SCHEDULE 1

Regulation 8

AMENDMENTS TO THE MEDICINES ACT 1968

1. In section 20 of the Act (grant or refusal of licence)—

(a) in subsection (3), omit "or, if for the time being there is no such committee, with the Commission";

(b) omit subsection (4).

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.

(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.".

3. For section 22 of the Act (procedure in other cases) substitute the following sections—

"**Procedure in other cases**

22.—(1) This section applies when—

(a) an application is made for the grant of a licence under this Part of this Act; and

(b) the appropriate committee—

(i) is not consulted under subsection (3) of section 20, or

(ii) is consulted under that subsection but does not give a provisional opinion in accordance with section 21(1).

(2) If the licensing authority propose—

(a) to refuse to grant the licence, or

(b) to grant it otherwise than in accordance with the application,

they shall notify the applicant of their proposals and the reasons for them.

(3) If the applicant is so notified, he may, within the time allowed—

(a) notify the licensing authority of his wish to appear before and be heard by a person appointed by the licensing authority with respect to the proposal; or

(b) make representations in writing to the licensing authority with respect to the proposal referred to in the notification.

(4) If the applicant makes written representations in accordance with subsection (3)(b) of this section, the licensing authority shall take those representations into account before determining the application.

Hearing before person appointed

22A.—(1) If the applicant gives notice under section 21(11) or section 22(3) of his wish to appear before and be heard by a person appointed by the licensing authority, the authority shall—

(a) make that appointment; and

(b) arrange for the applicant to have an opportunity of appearing before that person.

(2) The person appointed—

(a) shall not be, or at any time have been, a member of—

(i) the Commission on Human Medicines or any of its Expert Advisory Groups,

(ii) the Medicines Commission formerly established under section 2 of this Act or any of its committees, or

(iii) a committee established under section 4 of this Act, or any sub-committee of such a committee; and

(b) shall not be an officer or servant of any Minister of the Crown.

(3) Subject to subsection (4) of this section, the applicant shall provide the person appointed with—

(a) 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 three months beginning with the date of the notice referred to in subsection (1) of this section.

(4) If the applicant so requests, the person appointed may, after consulting the licensing authority, extend the time limit referred to in subsection (3) of this section, up to a maximum period of six months beginning with the date of the notice referred to in subsection (1) of this section.

(5) If the applicant fails to comply with the time limit in subsection (3) of this section, or, where he has been granted an extended time limit under subsection (4) of this section, that time limit—

(a) he may not appear before or be heard by the person appointed, and

(b) the licensing authority shall decide whether to grant or refuse the licence, or to grant it otherwise than in accordance with the application, and notify the applicant accordingly.

(6) The applicant may not submit any additional written representations or documents once the time limit has expired, except with the permission of the person appointed.

(7) At the hearing before the person appointed, both the applicant and the licensing authority may make representations.

(8) If the applicant so requests the hearing shall be in public.

(9) After the hearing—

(a) the person appointed shall provide a report to the licensing authority; and

(b) the licensing authority shall take the report into account and decide whether to grant or refuse the licence, or to grant it otherwise than in accordance with the application, or to confirm or alter their decision, as the case may be.

(10) The licensing authority shall then—

(a) notify the applicant of their decision;

(b) if the applicant so requests, provide the applicant with a copy of the report of the person appointed.".

4. In section 24 (duration and renewal of licence), in subsection (4), for "21 and 22", substitute "21 to 22A".

5. In section 27 (proceedings on application for licence of right)—

(a) in subsection (1), for "22" substitute "22A"; and

(b) for subsection (8), substitute the following subsection—

"Subsections (2), (8) and (10)(b) of section 22A of this Act shall have effect in relation to a person appointed under subsection (3) of this section and to proceedings before him and his report as they have effect for the purposes of that section."

6. In section 36 (application for, and issue of, certificate), in subsection (3), for "22" substitute "22A".

7. In section 38 (duration and renewal of certificate)—

(a) in subsection (5), for "21 and 22" substitute "21 to 22A"; and

(b) in subsection (6), for "section 21 or section 22" substitute "section 21, 22 or 22A".

8. In section 43 (extension of section 7 to certain special circumstances), in subsection (4), for "22" substitute "22A".

