STATUTORY INSTRUMENTS

2005 No. 2753

MEDICINES

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

Made - - - -	*6th October 2005*
Laid before Parliament	*7th October 2005*
Coming into force - -	*30th October 2005*

The Secretary of State, being a Minister designated(**1**) for the purposes of section 2(2) of the European Communities Act 1972(**2**) in relation to medicinal products, in exercise of the powers conferred by the said section 2(2), makes the following Regulations:

Citation, commencement and interpretation

1.—(1) These Regulations may be cited as the Medicines (Homoeopathic Medicinal Products for Human Use) Amendment Regulations 2005 and shall come into force on 30th October 2005.

(2) In these Regulations "the Homoeopathic Regulations" means the Medicines (Homoeopathic Medicinal Products for Human Use) Regulations 1994(**3**).

Amendment of regulation 1 of the Homoeopathic Regulations

2.—(1) Regulation 1 of the Homoeopathic Regulations (citation, commencement and interpretation) is amended as follows.

(2) In paragraph (2)—

(a) after the definition of "certificate of registration" insert the following definition—

> ""concerned member State" means an EEA state, the competent authority of which receives an application to obtain recognition, according to the procedure laid down in Articles 28 and 29(1) to (3) of the 2001 Directive, of an EC registration;";

(b) in the definition of "the 2001 Directive"(**4**) after "as amended" insert—

> "by—

(**1**) S.I.1972/1811.
(**2**) 1972 c. 68.
(**3**) S.I. 1994/105; as amended by S.I. 1994/899, 1995/541, 1996/482, 1998/574, 1999/566, 2001/795, 2002/236 and 542, 2003/625 and 2321, and 2004/666.
(**4**) The definition of "the 2001 Directive" was inserted by regulation 9(a) of S.I. 2002/236 and amended by regulation 5 of S.I. 2003/2321.

(a) Directive 2002/98/EC of the European Parliament and of the Council setting standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components(**5**),

(b) Commission Directive 2003/63/EC amending Directive 2001/83/EC on the Community code relating to medicinal products for human use(**6**),

(c) Directive 2004/24/EC of the European Parliament and of the Council amending, as regards traditional herbal medicinal products, Directive 2001/83/EC on the Community code relating to medicinal products for human use(**7**), and

(d) Directive 2004/27/EC of the European Parliament and of the Council amending Directive 2001/83/EC on the Community code relating to medicinal products for human use(**8**);";

(c) after the definition of "the 2001 Directive" insert the following definitions—

""EEA State" means a Member State, Norway, Iceland or Liechtenstein;

"EC registration" means a registration granted by a competent authority of an EEA State in accordance with the procedure set out in Article 14 of the 2001 Directive;";

(d) in the definition of "homoeopathic medicinal product" omit "products," and "or compositions"; and

(e) after the definition of "homoeopathic medicinal product" insert the following definition—

""set of applications" means—

(a) a number of applications to the licensing authority for regulatory assistance in connection with obtaining recognition according to the procedure laid down in Articles 28 and 29(1) to (3) of the 2001 Directive of a single certificate of registration in other EEA States, where those applications to the licensing authority all relate to applications for EC certificates of registration in other EEA States that have the same 90 day assessment period for the purposes of Article 28(4) of the 2001 Directive; or

(b) a number of applications to competent authorities of other EEA States for EC certificates of registration relating to a single certificate of registration, where those applications all have the same 90 day assessment period for the purposes of Article 28(4) of the 2001 Directive.".

(3) In paragraph (3), for sub-paragraph (c) substitute the following sub-paragraph—

"(c) any expressions which are also used in the 2001 Directive shall have the same meaning as they have in the 2001 Directive and related expressions shall be construed accordingly.".

Amendment of regulation 2 of the Homoeopathic Regulations

3. In regulation 2 of the Homoeopathic Regulations (application) after "homoeopathic medicinal products for human use" insert "to which the 2001 Directive applies and that fulfil the conditions laid down in Article 14(1) of the 2001 Directive".

