

SCHEDULES

SCHEDULE 2

SUSPENSION, REVOCATION OR VARIATION OF LICENCE

Consultation with appropriate committee or Commission

- 1 Except as provided by paragraph 11 of this Schedule, 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 of a description 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 or, if for the time being there is no such committee, with the Commission.
- 2 Where the appropriate committee or the Commission are consulted under the preceding paragraph, and on any such grounds as are mentioned in that paragraph they have reason to think that they may have to advise the licensing authority that the product licence ought to be suspended, revoked or varied, the committee or Commission shall notify the holder of the licence accordingly, and, before giving any such advice to the licensing authority, shall afford to him an opportunity of appearing before and being heard by them, or of making representations in writing to them with respect to those grounds.
- 3 Where the holder of the licence has availed himself of the opportunity of being heard under paragraph 2 of this Schedule, or after considering any representations made by him under that paragraph, the appropriate committee or the Commission, as the case may be, shall report to the licensing authority their findings and advice and the reasons for their advice, and the licensing authority shall take that report into account in making their decision.
- 4 Whether the holder of the licence has been heard or has made representations under paragraph 2 of this Schedule or not, if the appropriate committee or the Commission advise the licensing authority that the licence ought on any such grounds as are mentioned in paragraph 1 of this Schedule to be suspended or revoked, or to be varied so as to contain provisions specified in their advice, the licensing authority shall serve notice on the holder of the licence stating the advice so given to the authority and the reasons stated by the appropriate committee or the Commission for giving that advice.
- 5 If, within the time allowed after the service of a notice under paragraph 4 of this Schedule, in a case where the holder of the licence has not been heard by, or made representations to, the Commission under paragraph 2 of this Schedule, the holder

Status: This is the original version (as it was originally enacted).

of the licence gives notice to the licensing authority of his desire to be heard with respect to the advice given to the authority, or makes representations in writing to the licensing authority with respect to that advice, then, before determining the matter.—

- (a) if the holder of the licence has given notice of his desire to be heard, the licensing authority shall arrange for him to have an opportunity of appearing before and being heard by the Commission, or
- (b) if he has made representations in writing, the licensing authority shall refer those representations to the Commission,

and, where the holder of the licence has availed himself of the opportunity of being heard, or after considering the representations, as the case may be, the Commission shall report to the licensing authority their findings and advice and the reasons for their advice, and the licensing authority shall take that report into account in making their decision.

6 If the licensing authority—

- (a) propose to determine the matter in a way which differs from the advice of the Commission under paragraph 3 or paragraph 5 of this Schedule, or
- (b) where there has been no hearing before, and no representations have been made or referred to, the Commission, propose to determine the matter in a way which differs from the advice of the appropriate committee under paragraph 3 of this Schedule, or
- (c) in the absence of any such advice as is mentioned in either of the preceding sub-paragraphs, propose to determine the matter in a way which differs from the advice given by the appropriate committee or the Commission, or
- (d) propose to suspend, revoke or vary the licence on grounds not relating to safety, quality or efficacy,

the licensing authority shall notify the holder of the licence accordingly, and, before determining the matter, shall afford to him an opportunity of appearing before, and being heard by, a person appointed for the purpose by the licensing authority, or of making representations in writing to the licensing authority with respect to that proposal.

7 Any notification given to the holder of the licence under paragraph 6 of this Schedule—

- (a) in a case falling within sub-paragraph (a) or sub-paragraph (b) of that paragraph, shall state the advice of the Commission or the appropriate committee and the reasons stated by the Commission or the committee for giving that advice, or
- (b) in a case falling within sub-paragraph (c) of that paragraph, shall state the advice given by the appropriate committee or the Commission and the reasons stated by the committee or the Commission for giving that advice,

and in a case falling within sub-paragraph (d) of that paragraph (whether it also falls within any of the other sub-paragraphs of that paragraph or not) the notification shall include a statement of the proposals of the licensing authority and of the reasons for them.