9. In section 44 of the Act (provision of information to licensing authority), in subsection (3), omit "by the Commission or" in both places where it occurs.

10. In section 58 of the Act (medicinal products on prescription only), in subsection (6), omit ", or, if for the time being there is no such committee, shall consult the Commission".

11. In section 60 of the Act (restricted sale, supply and administration of certain medicinal products), in subsection (7), omit ", or, if for the time being there is no such committee, shall consult the Commission".

12.—(1) Section 62 of the Act (prohibition of sale, supply, or importation, of certain medicinal products) shall be amended as follows.

(2) In subsection (3) omit ", or if for the time being there is no such committee, shall consult the Commission".

(3) In subsection (4) omit "or the Commission".

(4) In subsection (5), for "Commission" (at each place where it occurs) substitute "appropriate committee".

(5) For subsection (7) substitute—

"(7) If an order is made under this section and either—

(a) the appropriate committee have not considered the proposal to make the order, or

(b) the order is made contrary to the advice of the appropriate committee,

the order shall include a statement of the fact that it has been so made.".

13. In section 65 of the Act (compliance with standards specified in monographs), in subsection (8), for "Medicines Commission" substitute "Commission".

14. In section 132 of the Act (general interpretation provisions), in subsection (1)—

(a) before the definition of "analysis", insert the following definition—

""Advisory Body" has the meaning given to it by paragraph 1 of Schedule 1A to this Act;",

(b) in the definition of "the Commission", for "Medicines Commission" substitute "Commission for Human Medicines";

(c) after the definition of "enforcement authority", insert the following definition—

""Expert Advisory Group" means an Expert Advisory Group established under paragraph 3 or 4 of Schedule 1A to this Act;";

(d) after the definition of "herd", insert the following definition—

""the Homoeopathic Regulations" means the Medicines (Homoeopathic Medicinal Products for Human Use) Regulations 1994(**1**)

(e) after the definition of "manufacture", insert the following definition—

""the Marketing Authorisation Regulations" means the Medicines for Human Use (Marketing Authorisations Etc.) Regulations 1994;";

(f) in the definition of "the time allowed", for "section 21(8)" substitute "section 21(12)".

15. For Schedule 2 to the Act (procedure for suspension, revocation or variation of licence), substitute—

"SCHEDULE 2 Section 29

SUSPENSION, REVOCATION OR VARIATION OF LICENCE

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.

(**1**) S.I. 1994/105.

(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—

(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—

(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.

Procedure in other cases

6.—(1) This paragraph applies where the licensing authority propose, in the exercise of the powers conferred by section 28 of this Act—

(a) to suspend, revoke or vary a licence under Part 2 of this Act, other than a product licence; or

(b) to suspend, revoke or vary a product licence where the holder of the licence has been given neither—

(i) notice of any provisional opinion or any advice of the appropriate committee which led to that proposal under paragraphs 2 and 3 of this Schedule; nor

(ii) notice of that proposal under paragraph 4 of this Schedule,

and the provisions of paragraph 8 of this Schedule do not apply.

(2) The licensing authority shall notify the holder of the licence of—

(a) their proposals;

(b) the reasons for them; and

(c) the date (not being earlier than twenty-eight days from the date of the notification) on which it is proposed that the suspension, revocation or variation should take effect.

(3) The holder of the licence may, before the date specified in the notification—

(a) notify the licensing authority of his wish to appear before and be heard by a person appointed by the licensing authority with respect to the decision; or

(b) make representations in writing to the licensing authority with respect to the proposal referred to in the notification.

(4) If the applicant makes written representations in accordance with sub-paragraph (3)(b) of this paragraph, the licensing authority shall take those representations into account before determining the matter.

Hearing before person appointed

7.—(1) If the holder of the licence gives notice under paragraph 5 or 6 of this Schedule of his wish to appear before and be heard by a person appointed by the licensing authority, the authority shall—

(a) make that appointment; and

(b) arrange for the applicant to have an opportunity of appearing before that person.

(2) The person appointed—

(a) shall not be, or at any time have been, a member of—

(i) the Commission on Human Medicines or any of its Expert Advisory Groups,

(ii) the Medicines Commission formerly established under section 2 of this Act or any of its committees, or

(iii) a committee established under section 4 of this Act, or any sub-committee of such a committee; and

(b) shall not be an officer or servant of any Minister of the Crown.

