SCHEDULE 5 Regulation 5

TRANSITIONAL PROVISIONS

PART 1

TRANSITIONAL PROVISIONS IN RELATION TO THE GRANT, RENEWAL, REVOCATION, SUSPENSION OR VARIATION OF LICENCES UNDER THE MEDICINES ACT 1968

Licence applications or proposals where appropriate committee has given provisional opinion before 30th October 2005

1. Paragraphs 2 to 6 apply where, before 30th October 2005—

(a) the licensing authority have, in relation to a licence, consulted a committee established under section 4 of the Act in accordance with—

(i) section 20(3) of the Act, or

(ii) paragraph 1 of Schedule 2 to the Act;

(b) the committee have sent notification to the applicant for, or holder of, that licence—

(i) under section 21(1) of the Act, that they may be unable to advise the licensing authority to grant or renew the licence, or may be unable to advise the licensing authority to grant it unless it contains provisions otherwise than in accordance with the application, or

(ii) under paragraph 2 of Schedule 2 to the Act, that they may have to advise the licensing authority that the product licence ought to be suspended, revoked or varied;

(c) the committee have not reported findings and advice to the licensing authority in relation to the application or the proposal to suspend, revoke or vary the licence.

2.—(1) This sub-paragraph applies if, before 30th October 2005, the applicant or holder—

(a) has not given notice of his wish to make written or oral representations in relation to the matters set out in the notification referred to in paragraph 1(b); or

(b) has made representations in writing in relation to those matters.

(2) If sub-paragraph (1) applies, the applicant or holder may, by 30th November 2005, give notice of his wish to make—

(a) oral representations, or

(b) written representations, or additional written representations, as the case may be,

to the appropriate committee.

(3) If the applicant or holder does not give notice in accordance with sub-paragraph (2)—

(a) the appropriate committee shall—

(i) if the applicant or holder made written representations before 30th October, take those representations into account; and

(ii) report their findings and advice to the licensing authority, together with the reasons for their advice; and

(b) subject to sub-paragraphs (4) and (5), the report shall be treated as if—

(i) in the case where the report relates to an application for a licence, it has been given under section 21(8)(b) of the Act, or

(ii) in the case where the report relates to a proposal to suspend, revoke or vary a licence, it has been given under paragraph 2(8)(b) of Schedule 2 to the Act.

(4) Where sub-paragraph (3)(b)(i) applies, section 21(11)(a) and (b) of the Act shall apply as if for "representations in accordance with this section" there were substituted "written representations prior to 30th October".

(5) Where sub-paragraph (3)(b)(ii) applies, paragraph 5(4)(a) of Schedule 2 to the Act shall apply as if for the words from "in accordance with" to "Schedule" there were substituted "written representations prior to 30th October".

3.—(1) This paragraph and paragraph (4) apply if the applicant or holder—

(a) gave notice of his wish to make written or oral representations to the appropriate committee before 30th October 2005, but has not made any such representations; or

(b) gives notice under paragraph 2(2).

(2) The applicant or holder shall, before 31st May 2006, provide the appropriate committee with—

(a) his written representations, or any additional written representations, if he provided written representations before 30th October 2005; or

(b) a summary of the oral representations he intends to make,

and any documents on which he wishes to rely in support of those representations.

(3) If the applicant or holder so requests, the appropriate committee may extend the time limit referred to in sub-paragraph (2), up to a maximum of twelve months from 30th November 2005.

(4) The applicant or holder may not submit any additional written representations or documents once the time limit referred to in sub-paragraphs (2) and (3) has expired, except with the permission of the appropriate committee.

4.—(1) When the applicant or holder has submitted the representations and documents referred to in paragraph 3(2), the appropriate committee shall—

(a) take into account the representations and documents which he has provided; and

(b) notify the applicant or holder if, on grounds which are additional to or different from those notified to him before 30th October 2005, they are of the provisional opinion that they—

(i) may be unable to advise the licensing authority to grant or renew the licence, or may be unable to advise the licensing authority to grant it unless it contains provisions in accordance with the application, or

(ii) may have to advise the licensing authority that the licence ought to be suspended, revoked or varied.

(2) If the appropriate committee give the notification referred to in sub-paragraph (1)(b)—

(a) they shall state in the notification which, if any, of the grounds notified before 30th October 2005 they consider still apply; and

(b) the provisions of—

(i) section 21(2) to (7) to the Act; or

(ii) paragraph 2(2) to (7) of Schedule 2 to the Act,

whichever is applicable, shall apply in relation to the grounds set out in the notification, including any grounds notified under paragraph (a).

5.—(1) This paragraph applies if—

(a) the appropriate committee do not give any notification under paragraph 4(1)(b); and

(b) the applicant or holder gave notice of his wish to make oral representations—

(i) before 30th October 2005; or

(ii) under paragraph 2(2).

(2) The appropriate committee shall, after receiving a written summary and any other documents in accordance with paragraph 3(2), arrange for the applicant or holder to make such representations at a hearing before the committee.

6.—(1) The appropriate committee shall—

(a) take into account such representations as are made in accordance with paragraphs 3 to 5; and

(b) report their findings and advice to the licensing authority, together with the reasons for their advice.