(**5**) OJNo. L33, 8.2.2003, p.30.
(**6**) OJ No. L159, 27.6.2003, p.46.
(**7**) OJ No. L136, 30.4.2004, p.85.
(**8**) OJ No. L136, 30.4.2004, p.34.

Insertion of regulation 2A of the Homoeopathic Regulations

4. After regulation 2 of the Homoeopathic Regulations insert the following regulation—

"**Responsibility for Member States' functions in relation to homoeopathic medicinal products**

2A.—(1) In so far as they relate to homoeopathic medicinal products to which these Regulations apply and fall to be performed by, or by any authority of, the United Kingdom, the functions of a Member State, or of the competent authority of a Member State, under any of the provisions of the 2001 Directive shall, subject to paragraph (2), be performed by the licensing authority.

(2) Paragraph (1) shall not apply in so far as any such functions fall to be performed by the exercise of any powers or duties which are conferred by any provision of these Regulations, or by any provision of the Act as applied by these Regulations, on a person or body other than the licensing authority.".

Amendment of regulation 4 of the Homoeopathic Regulations

5. In regulation 4 of the Homoeopathic Regulations (application for certificate), for paragraph (1) substitute the following paragraph—

"(1) Every application for the grant or renewal of a certificate of registration shall be made in writing in accordance with the provisions of the 2001 Directive and the applicant shall comply with so much of the provisions of the 2001 Directive as contain requirements for applications, as are applicable to the application or the consideration of it.".

Amendment of regulation 5 of the Homoeopathic Regulations

6.—(1) Regulation 5 of the Homoeopathic Regulations (determination of application for certificate) is amended as follows.

(2) For paragraph (1) substitute the following paragraph—

"(1) The licensing authority shall consider every application for the grant of a certificate of registration in accordance with the provisions of the 2001 Directive and shall grant or refuse to grant the certificate in accordance with those provisions.".

(3) Omit paragraphs (2) and (3).

(4) For paragraph (4) substitute the following paragraph—

"(4) Schedule 5 shall have effect to regulate the procedure for receiving advice and representations before granting or refusing to grant a certificate of registration.".

(5) Omit paragraphs (5) and (6).

Amendment of regulation 7 of the Homoeopathic Regulations

7. Omit regulation 7 of the Homoeopathic Regulations (requirements in respect of controls).

Insertion of regulation 7A of the Homoeopathic Regulations

8. After regulation 7 of the Homoeopathic Regulations insert the following regulation—

"**Obligations of holders of certificates of registration, and offences by holders of certificates of registration and other persons**

7A.—(1) Every holder of a certificate of registration shall comply with all obligations which relate to him by virtue of the 2001 Directive.

(2) The holder of a certificate of registration shall keep such documents as will facilitate the withdrawal or recall from sale or supply of any homoeopathic medicinal product to which the certificate relates.

(3) Schedule 6 shall have effect to create certain criminal offences in connection with the obligations of applicants for, and holders of, certificates of registration and other persons arising under the 2001 Directive.

(4) Where, by or under any provision of the 2001 Directive or of these Regulations, a person is required to provide any information or furnish any document to the licensing authority and no time is specified in that provision within which that obligation is to be performed, it shall be performed within such time as may be specified in a written notice served on that person by the licensing authority.".

Amendment of regulation 8 of the Homoeopathic Regulations

9.—(1) Regulation 8 of the Homoeopathic Regulations (duration and renewal of certificates) is amended as follows.

(2) In paragraph (1)—

(a) before "A certificate of registration" insert "Subject to paragraph 2A,"; and

(b) omit the words from "or the date from which" to the end.

(3) In paragraph (2)—

(a) after "the licensing authority" insert "in accordance with the provisions of the 2001 Directive"; and

(b) omit the words from "for five years" to the end.

(4) After paragraph (2) insert the following paragraph—

"(2A) A certificate of registration shall cease to be valid if the homoeopathic medicinal product in respect of which it was granted is not placed on the market in the UK for a period of three consecutive years.".

(5) Omit paragraphs (3) and (4).

(6) After paragraph (4) insert the following paragraph—

"(5) Schedule 5 shall have effect to regulate the procedure for receiving advice and representations before renewing or refusing to renew a certificate of registration.".