(3) Subject to sub-paragraph (4) of this paragraph, the holder of the licence shall provide the person appointed with—

(a) 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 three months beginning with the date of the notice referred to in sub-paragraph (1) of this paragraph.

(4) If the holder of the licence so requests, the person appointed may, after consulting the licensing authority, extend the time limit referred to in sub-paragraph (3) of this paragraph, up to a maximum period of six months beginning with the date of the notice referred to in sub-paragraph (1) of this paragraph.

(5) If the holder of the licence fails to comply with the time limit in sub-paragraph (3) of this paragraph, or, where he has been granted an extended time limit under sub-paragraph (4) of this paragraph, that time limit—

(a) he may not appear before or be heard by the person appointed, and

(b) the licensing authority shall decide whether to grant or refuse the licence, or to grant it otherwise than in accordance with the application, and notify the applicant accordingly.

(6) The holder of the licence may not submit any additional written representations or documents once the time limit has expired, except with the permission of the person appointed.

(7) At the hearing before the person appointed, both the holder of the licence and the licensing authority may make representations.

(8) If the holder of the licence so requests the hearing shall be in public.

(9) After the hearing—

(a) the person appointed shall provide a report to the licensing authority; and

(b) the licensing authority shall take this report into account and decide whether to revoke, vary or suspend the licence.

(10) The licensing authority shall then—

(a) notify the holder of the licence of their decision;

(b) if the holder so requests, provide the holder with a copy of the report of the person appointed.

Procedure in cases of urgency

8. Notwithstanding anything in paragraphs 1 to 7 of this Schedule, where it appears to the licensing authority that in the interests of safety it is necessary to suspend a licence under Part 2 of this Act with immediate effect, the licensing authority may do so, for a period not exceeding three months.

9. If the licence is a product licence, the licensing authority shall report the suspension forthwith to the appropriate committee.

10. If, after the suspension has taken effect—

(a) it appears to the licensing authority; or

(b) in the case of a product licence, they are advised by the appropriate committee,

that it is necessary to consider whether the licence ought to be further suspended, or ought to be revoked or varied, the licensing authority (subject to paragraph 11 of this Schedule) shall proceed in accordance with such of the provisions of paragraphs 1 to 7 of this Schedule as are applicable in the circumstances.

11.—(1) This paragraph applies where, in the circumstances specified in paragraph 10 of this Schedule, the licensing authority proceed as mentioned in that paragraph and any proceedings under paragraphs 1 to 7 of this Schedule relating to a further suspension of the licence have not been finally disposed of before the end of the period—

(a) for which the licence was suspended under paragraph 8 of this Schedule; or

(b) for which it has been further suspended under this paragraph.

(2) If it appears to the licensing authority to be necessary in the interests of safety to do so, the authority may further suspend the licence for a period which (in the case of each such further suspension) shall not exceed three months.

(3) The provisions of section 27(7) of this Act shall, with the necessary modifications, have effect for the purpose of determining the date on which any proceedings are taken to be finally disposed of.

Interpretation

12. In this Schedule, the "the time allowed" means the period of twenty-eight days from the date of the relevant notification, or such longer period as the licensing authority may allow in any particular case.".

SCHEDULE 2 Regulation 9

CONSEQUENTIAL AND OTHER AMENDMENTS TO THE MARKETING AUTHORISATION REGULATIONS

1. In regulation 1 (citation, commencement and interpretation), in paragraph (2), after the definition of "the Act" insert the following definition—

""appropriate committee", for the purposes of any provision of these Regulations under which a function falls to be performed, means—

(a) in a case where—

(i) a committee has been established under section 4 of the Act for purposes which consist of or include any of those specified in subsection (3) of that section, and

(ii) the authority performing that function considers it to be the appropriate committee in the circumstances,

that committee; and

(b) in any other case, the Commission.".

2. In regulation 5 (consideration, and grant or refusal, of an application for, or for renewal or variation of, a United Kingdom marketing authorization), in paragraph (3), after "marketing authorization" insert ", or after notification of a decision relating to an application to vary such an authorization".