(2) Subject to sub-paragraphs (3) and (4)—

(a) where the report of the appropriate committee relates to an application for a licence, it shall be treated as if it has been given under section 21(8)(b) of the Act;

(b) where the report of the appropriate committee relates to a proposal to revoke, suspend or vary a licence, it shall be treated as if it had been given under paragraph 2(8)(b) of Schedule 2 to the Act.

(3) Where sub-paragraph 2(a) applies, section 21 of the Act shall apply as if, in subsection (11) (a) and (b), for "this section" there were substituted "paragraphs 3 to 5 of Part 1 of Schedule 5 to the Medicines (Advisory Bodies) (No. 2) Regulations 2005";

(4) Where sub-paragraph 2(b) applies, paragraph 5(4) of Schedule 2 to the Act shall apply as if, in paragraph (a), for "paragraph 2(4) to (7) of this Schedule" there were substituted "paragraphs 3 to 5 of Part 1 of Schedule 5 to the Medicines (Advisory Bodies) (No. 2) Regulations 2005".

Licence applications or proposals where appropriate committee has given advice to the licensing authority before 30th October 2005

7. Paragraphs 8 to 11 apply where, before 30th October 2005, a committee established under section 4 of the Act have given advice to the licensing authority—

(a) that an application for the grant or renewal of a licence ought to be refused, or ought if granted to contain provisions specified in their advice; or

(b) that a licence ought to be suspended, revoked or varied.

8.—(1) This paragraph applies where the licensing authority has not, before 30th October 2005, notified the applicant for, or holder of, the licence of the advice referred to in paragraph 7.

(2) The licensing authority shall so notify the applicant or holder.

(3) The applicant or holder may, within the time allowed, give notice to the licensing authority that he wishes to make written or oral representations to the Commission with respect to that advice.

9.—(1) This paragraph applies where, before 30th October 2005, the licensing authority has notified the applicant or holder of the advice referred to in paragraph 7.

(2) If, before 30th October 2005—

(a) the applicant or holder has not given notice of his desire to be heard by, or to make written representations to, the Medicines Commission; and

(b) the period of 28 days after the service of the notification referred to in sub-paragraph (1), or such longer period as the licensing authority has allowed in the particular case, has not expired,

the applicant or holder may, by 30th November 2005, give notice to the licensing authority of his wish to make written or oral representations to the Commission.

(3) If, before 30th October 2005—

(a) the applicant or holder made written representations in relation to the advice referred to in paragraph 1(b); and

(b) those representations were made within—

(i) the period of 28 days after the service of the notification referred to in sub-paragraph (1); or

(ii) such longer period as the licensing authority had allowed,

the applicant or holder may, by 30th November 2005, give notice of his wish to make oral representations, or additional written representations, to the Commission.

10.—(1) This paragraph applies where—

(a) the applicant or holder gives the notice referred to in paragraph 8(3), or 9(2) or (3); or

(b) before 30th October 2005, the applicant or holder gave notice of his wish to make written or oral representations to the Medicines Commission, within—

(i) the period of 28 days after the service of the licensing authority's notification referred to in paragraph 9(1), or

(ii) such longer period as the licensing authority had allowed.

(2) The applicant or holder shall, before the end of the period of six months beginning with the date of his notice referred to in sub-paragraph (1), provide the Commission with—

(a) his written representations, or any additional written representations, if he provided written representations before 30th October 2005; or

(b) a summary of the oral representations he intends to make,

and any documents on which he wishes to rely in support of those representations.

(3) If the applicant or holder so requests, the Commission may extend the time limit referred to in sub-paragraph (2), up to a maximum of twelve months from the date of the notice referred to in sub-paragraph (1).

(4) The applicant or holder may not submit any additional representations or documents when the time limit referred to in sub-paragraph (2) and (3) has expired, except with the permission of the Commission.

(5) If the applicant or holder gave notice of his wish to make oral representations, the Commission shall, after receiving a written summary and any other documents in accordance with sub-paragraph (2), arrange for the applicant to make such representations at a hearing before the Commission.

11.—(1) The Commission shall—

(a) take into account—

(i) such representations as are made in accordance with paragraph 10; or

(ii) any written representations made before 30th October 2005; and

(b) report their findings and advice to the licensing authority, together with the reasons for their advice.

(2) Subject to sub-paragraphs (3) and (4)—

(a) where the report of the Commission relates to an application for a licence, it shall be treated as if it has been given under section 21(8)(b) of the Act;

(b) where the report of the Commission relates to a proposal to revoke, suspend or vary a licence, it shall be treated as if it had been given under paragraph 2(8)(b) of Schedule 2 to the Act.

(3) Where sub-paragraph (1)(a) applies, section 21 of the Act shall apply as if, in subsection (11)(a) and (b), for "this section" there were substituted "paragraph 10 of Part 1 of Schedule 5 to the Medicines (Advisory Bodies) (No. 2) Regulations 2005, or has made written representations before 30th October 2005";

(4) Where sub-paragraph (1)(b) applies, paragraph 5(4)(a) of Schedule 2 to the Act shall apply as if for "paragraph 2(4) to (7) of this Schedule" there were substituted "paragraph 10 of Part 1 of Schedule 5 to the Medicines (Advisory Bodies) (No. 2) Regulations 2005, or has not made written representations before 30th October 2005".