Amendment of regulation 9 of the Homoeopathic Regulations

10. For regulation 9 of the Homoeopathic Regulations (suspension and revocation) substitute the following regulation—

"**Suspension, variation and revocation**

9.—(1) The licensing authority may and, where appropriate shall, subject to and in accordance with the provisions of the 2001 Directive, revoke, suspend or vary a certificate of registration.

(2) Schedule 5 shall have effect to regulate the procedure for receiving advice and representations before revocation, variation (otherwise than on the application of the holder) or suspension of a certificate of registration.".

Amendment of regulation 10 of the Homoeopathic Regulations

11. In regulation 10 (withdrawal from the market), for paragraph (2) substitute the following paragraph—

"(2) The licensing authority may, and where appropriate shall, issue a notice referred to in paragraph (1), subject to and in accordance with the provisions of the 2001 Directive.".

Amendment of regulation 11 of the Homoeopathic Regulations

12. Omit regulation 11 of the Homoeopathic Regulations (variation of certificates).

Amendment of regulation 13 of the Homoeopathic Regulations

13.—(1) Regulation 13 of the Homoeopathic Regulations (fees for applications for certificates) is amended as follows.

(2) Regulation 13 shall be renumbered as paragraph (1) of that regulation.

(3) After paragraph (1) insert the following paragraph—

"(2) In connection with each application or set of applications to the licensing authority for regulatory assistance in connection with obtaining recognition according to the procedure laid down in Articles 28 and 29(1) to (3) of the 2001 Directive of a single certificate of registration in another EEA State or in other EEA States, there shall be payable by the applicant the fee prescribed in Schedule 2A in connection with the application or set of applications.".

Amendment of regulation 16 of the Homoeopathic Regulations

14.—(1) Regulation 16 of the Homoeopathic Regulations (time for payment of fees) is amended as follows.

(2) In paragraph (1), for "13" substitute "13(1)".

(3) After paragraph (1), insert the following paragraph—

"(1A) Any fee to which regulation 13(2) of these Regulations refers shall be payable to the licensing authority at the time when, in connection with the application or set of applications for regulatory assistance, a request is made pursuant to Article 28(2) of the 2001 Directive for an assessment report to be prepared or updated.".

Amendment of Part IV of the Homoeopathic Regulations

15. After regulation 19 of the Homoeopathic Regulations (application of the act to certificates of registration) insert the following regulation—

"**Other Schedules to have effect**

20. Schedule 7 (transitional provisions) shall have effect.".

Revocation of Schedule 1 to the Homoeopathic Regulations

16. Schedule 1 to the Homoeopathic Regulations (accompanying material and information for applications for certificates of registration) is hereby revoked.

Amendment of Schedule 2 to the Homoeopathic Regulations

17.—(1) Schedule 2 to the Homoeopathic Regulations (fees for applications for the grant of certificates of registration) (**9**) is amended as follows.

(2) In paragraph 3—

(a) after the definition of "application" insert the following definition—

> ""decentralised procedure application" means an application relating to a homoeopathic medicinal product in respect of which at the time of the application—
>
> (a) an EC registration has not been granted in any EEA State; and
>
> (b) an application for an EC registration has been made in more than one EEA State pursuant to Article 28(1) and (3) of the 2001 Directive;";

(b) after the definition of "identical" insert the following definition—

> ""mutual recognition procedure incoming application" means an application relating to a homoeopathic medicinal product in respect of which—
>
> (a) an EC registration has already been granted in another EEA State; and
>
> (b) recognition of that certificate is sought from the licensing authority by way of the grant of a certificate of registration in the United Kingdom, pursuant to the procedure in Articles 28 and 29(1) to (3) of the 2001 Directive;"; and

(c) for the Table substitute the following Table—

"**Table**

Column (1) *Description of application*	Column (2) *Fees for applications in respect of products prepared from not more than 5 homoeopathic stocks*	Column (3) *Fees for other applications*
1 An application in respect of a product which is both prepared solely from repeat stocks and is of a repeat formulation	£134	£330
2 An application in respect of a product which is either— (a) prepared solely from repeat stocks; or (b) is of a repeat formulation	£402	£592
3 A mutual recognition procedure incoming application	£465	£608
4 A decentralised procedure application where the United Kingdom is a concerned Member State	£465	£608

(**9**) Schedule 2 was substituted by regulation 3 of S.I. 1996/482.

