedure following hearing

5.—(1) After the hearing the reviewers must provide a report to the licensing authority and to the applicant either—

(a) by the end of the period of 60 days beginning with the day after the conclusion of the hearing; or

(b) within such further period as the reviewers may notify to the licensing authority and to the applicant within that 60 day period.

(2) The licensing authority must take the report into account and decide whether—

(a) to proceed with its proposal to revoke, vary or suspend the licence;

(b) to confirm or alter its decision;

F9(c) . . . . . .

(d) to grant or renew the UK marketing authorisation, **[**F10parallel import licence,**]** certificate of registration or traditional herbal registration or to do so otherwise than in accordance with the application; F11...

[F12(e) to revoke, vary or suspend the authorisation, certificate or registration;

(f) to proceed to suspend, vary or remove a person's broker registration;

(g) to proceed to suspend, vary or remove a person's active substance registration; or

(h) to proceed to suspend, vary or remove a person's entry on the list,**]**

as the case may be.

(3) The licensing authority must notify the applicant of its decision.

Textual Amendments

F9 Sch. 5 para. 5(2)(c) omitted (31.12.2020) by virtue of The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **22(4)**; 2020 c. 1, Sch. 5 para. 1(1)

F10 Words in Sch. 5 para. 5(2)(d) inserted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **22(2)(a)**; 2020 c. 1, Sch. 5 para. 1(1)

F11 Word in Sch. 5 para. 5(2)(d) omitted (20.8.2013) by virtue of The Human Medicines (Amendment) Regulations 2013 (S.I. 2013/1855), regs. 1(1), **32(c)(i)**

F12 Sch. 5 para. 5(2)(e)-(h) substituted for Sch. 5 para. 5(2)(e) (20.8.2013) by The Human Medicines (Amendment) Regulations 2013 (S.I. 2013/1855), regs. 1(1), **32(c)(ii)**

Status:
Point in time view as at 31/12/2020.

Changes to legislation:
The Human Medicines Regulations 2012, SCHEDULE 5 is up to date with all changes known to be in force on or before 19 August 2024. There are changes that may be brought into force at a future date. Changes that have been made appear in the content and are referenced with annotations.