Right to be heard by person appointed in relation to licence applications or proposals made before 30th October 2005

12.—(1) This paragraph applies where, before 30th October 2005—

(a) the Medicines Commission have reported findings and advice to the licensing authority under—

(i) section 21(4) of the Act; or

(ii) paragraph 5 of Schedule 2 to the Act; and

(b) the licensing authority have not notified the applicant or holder of its proposals following the advice of the Medicines Commission.

(2) If the licensing authority propose to determine the application or matter in a way which differs from the advice of the Medicines Commission referred to in sub-paragraph (1)(a)—

(a) the licensing authority shall notify the applicant or holder accordingly; and

(b) the applicant or holder may, within the time allowed—

(i) notify the licensing authority that he wishes to appear before and be heard by a person appointed by the licensing authority with respect to those proposals; or

(ii) make written representations to the licensing authority.

13.—(1) This paragraph applies where, before 30th October 2005—

(a) the licensing authority have notified an applicant or holder of advice of a committee established under section 4 of the Act;

(b) the applicant did not give notice to the licensing authority that he wished to make representations to the Medicines Commission within—

(i) 28 days after the service of the notification referred to in paragraph (a); or

(ii) such longer period as the licensing authority had allowed; and

(c) the licensing authority have not notified the applicant or holder of any decision.

(2) If the licensing authority—

(a) propose to determine the application; or

(b) propose to refuse to renew or revoke, vary or suspend the licence,

in a way which differs from the advice given by the committee established under section 4 of the Act, the licensing authority shall notify the applicant or holder accordingly.

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

(a) give notice to the licensing authority of his wish to appear before and be heard by a person appointed by the licensing authority with respect to those proposals; or

(b) make written representations to the licensing authority.

14.—(1) This paragraph applies where, before 30th October 2005—

(a) the appropriate committee—

(i) have been consulted under—

(aa) section 20(3) of the Act; or

(bb) paragraph 1 of Schedule 2 to, the Act; and

(ii) have not given a provisional opinion in accordance with—

(aa) section 21(1) of the Act, or

(bb) paragraph 2 of Schedule 2 to the Act; and

(b) the licensing authority have not notified the applicant of any proposals.

(2) If the licensing authority propose to—

(a) refuse to grant or renew the licence,

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

(c) revoke, vary or suspend the licence;

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

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

(a) notify the licensing authority that he wishes to be heard by a person appointed by the licensing authority with respect to the proposal; or

(b) make written representations to the licensing authority.

15.—(1) This paragraph applies where—

(a) before 30th October 2005, the licensing authority have consulted the appropriate committee in accordance with section 20(3) of or paragraph 1 of Schedule 2 to, the Act;

(b) the licensing authority propose to—

(i) refuse to grant or renew the licence,

(ii) grant it otherwise than in accordance with the application, or

(iii) revoke, vary or suspend the licence;

on grounds not relating to safety, quality or efficacy; and

(c) the licensing authority have not notified the applicant or holder of their proposals.

(2) The licensing authority shall notify the applicant of their proposals and the reasons for them.

(3) The applicant or holder may, within the time allowed—

(a) notify the licensing authority that he wishes to be heard by a person appointed by the licensing authority with respect to the proposal; or

(b) make written representations to the licensing authority.

16.—(1) This paragraph applies where—

(a) paragraph 8 or 9 applies;

(b) the applicant or holder does not give notice that he wishes to make representations to the Commission in accordance with paragraph 8(3), or 9(2) or (3); and

(c) the licensing authority propose to determine the application or matter in a way which differs from the advice of the committee established under section 4 of the Act.

(2) The licensing authority shall notify the applicant or holder accordingly.

(3) The applicant or holder may, within the time allowed—

(a) notify the licensing authority that he wishes to appear before and be heard by a person appointed by the licensing authority with respect to those proposals; or

(b) make written representations to the licensing authority.

Other licensing authority proposals notified to applicant or holder before 30th October 2005

17.—(1) This paragraph applies where, before 30th October 2005—

(a) the licensing authority have notified an applicant for, or holder of, a licence of their proposals under—

(i) section 21(5) of the Act, or

(ii) paragraph 6 of Schedule 2 to the Act;

(b) the applicant or holder has not—

(i) given notice of his desire to appear before and be heard by a person appointed by the licensing authority; or

(ii) made representations in writing,

with respect to the relevant proposal; and

(c) the licensing authority has not determined the application or matter.

(2) The applicant or holder may, by 30th November 2005—

(a) 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 proposals; or

(b) make written representations to the licensing authority.

Licence applications or proposals where there was no requirement to refer to appropriate committee before 30th October 2005

18.—(1) This paragraph applies where, before 30th October 2005—

(a) the licensing authority—

(i) have served notice on an applicant under section 22(2) of the Act that they propose to refuse to grant or renew an application for a licence, or propose to grant it otherwise than in accordance with the application; or

(ii) have served notice on the holder of a licence under paragraph 8(a) or (b) of Schedule 2 to the Act that they propose to suspend, revoke or vary a licence;

(b) the applicant or holder of the licence has not—

(i) given notice of his desire to appear before and be heard by a person appointed by the licensing authority; or

(ii) made representations in writing,

with respect to the relevant proposal;

(c) the period of 28 days after the service of the notification by the licensing authority referred to in sub-paragraph (a), or such longer period as the licensing authority has allowed in the particular case, has not expired.

