STATUTORY INSTRUMENTS

2005 No. 2753

Medicines (Homoeopathic Medicinal Products for Human Use) Amendment Regulations 2005

Insertion of Schedules 5 to 7 to the Homoeopathic Regulations

20. After Schedule 4 insert the following Schedules—

"SCHEDULE 5 Regulations 5(4), 8(5) and 9(2)

PROCEDURAL PROVISIONS RELATING TO THE GRANT, RENEWAL, VARIATION, REVOCATION AND SUSPENSION OF CERTIFICATES OF REGISTRATION

PART 1

INTERPRETATION AND APPLICATION

Interpretation

1. In this Schedule—

"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.

Scope and application of this Schedule

2. Subject to paragraph 4, Part 2 applies to—

(a) any application for the grant of a certificate of registration for a homoeopathic medicinal product except one made pursuant to the procedure in Article 28 of the 2001 Directive;

(b) any application to renew a certificate of registration for a homoeopathic medicinal product; and

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

3. Subject to paragraph 4, Part 3 applies where—

(a) an applicant for a certificate of registration for a homoeopathic medicinal product, or for the renewal of such a certificate; or

(b) the holder of a certificate of registration for a homoeopathic medicinal product,

gives notice under paragraph 9 of his wish to appear before or be heard by a person appointed by the licensing authority.

4. This Schedule does not apply if the licensing authority—

(a) declines to assess an application because an application for an EC registration in another EEA State is being examined in that State and the application to the licensing authority has not been submitted in accordance with Article 28(1) and (3) of the 2001 Directive; or

(b) rejects an application where the homoeopathic medicinal product in question has an EC registration in another EEA State and the application has not been submitted in accordance with Article 28(1) and (2) of the 2001 Directive.

PART 2

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

Requirement to consult the appropriate committee

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

(a) refuse to grant or renew the certificate of registration applied for; or

(b) revoke, vary or (subject to paragraph 10 of this Schedule) suspend a certificate of registration,

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

Provisional opinion against certificate of registration

6.—(1) Where the appropriate committee are consulted under the preceding paragraph and are of the provisional opinion that, on grounds relating to safety or quality, they—

(a) may be unable to advise the licensing authority to grant or renew the certificate of registration; 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 certificate of registration 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

7.—(1) After receiving the report of the appropriate committee pursuant to paragraph 6(8) the licensing authority shall—

(a) decide whether to refuse to grant or renew the certificate of registration, 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 certificate of registration; 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

8.—(1) If—

(a) the appropriate committee was consulted pursuant to paragraph 5;

(b) the committee did not give a provisional opinion under paragraph 6(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 certificate of registration against such advice, or

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

(aa) not to grant or renew a certificate of registration,

(bb) to grant or renew a certificate of registration otherwise than in accordance with an application, or

(cc) to revoke, vary or suspend a certificate of registration,

the licensing authority shall notify the applicant or holder accordingly.

(2) If—

(a) the appropriate committee has not been consulted pursuant to paragraph 5; and

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

(i) not to grant or renew a certificate of registration,

(ii) to grant or renew a certificate of registration otherwise than in accordance with an application, or

(iii) to revoke, vary or suspend a certificate of registration,

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

9.—(1) Subject to sub-paragraph (4), a person to whom a notification has been given under paragraph 7(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 8(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 6(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

10.—(1) Paragraph 5 shall not apply to the suspension of a certificate of registration (whether or not it applies to any existing proposal to suspend or revoke the certificate) where it appears to the licensing authority that, in the interests of safety, it is necessary to suspend the certificate with immediate effect for a period not exceeding three months.

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

11. If, after suspending a certificate of registration with immediate effect by virtue of paragraph 10—

(a) it appears to the licensing authority; or

(b) the appropriate committee advise,

that the certificate of registration 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 10).

PART 3

HEARING BEFORE PERSON APPOINTED

Hearing before person appointed

12.—(1) If an applicant or holder of a certificate of registration gives notice under paragraph 9 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 certificate of registration,

(iii) to grant or renew the certificate of registration otherwise than in accordance with the application, or

(iv) to revoke, vary or suspend the certificate of registration,

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 certificate of registration,

(iii) to grant or renew the certificate of registration otherwise than in accordance with the application, or

(iv) to revoke, vary or suspend the certificate of registration,

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 6

Regulation 7A(3)

OFFENCES, PENALTIES ETC

Offences

1. Any person who, in breach of these Regulations, places a homoeopathic medicinal product on the market without holding a certificate of registration in respect of that product, or otherwise than in accordance with the terms of such a certificate, shall be guilty of an offence.

2. Any person who, in the course of a business carried on by him, sells, supplies, manufactures or assembles, or procures the sale, supply, manufacture or assembly of, a homoeopathic medicinal product, or who has in his possession a homoeopathic medicinal product, knowing or having reasonable cause to believe that the product was or is intended to be placed on the market contrary to paragraph 1 shall be guilty of an offence.