3. In regulation 9 (consequential and other amendments of the Act and the Medicines Act 1971), omit paragraph (1).

4. For Schedule 2, substitute—

"SCHEDULE 2 Regulation 5(3) and 6(7)

PROCEDURAL PROVISIONS RELATING TO THE GRANT, RENEWAL, VARIATION, REVOCATION AND SUSPENSION OF UNITED KINGDOM MARKETING AUTHORIZATIONS

PART 1

INTERPRETATION AND APPLICATION

Interpretation

1. In this Schedule—

"authorization" means a United Kingdom marketing authorization;

"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; and

"Type II variation application" means an application by the holder of an authorization to vary that authorization, if the variation applied for is a major variation of Type II within the meaning of Article 3(3) of Commission Regulation (EC) No. 1084/2003(**2**).

(**2**) OJ L 159, 27.6.2003, p.1.

Scope and application of this Schedule

2. Subject to paragraphs 5 and 6, Part 2 applies to—

(a) any application for the grant of an authorization for a relevant medicinal product where, throughout the period beginning with the date on which the application is made and ending with the date on which the licensing authority give a decision on the application, there is no other marketing authorization in force in respect of the product anywhere in the Community;

(b) any application to renew an authorization for a relevant medicinal product; and

(c) any proposal to revoke, vary or suspend an authorization for a relevant medicinal product, other than a variation on the application of the holder of that authorization.

3. Subject to paragraphs 5 and 6, Part 3 applies to any application to vary an authorization for a relevant medicinal product which is a Type II variation application.

4. Subject to paragraphs 5 and 6, Part 4 applies where—

(a) an applicant for an authorization for a relevant medicinal product, or for the variation or renewal of such an authorization; or

(b) the holder of an authorization for a relevant medicinal product,

gives notice under paragraph 11 or 16 of his wish to appear before or be heard by a person appointed by the licensing authority.

5. This Schedule shall cease to apply if at any time the relevant matter is, by virtue of any relevant Community provision, referred to the Committee for Medicinal Products for Human Use for the application of the procedure laid down in Articles 32 to 34 of the 2001 Directive.

6. This Schedule does not apply if—

(a) the licensing authority rejects, or declines to assess, an application in accordance with Article 17(2) or 18 of the 2001 Directive(**3**); or

(b) the application or proposal relates to the renewal, revocation, suspension or variation of a marketing authorization—

(i) which has been granted—

(aa) in accordance with the provisions of Title III, Chapter 4 of the 2001 Directive, or

(bb) by Member States in accordance with Article 4 of Council Directive 87/22/EEC(**4**) before 1st January 1995, or

(ii) which has not been so granted, but which has been subject to the procedure laid down in Articles 32 to 34 of the 2001 Directive following a referral under Article 30 or 31 of that Directive, unless the procedure was limited to certain specific parts of the authorization.

(**3**) OJ L 311, 28.11.2001, p.67; as amended by Directive 2004/27/EC (OJ L 136, 30.4.2004, p.34).
(**4**) OJ L 15, 17.1.1987, p.38.

PART 2

PROCEDURES RELATING TO GRANT, RENEWAL, COMPULSORY VARIATION, REVOCATION OR SUSPENSION OF AUTHORIZATIONS

Requirement to consult the appropriate committee

7. The licensing authority shall not, at any time while this Schedule applies—

(a) refuse to grant or renew the authorization applied for; or

(b) revoke, vary or (subject to paragraph 12 of this Schedule) suspend an authorization,

on grounds relating to safety, quality or efficacy, except after consultation with the appropriate committee.

Provisional opinion against authorization

8.—(1) Where the appropriate committee are consulted under the preceding paragraph 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 or renew the authorization; or

(b) may be unable to advise the licensing authority to grant it unless it contains provisions otherwise than in accordance with the application; or

(c) may have to advise the licensing authority that the authorization ought to be revoked, varied or suspended,

the appropriate committee shall notify the applicant or holder 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 or holder an opportunity to make such representations in accordance with sub-paragraphs (4) to (7).

(4) Subject to sub-paragraph (5), the applicant or holder 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 sub-paragraph (2), or within such shorter period as the appropriate committee may specify in the notification under sub-paragraph (1).