(2) The applicant or holder may, by 30th November 2005—

(a) notify the licensing authority that he wishes to appear before and be heard by a person appointed by the licensing authority;

(b) make representations in writing to the licensing authority.

Applicant has given notice of wish to appear before person appointed prior to 30th October

19.—(1) This paragraph applies where, before 30th October 2005, an applicant for, or holder of, a licence has given notice to the licensing authority of his wish to appear before, or be heard by, a person appointed by the licensing authority under—

(a) section 21(5), or 22(3) of, or

(b) paragraph 6 or 8 of Schedule 2 to,

the Act.

(2) If, before 30th October 2005, the licensing authority—

(a) have not made that appointment—

(i) they shall do so; and

(ii) 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) have made that appointment, the person appointed shall be treated as if he had been appointed under paragraph (a).

(3) Where this paragraph applies—

(a) the provisions of—

(i) section 22A of the Act; or

(ii) paragraph 7 of Schedule 2 to, the Act

shall not apply;

(b) the licensing authority shall arrange for the applicant to have an opportunity of appearing before and being heard by the person appointed;

(c) if the applicant or holder so requests—

(i) the hearing shall be in public, and

(ii) the licensing authority shall furnish to him a copy of the report of the person so appointed;

(d) the hearing before the person appointed shall be conducted in accordance with the Medicines Act 1968 (Hearings by Persons Appointed) Rules 1986(**1**); and

(e) the licensing authority shall take into account the report of the person so appointed before determining the application or matter.

Notice of wish to appear before person appointed given under this Part

20. Where, under any provision of any Part of this Schedule, an applicant or holder gives notice of his desire to be appear before and be heard by a person appointed by the licensing authority—

(**1**) S.I.1986/1761.

(a) where the matter relates to an application for a licence, the notice shall be treated as having been given under section 21(11), or 22(3) of the Act; and

(b) where the matter relates to a proposal to revoke, vary or suspend a licence, the notice shall be treated as having been given under paragraph 5(1) or 6(3)(a) of Schedule 2 to the Act.

Written representations made before 30th October 2005 or under this Part

21. Where—

(a) before 30th October, an applicant for, or holder of, a licence made written representations to the licensing authority pursuant to—

(i) section 21(5) or 22(3) of the Act; or

(ii) paragraph 6 or 9 of Schedule 2 to the Act, but the licensing authority had not yet determined the application or matter; or

(b) an applicant or holder makes written representations to the licensing authority under any provision of this Part,

the licensing authority shall take those representations into account before determining the application or matter.

Emergency suspensions in force on 30th October 2005

22.—(1) This sub-paragraph applies where—

(a) before 30th October 2005, the licensing authority have suspended a licence under paragraph 11 of Schedule 2 to the Act; and

(b) the suspension is in effect.

(2) Where sub-paragraph (1) applies, the suspension shall be treated as if it had been made under paragraph 8 of Schedule 2 to the Act.

(3) This sub-paragraph applies where—

(a) before 30th October 2005, the licensing authority have further suspended a licence under paragraph 14 of Schedule 2 to the Act; and

(b) the suspension is in effect.

(4) Where sub-paragraph (3) applies, the suspension shall be treated as if it had been made under paragraph 11(2) of Schedule 2 to the Act.

PART 2

TRANSITIONAL PROVISIONS APPLICABLE TO OTHER PROVISIONS UNDER THE ACT

1.—(1) This paragraph applies where, before 30th October 2005—

(a) the appropriate Ministers have consulted the Committee on Safety of Medicines on a proposal to make an order under section 58(6) of the Act; and

(b) no order has been made.

(2) For the purposes of section 58(6) of the Act, the consultation with the Committee on Safety of Medicines shall be treated as a consultation with the appropriate committee.

2.—(1) This paragraph applies where, before 30th October 2005—

(a) the appropriate Ministers have consulted the Committee on Safety of Medicines on a proposal to make regulations under section 60(7) of the Act; and

(b) no regulations have been made.

(2) For the purposes of section 60(7) of the Act, the consultation with the Committee on Safety of Medicines shall be treated as a consultation with the appropriate committee.

3.—(1) This paragraph applies where, before 30th October 2005—

(a) the appropriate Ministers have consulted the Committee on Safety of Medicines on a proposal to make an order under section 62(3) of the Act; and

(b) no order has been made.

(2) For the purposes of section 62(3) of the Act , the consultation with the Committee on Safety of Medicines shall be treated as a consultation with the appropriate committee under section 62(3) of the Act.

