

**Status:** This version of this contains provisions that are prospective.

**Changes to legislation:** There are outstanding changes not yet made by the legislation.gov.uk editorial team to The Medicines (Advisory Bodies) Regulations 2005. Any changes that have already been made by the team appear in the content and are referenced with annotations. (See end of Document for details) View outstanding changes

PROSPECTIVE

## SCHEDULE 1

### AMENDMENTS TO THE MEDICINES ACT 1968

2. For section 21 of the Act (procedure on reference to appropriate committee or Commission), substitute—

**“Procedure on reference to appropriate committee**

21.—(1) Where the appropriate committee are consulted under section 20(3) of this Act 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 the licence; or
- (b) may be unable to advise the licensing authority to grant it unless it contains provisions otherwise than in accordance with the application,

they shall notify the applicant 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 an opportunity to make such representations in accordance with subsections (4) to (7) of this section.

(4) Subject to subsection (5) of this section, 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 subsection (2) of this section, or within such shorter period as the appropriate committee may specify in the notification under subsection (1).

(5) If the applicant so requests, the appropriate committee may extend the time limit referred to in subsection (4) of this section, up to a maximum period of twelve months beginning with the date of the notice referred to in subsection (2) of this section.

(6) The applicant may not submit any additional written representations or documents once the time limit referred to in subsections (4) and (5) of this section 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 subsection (4) of this section, 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.

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(9) After receiving the report of the appropriate committee, the licensing authority shall—

- (a) decide whether to grant or refuse the application, or to grant it otherwise than in accordance with the application; and
- (b) take the report into account when making their decision.

(10) The licensing authority shall notify the applicant of—

- (a) the decision made pursuant to subsection (9) of this section; and
- (b) the advice given to them by the appropriate committee and the reasons for that advice.

(11) If—

- (a) the applicant has made representations in accordance with this section and the licensing authority have notified the applicant of the authority's decision to refuse to grant the licence, or to grant it otherwise than in accordance with the application; or
- (b) the applicant has not made representations in accordance with this section and the licensing authority have notified the applicant of the authority's decision to refuse to grant the licence, or to grant it otherwise than in accordance with the application, on grounds which differ from those relied on in the advice of the appropriate committee,

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.

(12) In this Part of the Act, “the time allowed” means the period of twenty-eight days beginning with the date of the relevant notification, or such longer period as the licensing authority may allow in any particular case.”.

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#### **Commencement Information**

**II** Sch. 1 para. 2 in force at 30.10.2005, see [reg. 1\(1\)](#)

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**Changes and effects yet to be applied to :**

- Sch. 1 para. 2 coming into force by [S.I. 2005/1094 reg. 1\(1\)](#)
- Sch. 1 para. 1-11 revoked by [S.I. 2012/1916 Sch. 35](#)