3. Without prejudice to any other sanction which may be available for the enforcement of conditions attaching to certificates of registration, any holder of a certificate of registration for a homoeopathic medicinal product who contravenes any condition of the certificate shall be guilty of an offence.

4. Any person who is or, immediately before its revocation or suspension, was the holder of a certificate of registration who fails to comply with a notice given to him under regulation 10 (withdrawal from the market) shall be guilty of an offence.

5. Any holder of a certificate of registration who fails promptly to—

(a) take any steps reasonably necessary to take account of technical and scientific progress for the purposes of making any changes or amendments as required by Article 23 of the 2001 Directive; or

(b) introduce any changes or make any amendments that may be required in accordance with that Article or paragraphs 3.2(9), 3.2.1.2(c) and 3.2.2.4(c) of Part I of Annex I to the 2001 Directive; or

(c) provide information to the licensing authority as required by the third or fourth paragraphs of Article 23 or the first paragraph of Article 23a of the 2001 Directive; or

(d) submit any application to the licensing authority to make any changes or variation as required by Article 23 of the 2001 Directive;

shall be guilty of an offence.

6. Any holder of a certificate of registration who fails to forward to the licensing authority any data requested by the authority pursuant to the final paragraph of Article 23 or of Article 23a of the Directive—

(a) where the licensing authority have served a written notice on the holder under regulation 7A(4) in relation to the request, within the time specified in that notice;

(b) where there is no such notice, promptly,

shall be guilty of an offence.

7. Subject to paragraph 14, any person who is the holder of a certificate of registration who fails, not less than two months before an interruption in the placing on the market of the product to which the certificate relates, to notify the licensing authority that the product is to cease to be placed on the market, shall be guilty of an offence.

8. Subject to paragraph 14, any person who is the holder of a certificate of registration who fails to ensure appropriate and continued supplies pursuant to the second paragraph of Article 81 of the 2001 Directive shall be guilty of an offence.

9.—(1) Subject to paragraph 14, any person who in the course of an application for the grant, renewal or variation of a certificate of registration for a homoeopathic medicinal product—

(a) fails to provide to the licensing authority any information which is relevant to an evaluation of the quality of the homoeopathic medicinal product as required by Article 15 of the 2001 Directive; or

(b) provides to the licensing authority any information which is relevant to an evaluation of the quality of the homoeopathic medicinal product but which is false or misleading in a material particular,

shall be guilty of an offence.

(2) Subject to paragraph 14, any person who—

(a) is responsible for placing a homoeopathic medicinal product on the market; or

(b) is the holder of a certificate of registration for a homoeopathic medicinal product;

who provides to the licensing authority any information which is relevant to an evaluation of the quality of the homoeopathic medicinal product but which is false or misleading in a material particular shall be guilty of an offence.

10. Any holder of a certificate of registration who sells or supplies or procures the sale or supply of a homoeopathic medicinal product to which the certificate of registration relates

the labelling of which, or any package insert accompanying which, does not comply with the applicable requirements of Title V of the 2001 Directive, shall be guilty of an offence.

11. Any person, other than the holder of a certificate of registration for a homoeopathic medicinal product, who in the course of a business carried on by him, sells or supplies or procures the sale or supply of a homoeopathic medicinal product knowing, or having reasonable cause to believe, that the labelling of the product, or any package insert accompanying the product, does not comply with the applicable requirements of Title V of the 2001 Directive, shall be guilty of an offence.

Penalties

12. Any person guilty of an offence under any of the preceding paragraphs shall be liable—

(a) on summary conviction, to a fine not exceeding the statutory maximum;

(b) on conviction on indictment, to a fine or to imprisonment for a term not exceeding two years or to both.

Miscellaneous

13. Where the holder of a certificate of registration is charged with an offence under these Regulations in respect of anything which has been manufactured or assembled to his order by another person and had been so manufactured or assembled as not to comply with the provisions of that certificate, it shall be a defence for him to prove—

(a) that he had communicated the provisions relating to the certificate of registration to that other person; and

(b) that he did not know, and could not by the exercise of reasonable care have known, that those provisions had not been complied with.

14.—(1) A person does not commit an offence under paragraphs 7, 8 or 9 if he took all reasonable precautions and exercised all due diligence to avoid the commission of that offence.

(2) Where evidence is adduced which is sufficient to raise an issue with respect to that defence, the court or jury shall assume that the defence is satisfied unless the prosecution proves beyond reasonable doubt that it is not.

SCHEDULE 7

Regulation 20

TRANSITIONAL PROVISIONS

1. The requirement in Article 56a of the 2001 Directive for the name of the homoeopathic medicinal product to be expressed in Braille format on the packaging shall not apply until 30th October 2010 for products in relation to which the certificate of registration was granted before 30th October 2005.

2. Until 30th October 2010, these Regulations shall apply, in so far as they relate to the labelling of medicinal products in respect of which a certificate of registration was granted before 30th October 2005, as if the 2001 Directive had not been amended by Article 1(51) of Directive 2004/27/EC.".