PART 3

TRANSITIONAL PROVISIONS IN RELATION TO THE GRANT, RENEWAL, REVOCATION, SUSPENSION OR VARIATION OF MARKETING AUTHORIZATIONS UNDER THE MARKETING AUTHORIZATION REGULATIONS

Applications for, or proposals in relation to, marketing authorizations, where appropriate committee has given provisional opinion before 30th October 2005

1. Paragraphs 2 to 6 apply where, before 30th October 2005—

(a) the licensing authority have consulted a committee established under section 4 of the Act in relation to a marketing authorization, in accordance with paragraph 5 of Schedule 2 to the Marketing Authorization Regulations;

(b) the committee have sent notification to the applicant for, or holder of, that marketing authorization—

(i) under paragraph 6(1)(a) of Schedule 2 to the Marketing Authorization Regulations, that they may be unable to advise the licensing authority to grant or renew the authorization;

(ii) under paragraph 6(1)(b) of that Schedule, that they may be unable to grant it unless it contains provisions otherwise than in accordance with the application; or

(iii) under paragraph 6(1)(c) of that Schedule, that they may have to advise the licensing authority that the authorization ought to be revoked, varied or suspended; and

(c) the committee have not reported findings and advice to the licensing authority in relation to the application, or the proposal to suspend, revoke or vary the authorization.

2.—(1) This sub-paragraph applies where, before 30th October 2005—

(a) the applicant or holder has not given notice of his wish to make written or oral representations in relation to the matters set out in the notification referred to in paragraph 1(b); and

(b) the period of 28 days after the giving of the notification, or such longer period as the licensing authority has allowed in the particular case, has not expired.

(2) Where sub-paragraph (1) applies, the applicant or holder may, by 30th November 2005, give notice of his wish to make oral or written representations to the appropriate committee.

(3) This sub-paragraph applies where, before 30th October 2005—

(a) the applicant or holder made written representations in relation to the matters set out in the notification referred to in paragraph 1(b); and

(b) those representations were made within—

(i) the period of 28 days from the giving of the notification; or

(ii) within such longer period as the licensing authority had allowed.

(4) Where sub-paragraph (3) applies, the applicant or holder may, by 30th November 2005, give notice of his wish to make—

(a) oral representations; or

(b) additional written representations,

to the appropriate committee.

(5) Where the applicant or holder does not give notice in accordance with sub-paragraph (2) or (4), the appropriate committee shall—

(a) if the applicant or holder made written representations before 30th October, take those representations into account; and

(b) report their findings and advice to the licensing authority, together with the reasons for their advice.

(6) Subject to sub-paragraph (7), the report of the appropriate committee shall be treated as if it has been given under paragraph 8(8)(b) of Schedule 2 to the Marketing Authorization Regulations.

(7) Paragraph 11(4)(a) of Schedule 2 to the Marketing Authorization Regulations shall apply as if for "any representations in accordance with paragraph 8(4) to (7)" there were substituted "written representations as referred to in paragraph 2(3) of Part III of Schedule 5 to the Medicines (Advisory Bodies) (No. 2) Regulations 2005".

3.—(1) This paragraph applies if the applicant or holder—

(a) gave notice of his wish to make written or oral representations to the appropriate committee before 30th October 2005; or

(b) gives notice under paragraph 2(2) or (4).

(2) The applicant or holder shall, before 31st May 2006, provide the appropriate committee with—

(a) his written representations, or any additional written representations, if he provided written representations before 30th October; or

(b) a summary of the oral representations he intends to make,

and any documents on which he wishes to rely in support of those representations.

(3) If the applicant or holder so requests, the appropriate committee may extend the time limit referred to in sub-paragraph (2), up to a maximum of twelve months from 30th November 2005.

(4) The applicant or holder may not submit any additional written representations or documents once the time limit referred to in sub-paragraphs (2) and (3) has expired, except with the permission of the appropriate committee.

4.—(1) When the applicant or holder has submitted the representations and documents referred to in paragraph 3(2), the appropriate committee shall—

(a) take into account the representations and documents which he has provided; and

(b) notify the applicant or holder if, on grounds which are additional to or different from those notified to him before 30th October 2005, they are of the provisional opinion that they—

(i) may be unable to advise the licensing authority to grant or renew the authorization, or may be unable to advise the licensing authority to grant it unless it contains provisions in accordance with the application, or

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

(2) If the appropriate committee give the notification referred to in sub-paragraph (1)(b)—

(a) they shall state in the notification which, if any, of the grounds notified before 30th October 2005 they consider still apply; and

(b) the provisions of paragraph 8(2) to (7) of Schedule 2 to the Marketing Authorization Regulations shall apply in relation to the grounds set out in the notification, including any grounds notified under paragraph (a).

5.—(1) This paragraph applies if—

(a) the appropriate committee do not give any notification under paragraph 4(1)(b); and

(b) the applicant or holder gave notice of his wish to make oral representations—

(i) before 30th October 2005; or

(ii) under paragraph 2(2) or (4).

(2) The appropriate committee shall, after receiving a written summary and any other documents in accordance with paragraph 3(2), arrange for the applicant or holder to make such representations at a hearing before the committee.

6.—(1) The appropriate committee shall—

(a) take into account such representations as are made in accordance with paragraphs 3 to 5; and

(b) report their findings and advice to the licensing authority, together with the reasons for their advice.

(2) Subject to sub-paragraph (3), the report of the appropriate committee shall be treated as if it has been given under paragraph 8(8)(b) of Schedule 2 to the Marketing Authorization Regulations.