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

(6) The applicant or holder may not submit any additional written representations or documents once the time limit referred to in sub-paragraphs (4) and (5) has expired, except with the permission of the appropriate committee.

(7) If the applicant or 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), arrange for the applicant or 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.

Licensing authority's decision after appropriate committee report

9.—(1) After receiving the report of the appropriate committee pursuant to paragraph 8(8) the licensing authority shall—

(a) decide whether to refuse to grant or renew the authorization, or to grant or renew it otherwise than in accordance with the application, or to proceed further with their proposal to revoke, vary or suspend the authorization; and

(b) take the report into account when making their decision.

(2) The licensing authority shall then notify the applicant or holder of—

(a) the decision made pursuant to sub-paragraph (1); and

(b) the advice given to them by the appropriate committee and the reasons for that advice.

Licensing authority proposals in other cases

10. If—

(a) the appropriate committee was consulted pursuant to paragraph 7;

(b) the committee did not give a provisional opinion under paragraph 8(1); and

(c) the licensing authority propose—

(i) to determine an application in a way which differs from the advice of the committee,

(ii) to revoke, vary or suspend a marketing authorization against such advice, or

(iii) on grounds not relating to safety, quality or efficacy—

(aa) not to grant or renew an authorization,

(bb) to grant or renew an authorization otherwise than in accordance with an application, or

(cc) to revoke, vary or suspend an authorization,

the licensing authority shall notify the applicant or holder accordingly.

(2) If—

(a) the appropriate committee has not been consulted pursuant to paragraph 7; and

(b) the licensing authority propose, on grounds not relating to safety, quality or efficacy—

(i) not to grant or renew an authorization,

(ii) to grant or renew an authorization otherwise than in accordance with an application, or

(iii) to revoke, vary or suspend an authorization,

the licensing authority shall notify the applicant or holder accordingly.

(3) A notification given under sub-paragraph (1) or (2) shall state—

(a) the advice of the appropriate committee, if any, and the reasons stated by the committee for any such advice; and

(b) the proposals of the licensing authority and the reasons for them.

Right to be heard by a person appointed or to make further representations

11.—(1) Subject to sub-paragraph (4), a person to whom a notification has been given under paragraph 9(2) 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 10(1) or (2) 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) shall not apply where—

(a) the person has not made any representations in accordance with paragraph 8(4) to (7); and

(b) the decision of the licensing authority was in accordance with the advice of the appropriate committee.

Cases where suspension is to have immediate effect

12.—(1) Paragraph 7 shall not apply to the suspension of an authorization (whether or not it applies to any existing proposal to suspend or revoke the authorization) where it appears to the licensing authority that, in the interests of safety, it is necessary to suspend the authorization with immediate effect for a period not exceeding three months.

(2) Where the licensing authority so suspend an authorization they shall report the suspension forthwith to the appropriate committee.

13. If, after suspending an authorization with immediate effect by virtue of paragraph 12—

(a) it appears to the licensing authority; or

(b) the appropriate committee advise,

that the authorization ought to be further suspended, or ought to be varied or revoked, the licensing authority shall proceed in accordance with the applicable provisions of this Schedule (including paragraph 12).

PART 3

VARIATION OF AUTHORIZATION ON APPLICATION OF HOLDER

Hearing before appropriate committee relating to Type II variation applications

14.—(1) If the licensing authority decide, on grounds relating to safety, quality or efficacy—

(a) to refuse to grant a Type II variation application; or

(b) to grant it otherwise than in accordance with the application,

they shall notify the applicant accordingly.

(2) A person who has been notified in accordance with sub-paragraph (1) may, within the time allowed, give notice to the licensing authority of his wish to make written or oral representations to the appropriate committee.

(3) On receipt of a notice under sub-paragraph (2), the licensing authority shall inform the appropriate committee and the committee shall give the applicant an opportunity to make such representations in accordance with sub-paragraphs (4) to (7).

(4) Subject to sub-paragraph (5), 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 sub-paragraph (1), or within such shorter period as the licensing authority may specify in the notification referred to in sub-paragraph (1).

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

(6) The applicant may not submit any additional written representations or documents once the time limit referred to in sub-paragraphs (4) and (5) 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 sub-paragraph (4), 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.