Column (1) *Description of application*	Column (2) *Fees for applications in respect of products prepared from not more than 5 homoeopathic stocks*	Column (3) *Fees for other applications*
5 A decentralised procedure application where the United Kingdom is the reference Member State	£930	£1,217
6 Any other application	£664	£869”

Insertion of Schedule 2A to the Homoeopathic Regulations

18. After Schedule 2 insert the following schedule—

“SCHEDULE 2A Regulation 13(2)

FEES FOR ASSISTANCE IN OBTAINING CERTIFICATES OF REGISTRATION IN OTHER EEA STATES

1. In this Schedule, a reference to—

(a) an application to the licensing authority for regulatory assistance means a reference to—

(i) a single application of that type, or

(ii) a set of applications of that type,

relating to a single certificate of registration; and

(b) an application for an EC registration in a concerned member State means a reference to—

(i) a single application of that type, or

(ii) a set of applications of that type in a number of concerned member States,

relating to a single certificate of registration.

Outgoing mutual recognition applications

2. The fee payable under regulation 13(2) in connection with an application to the licensing authority for regulatory assistance in connection with obtaining recognition in accordance with the procedure laid down in Article 28 and 29(1) to (3) of the 2001 Directive of a single certificate of registration in a concerned member State shall be—

(a) if the application is in respect of a homoeopathic medicinal product prepared from not more than 5 homoeopathic stocks, £266; and

(b) in any other case, £348.”.

Amendment of Schedule 4 to the Homoeopathic Regulations

19.—(1) Schedule 4 to the Homoeopathic Regulations (application of provisions of the Act) is amended as follows.

(2) Omit the entries relating to sections 6, 21, 22, 29, 46 and Schedule 2 of the Act.

(3) In the entry relating to section 44 of the Act—

(a) for the entry relating to subsection (3) substitute the following entry—

"as though in subsection (3) the words from the beginning to "subsection (4) of this section," were omitted and as though "licence or" were omitted;"; and

(b) for the entry relating to subsection (5) substitute the following entry—

"as though subsection (5) were omitted".

(4) For the entry relating to section 45 of the Act substitute the following entry—

"as though subsections (1) to (5) were omitted;

as though in subsection (8) for "subsections (1) to (6)" there were substituted "subsection (6)"".

(5) For the entry relating to section 92 of the Act substitute the following entry—

"as though in paragraph (b) of subsection (4) for "licence" there were substituted "certificate" and as though after "this Act" there were inserted "or is engaged in placing medicinal products of that description on the market within the meaning of the 2001 Directive"".

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.".

Other Schedules to have effect

21. The Schedule (consequential amendments of the Act and other regulations) shall have effect.

Signed by authority of the Secretary of State for Health

Warner
Minister of State,
Department of Health

6th October 2005

SCHEDULE

Regulation 21

CONSEQUENTIAL AMENDMENTS OF THE ACT AND OTHER REGULATIONS

1.—(1) Section 7 of the Act (general provisions as to dealing with medicinal products) is amended as follows.

(2) Subsections (2A) and (2B)(**10**) are repealed.

(3) After subsection 3A(**11**) insert the following subsection—

"(3B) The restrictions imposed by subsections (2) and (3) of this section shall not apply where the medicinal product concerned is a homoeopathic medicinal product to which the 2001 Directive applies and which fulfils the conditions laid down in Article 14(1) of that Directive.".

(4) In subsection (7)(**12**)—

(a) the definition of "certificate of registration" is repealed; and

(b) in the definition of "homoeopathic medicinal product", the words "products," and "or compositions" are repealed.