(3) Paragraph 11(4)(a) of Schedule 2 to the Marketing Authorization Regulations shall apply as if, for "paragraph 8(4) to (7)" there were substituted "paragraphs 3 to 5 of Part 3 of Schedule 5 to the Medicines (Advisory Bodies) (No. 2) Regulations 2005".

Marketing authorisation applications or proposals where appropriate committee has given advice to the licensing authority before 30th October 2005

7. Paragraphs 8 to 11 apply where, before 30th October 2005, a committee established under section 4 of the Act have given advice to the licensing authority—

(a) that an application for the grant or renewal of a marketing authorization ought to be refused, or ought if granted to contain provisions specified in their advice; or

(b) that an authorization ought to be suspended, revoked or varied.

8.—(1) This paragraph applies where the licensing authority have not, before 30th October 2005, notified the applicant for, or holder of, the authorization of the advice referred to in paragraph 7.

(2) If they have not done so before 30th October 2005, the licensing authority shall—

(a) in the case of an application for the grant of an authorization, grant or refuse the application, or grant it with provisions otherwise than in accordance with the application;

(b) in the case of an application for the renewal of an authorization, renew the application (whether or not in accordance with the application), or decide that they are still minded to refuse it;

(c) in the case of a proposal to revoke, suspend or vary an authorization, decide whether to proceed further with their proposal.

(3) The licensing authority shall notify the applicant or holder of the advice referred to in paragraph 7 of this Schedule and of its decision—

(a) made before 30th October 2005 under paragraph 7 of Schedule 2 to the Marketing Authorization Regulations; or

(b) made under sub-paragraph (2)(a), (b), or (c).

(4) If the applicant or holder is dissatisfied, he may, within the time allowed, give notice to the licensing authority that he wishes to make written or oral representations to the Commission with respect to the licensing authority's decision.

9.—(1) This paragraph applies where, before 30th October 2005, the licensing authority have given notice to the applicant or holder of—

(a) the advice referred to in paragraph 7 of this Schedule; and

(b) of its decision made under paragraph 7 of Schedule 2 to the Marketing Authorization Regulations.

(2) If, before 30th October 2005—

(a) the applicant or holder has not given notice of his desire to be heard by, or to make written representations to, the Medicines Commission; and

(b) the period of 28 days after the service of the notice referred to in sub-paragraph (1), or such longer period as the licensing authority has allowed in the particular case, has not expired,

the applicant or holder may, by 30th November 2005, give notice to the licensing authority of his wish to make written or oral representations to the Commission.

(3) If, before 30th October 2005—

(a) the applicant or holder made written representations in relation to a decision of the licensing authority which was made after the advice referred to in paragraph 7 had been given; and

(b) those representations were made within—

(i) the period of 28 days after the service of the licensing authority's notice referred to in sub-paragraph (1), or

(ii) such longer period as the licensing authority had allowed,

the applicant or holder may, by 30th November 2005, give notice of his wish to make oral representations, or additional written representations, to the Commission.

10.—(1) This paragraph applies where—

(a) the applicant or holder gives the notice referred to in paragraph 8(4), or 9(2) or (3); or

(b) before 30th October 2005, within—

(i) the period of 28 days after the giving of the licensing authority's notice referred to in paragraph 9(1), or

(ii) such longer period as the licensing authority had allowed,

the applicant or holder gave notice of his wish to make written or oral representations to the Medicines Commission.

(2) The applicant or holder shall, before the end of the period of six months beginning with the date of his notice referred to in sub-paragraph (1), provide the Commission with—

(a) his written representations, or any additional written representations, if he provided written representations before 30th October 2005; or

(b) a summary of the oral representations he intends to make,

and any documents on which he wishes to rely in support of those representations.

(3) If the applicant or holder so requests, the Commission may extend the time limit referred to in sub-paragraph (2), up to a maximum of twelve months from the date of the notice referred to in sub-paragraph (1).

(4) The applicant or holder may not submit any additional representations or documents when the time limit referred to in sub-paragraph (2) and (3) has expired, except with the permission of the Commission.

(5) If the applicant or holder gave notice of his wish to make oral representations, the Commission shall, after receiving a written summary and any other documents in accordance with sub-paragraph (2), arrange for the applicant or holder to make such representations at a hearing before the Commission.

11.—(1) The Commission shall—

(a) take into account—

(i) such representations as are made in accordance with paragraph 10; or

(ii) any written representations made before 30th October 2005; and

(b) report their findings and advice to the licensing authority, together with the reasons for their advice.

(2) Subject to sub-paragraph (3), the report of the Commission shall be treated as if it had been given under paragraph 8(8)(b) of Schedule 2 to the Marketing Authorization Regulations.

(3) Paragraph 11(4)(a) of Schedule 2 to the Marketing Authorization Regulations shall apply as if for "paragraph 8(4) to (7)" there were substituted "paragraph 10 of Part 3 of Schedule 5 to the Medicines (Advisory Bodies) (No. 2) Regulations 2005, or has not made written representations before 30th October".

