

*Status: Point in time view as at 30/10/2005.*

*Changes to legislation: Medicines Act 1968, Cross Heading: Procedure on consultation with appropriate committee is up to date with all changes known to be in force on or before 04 July 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. (See end of Document for details)*

## SCHEDULES

### [F1] SCHEDULE 2

#### SUSPENSION, REVOCATION OR VARIATION OF LICENCE

##### Textual Amendments

- F1** Sch. 2 substituted (30.10.2005) by [Medicines \(Advisory Bodies\) Regulations 2005 \(S.I. 2005/1094\)](#), reg. 1(1), [Sch. 1 para. 15](#)

##### Modifications etc. (not altering text)

- C1** Sch. 2 applied (with modifications) (3.4.1992) by [S.I. 1992/605](#), [reg. 2\(1\)\(2\)](#), Sch. 2 extended (with modifications) (14.2.1994) by [S.I. 1994/105](#), [reg. 19](#), [Sch. 4](#)
- C1** Sch. 2 amendment to earlier affecting provision SI 1994/105 Sch. 4 (30.10.2005) by [Medicines \(Homoeopathic Medicinal Products for Human Use\) Amendment Regulations 2005 \(S.I. 2005/2753\)](#), regs. 1(1), [19\(2\)](#)
- C1** Sch. 2 amendment to earlier affecting provision SI 1992/605 Sch. (30.10.2005) by [Medicines \(Advisory Bodies\) \(No.2\) Regulations 2005 \(S.I. 2005/2754\)](#), reg. 1(2)(b), [Sch. 4 para. 6\(b\)](#)

##### *Procedure on consultation with appropriate committee*

- 1 Subject to paragraph 8 below, where the licensing authority propose, in the exercise of their powers under section 28 of this Act—
- (a) to suspend, revoke or vary a product licence on the grounds specified in paragraph (a) or paragraph (c) of subsection (3) of that section, in a case where it appears to the licensing authority that the matters or characteristics in question are such as to affect the safety, efficacy or quality of medicinal products to which the licence relates, or
  - (b) to suspend, revoke or vary a product licence on any of the grounds specified in paragraph (g) or paragraph (h) of that subsection,
- the licensing authority shall not suspend, revoke or vary the licence except after consultation with the appropriate committee.
- 2 (1) Where the appropriate committee are consulted under the preceding paragraph and are of the provisional opinion that, on such grounds as are mentioned in that paragraph, they may have to advise the licensing authority that the product licence ought to be revoked, varied or suspended, the appropriate committee shall notify the holder of the licence 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 holder of the licence an opportunity to make such representations in accordance with sub-paragraphs (4) to (7) of this paragraph.
  - (4) Subject to sub-paragraph (5) of this paragraph, the holder of the licence shall provide the appropriate committee with—

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- (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) of this paragraph, or within such shorter period as the appropriate committee may specify in the notification under sub-paragraph (1) of this paragraph.
- (5) If the holder of the licence so requests, the appropriate committee may extend the time limit referred to in sub-paragraph (4) of this paragraph, up to a maximum period of twelve months beginning with the date of the notice referred to in sub-paragraph (2) of this paragraph.
  - (6) The holder of the licence may not submit any additional written representations or documents once the time limit referred to in sub-paragraphs (4) and (5) of this paragraph has expired, except with the permission of the appropriate committee.
  - (7) If the 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) of this paragraph, arrange for the 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.
- 3 (1) After receiving the report of the appropriate committee the licensing authority shall—
- (a) decide whether to continue with the proposal to revoke, vary or suspend the product licence; and
  - (b) take the report into account when making their decision.
- (2) The licensing authority shall then notify the holder of the licence of—
- (a) the decision made pursuant to sub-paragraph (1) of this paragraph; and
  - (b) the advice given to them by the appropriate committee and the reasons for that advice.
- 4 If—
- (a) the appropriate committee was consulted under paragraph 1 of this Schedule;
  - (b) the committee did not give a provisional opinion under paragraph 2(1) of this Schedule; and
  - (c) the licensing authority propose—
    - (i) to determine the matter in a way which differs from the advice of the committee, or
    - (ii) to suspend, revoke or vary the licence on grounds not relating to safety, quality or efficacy,
- the authority shall notify the holder of the licence accordingly.
- (2) A notification given under sub-paragraph (1) of this paragraph shall state—

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- (a) the advice of the committee and the reasons stated by the committee for that advice; and
  - (b) the proposals of the licensing authority and the reasons for them.
- 5 (1) Subject to sub-paragraph (4) of this paragraph, a person to whom a notification has been given under paragraph 3(2) of this Schedule 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 4(1) of this Schedule 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) of this paragraph shall not apply where—
  - (a) the person has not made any representations in accordance with paragraph 2(4) to (7) of this Schedule; and
  - (b) the decision of the licensing authority was in accordance with the advice of the appropriate committee.]

**Modifications etc. (not altering text)**

- C1** Sch. 2 para. 5(4) applied (with modifications) (30.10.2005) by Medicines (Advisory Bodies) (No.2) Regulations 2005 (S.I. 2005/2754), reg. 1(2)(b), **Sch. 5 para. 6(4)**
- C2** Sch. 2 para. 5(4)(a) applied (with modifications) (30.10.2005) by Medicines (Advisory Bodies) (No.2) Regulations 2005 (S.I. 2005/2754), reg. 1(2)(b), **Sch. 5 para. 2(5)**
- C3** Sch. 2 para. 5(4)(a) applied (with modifications) (30.10.2005) by Medicines (Advisory Bodies) (No.2) Regulations 2005 (S.I. 2005/2754), reg. 1(2)(b), **Sch. 5 para. 11(4)**

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