STATUTORY INSTRUMENTS

1986 No. 1761

TRIBUNALS AND INQUIRIES

The Medicines Act 1968 (Hearings By Persons Appointed) Rules 1986

Made - - - -	*7th October 1986*
Laid before Parliament	*20th October 1986*
Coming into Operation	*10th November 1986*

The Lord Chancellor, in exercise of the powers conferred on him by section 11 of the Tribunals and Inquiries Act 1971 and after consultation with the Council on Tribunals hereby makes the following Rules:—

Citation and commencement

1. These Rules may be cited as the Medicines Act 1968 (Hearings by Persons Appointed) Rules 1986 and shall come into operation on 10th November 1986.

Interpretation

2. In these Rules, unless the context otherwise requires—

(a) a reference

(i) to a numbered section, Part or Schedule is a reference to the section of or, as the case may be, the Part of or Schedule to the Act bearing that number;

(ii) to a numbered Rule is to the Rule bearing that number in these Rules;

(b) "the Act" means the Medicines Act 1968;

"applicant" means an applicant for a licence or certificate under Part II or a direction under section 47(6) (application for a direction concerning incorporation of standard conditions into a licence or certificate) or a certificate for the purposes of section 60 (restricted sale, supply and administration of certain medicinal products) or an applicant for registration of premises under section 75 (registration of pharmacy premises) or an applicant for the renewal of any such licence or certificate;

"duly authorised person" means any person duly authorised in writing by the relevant Minister;

"person appointed" means a person appointed under any of the following provisions of, or made under, the Act, namely—

(i) section 21(5) (applications for licences referred to the appropriate committee or the Medicines Commission),

(ii) section 22(3) (applications for licences in other cases),

(iii) section 47(7) (refusal to give a direction),

(iv) section 75(5) (proposal to certify that premises are unsuitable for registration),

(v) paragraph 6 of Schedule 2 (proposals to suspend, revoke or vary a product licence which are referred to the appropriate committee or the Medicines Commission),

(vi) paragraph 9 of Schedule 2 (proposals to suspend, revoke or vary licences in other cases), and

(vii) regulations made under section 60(**1**) (concerning restricted sale, supply and administration of certain medicinal products),

including, in the case of sections 21(5) and 22(3), those provisions as applied by section 24(4) (renewal of licences), section 36(3) (applications for certificates) and section 38(5) (renewal of certificates) and including, in the case of paragraphs 6 and 9 of Schedule 2, those provisions as applied by section 39(3) (suspension, revocation or variation of certificates);

"relevant Minister" means—

(i) in relation to a licence, certificate or direction under Part II, the licensing authority as defined in section 6(3),

(ii) in relation to a certificate for the purposes of section 60, the appropriate Ministers as defined in section 1(2), and

(iii) in relation to the registration of premises under section 75, the appropriate Minister as defined in sub-section (8) of that section;

and other expressions have the same meanings as in the Act;

(c) the provisions of section 127 shall apply to notices and other documents required or authorised to be given or sent by any provision of these Rules as they apply to notices or other documents required or authorised to be given or sent by any provision of the Act.

Notice of hearing

3. Where an applicant gives notice to the relevant Minister of his desire to be heard by a person appointed, the relevant Minister shall give at least 28 days' notice in writing to the applicant of the date, time and place of the hearing by the person appointed and such notice shall request the applicant to state whether he wishes the hearing to be in public.

Service of documents

4. The relevant Minister shall prepare a list of documents relevant to the hearing and shall send a copy of such list, together with a copy of each of the documents referred to in it, both to the applicant and to the person appointed, at least 21 days before the date of the hearing.

Reports by authorised persons

5.—(1) Where the documents which are sent pursuant to Rule 4 include a report by a duly authorised person of an inspection of any premises to which the application, certificate or licence

(**1**) *See* regulation 7 of the Medicines (Administration of Radioactive Substances) Regulations 1978 (S.I. 1978/1006).

in question relates, the relevant Minister shall invite the applicant to notify him not less than 7 days prior to the date of the hearing whether he intends to dispute any fact contained in that report.

(2) Where the applicant has given to the relevant Minister 7 days' notice of his intention to dispute any fact contained in the report, the duly authorised person shall attend the hearing and the applicant shall be entitled to question him about any matter of fact contained in the report.

Procedure at hearings by persons appointed

6.—(1) Subject to the provisions of the Act and the other provisions of these Rules, the person appointed shall, in his discretion, determine the procedure at the hearing.

(2) The applicant may appear in person at the hearing, or may be represented by any other person, and shall be entitled to call witnesses and to address the person appointed.

(3) Any member of the Council on Tribunals in his capacity as such may attend any hearing by a person appointed.

(4) If the applicant so requests, the hearing by the person appointed shall be in public.

Appointed person's report

7. At the conclusion of the hearing, the person appointed shall prepare a written report of his findings and shall send it to the relevant Minister who shall send a copy of it to the applicant.

Site inspections

8.—(1) A person appointed may, at the request or with the consent of the applicant, carry out an inspection of any premises to which the application, certificate or licence relates.

(2) If the person appointed decides to make such an inspection he shall give the applicant reasonable notice of the date and time at which he proposes to do so.

Postponement or adjournment

9. A person appointed may, if he thinks fit, postpone or adjourn any hearing pending before him, or any inspection of premises to be carried out under Rule 8(1), and shall give the applicant reasonable notice of the date and time of the subsequent hearing or inspection.

Extent of application

10. These Rules shall apply to England, Wales and Northern Ireland.

7th October 1986 *Hailsham of St Marylebone, C*

EXPLANATORY NOTE

These Rules prescribe the procedure to be followed in connection with hearings by persons appointed under the Medicines Act 1968 or under regulations made under section 60 of that Act. These hearings form part of the licensing procedures for medicinal products and the procedure for registration of premises as registered pharmacies. Persons appointed in accordance with these provisions are required to prepare a report (Rule 7) for the "relevant Minister", which expression is defined in Rule 2 for the purposes of these Rules.