Right to be heard by person appointed in relation to marketing authorisation applications or proposals made before 30th October 2005

12.—(1) This paragraph applies where, before 30th October 2005—

(a) the Medicines Commission have reported findings and advice to the licensing authority under paragraph 8(3) of Schedule 2 to the Marketing Authorization Regulations; and

(b) the licensing authority have not notified the applicant or holder of—

(i) that advice; or

(ii) the confirmation or alteration of their decision under paragraph 7 of Schedule 2 to those regulations.

(2) The licensing authority shall give notice to the applicant or holder of—

(i) the Medicines Commission's advice and the reasons for it;

(ii) the confirmation or alteration of their decision.

(3) The applicant or holder may, within the time allowed—

(a) notify the licensing authority that he wishes to appear before and be heard by a person appointed by the licensing authority; or

(b) make written representations to the licensing authority.

13.—(1) This paragraph applies where, before 30th October 2005—

(a) the appropriate committee—

(i) have been consulted under paragraph 5 of Schedule 2 to the Marketing Authorization Regulations; and

(ii) have not given a provisional opinion in accordance with paragraph 6 of that Schedule; and

(b) the licensing authority have not notified the applicant or holder of a decision, or of any proposals.

(2) If the licensing authority—

(a) propose to refuse to grant or renew the authorization, or grant it otherwise than in accordance with the application; or

(b) propose to revoke, vary or suspend the authorization,

the licensing authority shall notify the applicant or holder of their proposals and the reasons for them.

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

(a) give notice to the licensing authority of his wish to appear before and be heard by a person appointed by the licensing authority with respect to those proposals; or

(b) make written representations to the licensing authority.

14.—(1) This paragraph applies where—

(a) before 30th October 2005, the licensing authority have consulted the appropriate committee under paragraph 5 of Schedule 2 to the Marketing Authorization Regulations;

(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; and

(c) the licensing authority have not notified the applicant or holder of their proposals.

(2) The licensing authority shall notify the applicant or holder of their proposals and the reasons for them.

(3) The applicant or holder may, within the time allowed—

(a) notify the licensing authority that he wishes to be heard by a person appointed by the licensing authority with respect to the proposal;

(b) make written representations to the licensing authority.

15.—(1) This paragraph applies where—

(a) paragraph 8 or 9 applies;

(b) the applicant or holder does not give notice that he wishes to make representations to the Commission in accordance with paragraph 8(4), or 9(2) or (3); and

(c) the licensing authority propose to determine the application or matter in a way which differs from the advice of the appropriate committee.

(2) The licensing authority shall notify the applicant or holder accordingly.

(3) The applicant or holder may, within the time allowed—

(a) notify the licensing authority that he wishes to appear before and be heard by a person appointed by the licensing authority with respect to those proposals; or

(b) make written representations to the licensing authority.

Other licensing authority proposals notified to applicant or holder before 30th October 2005

16.—(1) This paragraph applies where, before 30th October 2005—

(a) the licensing authority have notified an applicant for, or holder of, a marketing authorization of their determination, or of their proposals, under paragraph 9 of Schedule 2 to the Marketing Authorization Regulations;

(b) the applicant or holder has not—

(i) given notice of his desire to appear before and be heard by a person appointed by the licensing authority; or

(ii) made representations in writing; and

(c) the period of 28 days after the licensing authority gave their notification, or such longer period as the licensing authority has allowed in the particular case, has not expired.

(2) The applicant or holder may, by 30th November 2005—

(a) 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 proposals; or

(b) make written representations to the licensing authority.

Marketing authorization applications or proposals where there was no requirement to refer to appropriate committee before 30th October 2005

17.—(1) This paragraph applies where, before 30th October 2005—

(a) the licensing authority have notified an applicant for, or holder of, a marketing authorisation that they 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 the application; or

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

(b) the applicant or holder of the licence has not given notice of his desire to be heard with respect to the relevant proposal; and

(c) the period of 28 days after the licensing authority gave their notification, or such longer period as the licensing authority has allowed in the particular case, has not expired.

(2) The applicant or holder may, by 30th November 2005—

(a) 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 proposal; or

(b) make written representations to the licensing authority.

Applicant has given notice of wish to appear before person appointed prior to 30th October

18.—(1) This paragraph applies where, before 30th October 2005, an applicant for, or holder of, a marketing authorization has, under paragraph 11 of Schedule 2 to the Marketing Authorization

Regulations, given notice of his wish to appear before and be heard by a person appointed by the licensing authority.

(2) If, before 30th October 2005, the licensing authority—

(a) have not made that appointment, they shall do so and 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) have made that appointment, that person shall remain appointed for the purposes of this paragraph.

(3) Where this paragraph applies—

(a) the provisions of Part 4 of Schedule 2 to the Marketing Authorization Regulations shall not apply;

(b) the licensing authority shall arrange for the applicant or holder to have an opportunity of appearing before and being heard by the person appointed;

(c) if the applicant or holder so requests—

(i) the hearing shall be in public, and

(ii) the licensing authority shall furnish to him a copy of the report of the person so appointed; and

(d) the licensing authority shall take into account the report of the person so appointed before determining the application or matter.