Licensing authority decision

15.—(1) After receiving the report of the appropriate committee, the licensing authority shall—

(a) confirm or alter their decision; and

(b) take the report into account before doing so.

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

(a) the decision made pursuant to sub-paragraph (1); and

(b) the advice given to them by the appropriate committee and the reasons for that advice.

Right to be heard by a person appointed

16.—(1) Subject to sub-paragraph (2), if the licensing authority notify the applicant of the authority's decision—

(a) to refuse the application; or

(b) to grant it otherwise than in accordance with the application,

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.

(2) Sub-paragraph (1) shall not apply where—

(a) the person had not made any representations in accordance with paragraph 14(4) to (7); and

(b) the decision of the licensing authority was in accordance with the advice of the appropriate committee.

PART 4

HEARING BEFORE PERSON APPOINTED

Hearing before person appointed

17.—(1) If an applicant or holder of an authorization gives notice under paragraph 11 or 16 of his wish to appear before or be heard by a person appointed by the licensing authority, the authority shall—

(a) make that appointment; and

(b) arrange for the applicant or holder to have an opportunity of appearing before that person.

(2) The person appointed—

(a) shall not be, or at any time have been, a member of—

(i) the Commission on Human Medicines or any of its Expert Advisory Groups,

(ii) the Medicines Commission formerly established under section 2 of the Act or any of its committees, or

(iii) a committee established under section 4 of the Act, or any sub-committee of such a committee; and

(b) shall not be an officer or servant of a Minister of the Crown.

(3) Subject to sub-paragraph (4), the applicant or holder shall provide the person appointed with—

(a) 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 three months beginning with the date of the notice referred to in sub-paragraph (1).

(4) If the applicant or holder so requests, the person appointed may, after consulting the licensing authority, extend the time limit referred to in sub-paragraph (3), up to a maximum period of six months beginning with the date of the notice referred to in sub-paragraph (1).

(5) If the applicant or holder fails to comply with the time limit in sub-paragraph (3) or, where he has been granted an extended time limit under sub-paragraph (4), that time limit—

(a) he may not appear before or be heard by the person appointed; and

(b) the licensing authority shall decide whether—

(i) to confirm or alter their decision,

(ii) to grant or renew the authorization,

(iii) to grant or renew the authorization otherwise than in accordance with the application, or

(iv) to revoke, vary or suspend the authorization,

as the case may be.

(6) The applicant or holder may not submit any additional written representations or documents once the time limit has expired, except with the permission of the person appointed.

(7) At the hearing before the person appointed, both the applicant or holder and the licensing authority may make representations.

(8) If the applicant or holder so requests the hearing shall be in public.

(9) After the hearing—

(a) the person appointed shall provide a report to the licensing authority; and

(b) the licensing authority shall take this report into account and decide whether—

(i) to confirm or alter their decision,

(ii) to grant or renew the authorization,

(iii) to grant or renew the authorization otherwise than in accordance with the application, or

(iv) to revoke, vary or suspend the authorization,

as the case may be.

(10) The licensing authority shall then—

(a) notify the applicant or holder of their decision;

(b) if the applicant or holder so requests, provide the applicant or holder with a copy of the report of the person appointed.”.

SCHEDULE 3

Regulation 10

AMENDMENTS TO OTHER ENACTMENTS

The House of Commons Disqualification Act 1975

1. In Schedule 1 to the House of Commons Disqualification Act 1975(**5**) (offices disqualifying for membership), in Part 2 (bodies of which all members are disqualified)—

(a) omit the entry relating to the Medicines Commission and any committee established under section 4 of the Medicines Act 1968; and

(b) insert, at the appropriate place, the following entry—

"The Commission for Human Medicines and any committee established under section 4 of the Medicines Act 1968".

The Northern Ireland Assembly Disqualification Act 1975

2. In Schedule 1 to the Northern Ireland Assembly Disqualification Act 1975(**6**) (offices disqualifying for membership), in Part 2 (bodies of which all members are disqualified)—

(a) omit the entry relating to the Medicines Commission and any committee established under section 4 of the Medicines Act 1968; and

(b) insert, at the appropriate place, the following entry—

"The Commission for Human Medicines and any committee established under section 4 of the Medicines Act 1968".

(**5**) 1975 c. 24.
(**6**) 1975 c. 25.