

SCHEDULE 8

Regulations 40(5) and 44(6)

PROCEDURAL PROVISIONS RELATING TO PROPOSALS TO GRANT, REFUSE TO GRANT, VARY, SUSPEND OR REVOKE MANUFACTURING AUTHORISATIONS

1. In this Schedule—

“authorisation” means a manufacturing authorisation; and

“time allowed” means the period of 28 days or such extended period as the licensing authority may in any particular case allow.

2. Subject to paragraph 6, if the licensing authority propose—

(a) not to grant an authorisation;

(b) to grant an authorisation other than in accordance with the application; or

(c) to revoke, vary or suspend an authorisation,

the licensing authority shall notify the applicant or holder accordingly.

3. Any notification given under paragraph 2 shall include a statement of the proposals of the licensing authority and of the reasons for them.

4. A person to whom notification has been given under paragraph 2 may, within the time allowed after the notification was given, give notice of his wish to appear before and be 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 the decision or proposal referred to in the notification.

5.—(1) Where an applicant or the holder gives notice under paragraph 4 of his wish to appear before and be heard by a person appointed for the purpose by the licensing authority, the licensing authority shall make that appointment and—

(a) the person so appointed shall not, except with the consent of the applicant or holder, be an officer or servant of any of the Ministers specified in paragraphs (a) and (b) of section 1(1) of the Act;

(b) if the applicant or holder so requests, the hearing shall be in public; and

(c) if the applicant or holder so requests, the licensing authority shall furnish to him a copy of the report of the person so appointed.

(2) The licensing authority shall take into account the report of the person appointed and decide whether to grant the authorisation, revoke, vary or suspend the authorisation or confirm or alter their decision, as the case may be.

6.—(1) Paragraph 2 shall not apply to the suspension of an authorisation where it appears to the licensing authority that, in the interests of safety, it is necessary to suspend the authorisation with immediate effect for a period not exceeding 3 months.

(2) If, after the suspension has taken effect, it appears to the licensing authority that the authorisation should be further suspended or revoked, the licensing authority shall proceed in accordance with the provisions of paragraphs 2 to 5.