Notice of wish to appear before person appointed given under this Part

19.—(1) This paragraph applies where, under any provision of this Part, an applicant or holder gives notice of his desire to appear before and be heard by a person appointed by the licensing authority.

(2) The notice shall be treated as having been given under paragraph 11 of Schedule 2 to the Marketing Authorization Regulations.

Written representations made prior to 30th October or under this Part

20. Where—

(a) before 30th October 2005, the applicant for, or holder of, a marketing authorization made written representations to the licensing authority pursuant to paragraph 11 of the Marketing Authorization Regulations, but the licensing authority had not determined the application or matter; or

(b) an applicant or holder makes written representations to the licensing authority under any provision of this Part,

the licensing authority shall take those representations into account before determining the application or matter.

Procedure in cases of emergency

21.—(1) This sub-paragraph applies where—

(a) before 30th October 2005, the licensing authority have suspended a marketing authorization under paragraph 13 of Schedule 2 to the Marketing Authorization Regulations; and

(b) the suspension is in effect.

(2) Where sub-paragraph (1) applies, the licensing authority shall be treated as if it had suspended the authorization by virtue of paragraph 12 of Schedule 2 to the Marketing Authorization Regulations.

PART 4

TRANSITIONAL PROVISIONS APPLICABLE TO THE CLINICAL TRIALS REGULATIONS

Procedural provisions relating to the refusal or amendment of, or imposition of conditions relating to, clinical trial authorizations and the suspension or termination of clinical trials

1.—(1) This paragraph applies where, before 30th October 2005—

(a) a sponsor has been given a notice as referred to in regulation 26(1) of the Clinical Trials Regulations; or

(b) a sponsor or investigator has been served with a notice in accordance with regulation 31(1) of the Clinical Trials Regulations.

(2) If—

(a) the period of 28 days; or

(b) such longer period as the licensing authority has allowed in the particular case,

has not expired, the sponsor or investigator may, by 30th November 2005, give notice of his wish to make written or oral representations to the appropriate committee.

(3) If the sponsor or investigator gives this notice, he shall be treated as if he had given notice of his wish to make written or oral representations to the appropriate committee in accordance with regulation 26(1) or regulation 31(7) of the Clinical Trials Regulations.

2.—(1) This paragraph applies where, before 30th October 2005—

(a) the licensing authority have been notified of the sponsor's or investigator's wish, in accordance with regulation 26(1) or 31(7) of the Clinical Trials Regulations, to make written or oral representations, but the sponsor or investigator has not made those representations; or

(b) the sponsor or investigator has made written representations under regulation 26(1) or 31(7), but a committee established under section 4 of the Act has not considered those representations.

(2) If the sponsor or investigator has notified the licensing authority of his wish to make oral representations, the licensing authority shall afford him an opportunity to make those representations at a hearing before the appropriate committee.

(3) The appropriate committee shall—

(a) take into account such representations as are made; and

(b) report their findings and advice to the licensing authority, together with the reasons for their advice.

(4) The report of the appropriate committee under sub-paragraph (3)(b) shall be treated as the report of the appropriate committee under paragraph 1(6)(b) of Schedule 5 to the Clinical Trials Regulations.

3.—(1) This paragraph applies where, before 30th October 2005—

(a) a committee established under section 4 of the Act—

(i) has considered written or oral representations of the sponsor or investigator; and

(ii) has reported findings and advice to the licensing authority; and

(b) the licensing authority have not made a decision under paragraph 1(3), (4), or (5) of Schedule 5 to the Clinical Trials Regulations.

(2) The report of the committee referred to in sub-paragraph 1(a)(ii) shall be treated as the report of the appropriate committee under paragraph 1(6)(b) of Schedule 5 to those regulations.

Procedural provisions relating to proposals to grant, refuse to grant, vary, suspend or revoke manufacturing authorizations

4.—(1) This paragraph applies where, before 30th October 2005—

(a) notification has been given to an applicant for, or holder of, a manufacturing authorization under paragraph 2 of Schedule 8 to the Clinical Trials Regulations;

(b) the person has not given notice of his wish to—

(i) appear before, or be heard by, a person appointed by the licensing authority; or

(ii) make representations in writing to the licensing authority,

with respect to the decision or proposal referred to in the notification; and

(c) the period of 28 days after the notification was given, or such extended period as the licensing authority has allowed, has not expired.

(2) The applicant or holder may, by 30th November 2005—

(a) give notice of his wish to appear before and be heard by a person appointed by the licensing authority; or

(b) make representations in writing to the licensing authority.

(3) If the applicant or holder gives notice under sub-paragraph (2)(a), he shall be treated as if he had given notice under paragraph 4(1)(a) of Schedule 8 to the Clinical Trials Regulations.

5. If—

(a) the applicant or holder made written representations to the licensing authority before 30th October; or

(b) makes written representations under paragraph 4(2)(b),

the licensing authority shall take those representations into account before determining the application or matter.

6. Where before 30th October—

(a) an applicant or holder gives notice under paragraph 4 of Schedule 8 to the Clinical Trials Regulations; and

(b) the applicant or holder has not appeared before a person appointed,

the applicant or holder shall be treated as if he had given a notice under paragraph 4(1)(a) of Schedule 8 to the Clinical Trials Regulations.