2. In the Medicines (Labelling) Regulations 1976(**13**), for paragraph (2) of regulation 1 (citation and scope) substitute the following paragraph—

"(2) Nothing in these Regulations applies to—

(a) a medicinal product for human use to which—

(i) the Medicines for Human Use (Marketing Authorisations Etc.) Regulations 1994(**14**),

(ii) the Medicines (Homoeopathic Medicinal Products for Human Use) Regulations 1994, or

(iii) the Medicines (Traditional Herbal Medicinal Products for Human Use) Regulations 2005,(**15**)

apply; or

(b) a medicinal product which is an investigational medicinal product within the meaning of the Medicines for Human Use (Clinical Trials) Regulations 2004(**16**).".

3. In the Medicines (Leaflets) Regulations 1977(**17**), for paragraph (2) of regulation 1 (citation, commencement and scope) substitute the following paragraph—

"(2) Nothing in these Regulations applies to a medicinal product for human use to which—

(a) the Medicines for Human Use (Marketing Authorisations Etc.) Regulations 1994;

(b) the Medicines (Homoeopathic Medicinal Products for Human Use) Regulations 1994; or

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(**10**) Subsections (2A) and (2B) were inserted by regulation 3(2) of S.I. 1994/276.
(**11**) Subsection (3A) was inserted by regulation 54 of S.I. 2004/1031.
(**12**) Subsection (7) was substituted by regulation 2(3) of S.I. 1983/1724 and amended by regulation 2(5) of S.I. 1992/604 and regulation 3(4) of S.I. 1994/276.
(**13**) S.I. 1976/1726, regulation 1 was amended by regulation 11 and paragraph 3 of Schedule 7 to S.I. 1994/3144, and by regulation 54 and paragraph 6 of Part 2 of Schedule 10 to S.I. 2004/1031.
(**14**) S.I. 1994/3144, as amended by S.I. 1998/3105, 2000/292, 2001/795, 2002/236 and 542, 2003/2321, 2004/3224, 2005/50 and 1710.
(**15**) S.I. 2005/2750.
(**16**) S.I. 2004/1031.
(**17**) S.I. 1977/1055, regulation 1 was amended by regulation 11 and paragraph 5 of Schedule 7 to S.I. 1994/3144.

(c) the Medicines (Traditional Herbal Medicinal Products for Human Use) Regulations 2005,

apply.".

4.—(1) The Medicines (Advisory Board on the Registration of Homoeopathic Products) Order 1995(**18**) is amended as follows.

(2) In regulation 1 (citation, commencement and interpretation), in paragraph (2), in the definition of "homoeopathic medicinal product" omit "products," and "or compositions".

(3) In regulation 2 (Advisory Board on the Registration of Homoeopathic Products)—

(a) omit paragraph (1)(b);

(b) in paragraph (2)(a), after "human use" insert "as amended by Directive 2002/98/EC of the European Parliament and of the Council setting standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components(**19**), Commission Directive 2003/63/EC amending Directive 2001/83/EC on the Community code relating to medicinal products for human use(**20**), Directive 2004/24/EC of the European Parliament and of the Council amending, as regards traditional herbal medicinal products, Directive 2001/83/EC on the Community code relating to medicinal products for human use(**21**) and Directive 2004/27/EC of the European Parliament and of the Council amending Directive 2001/83/EC on the Community code relating to medicinal products for human use(**22**)"; and

(c) in paragraph (2)(d)—

(i) in head (ii) for "8(3)" substitute "8(2)", and

(ii) in head (iii) for "suspend or revoke" substitute "suspend, vary or revoke".

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations make further amendments to the Medicines (Homoeopathic Medicinal Products for Human Use) Regulations 1994 ("the Homoeopathic Regulations") and consequential amendments to the Medicines Act and other Regulations.

The Homoeopathic Regulations implemented in part Council Directive 92/73/EEC(**23**) (now repealed and re-enacted in Directive 2001/83/EC(**24**)) by introducing a new registration procedure for the marketing of certain homoeopathic medicinal products for human use. The Homoeopathic Regulations also make provision for capital fees payable for applications for the grant and variation of certificates of registration and for periodic fees payable by holders of these certificates.

(**18**) S.I. 1995/309; regulation 2(2)(a) was amended by S.I. 2002/236.
(**19**) OJ No. L33, 8.2.2003, p.30.
(**20**) OJ No. L159, 27.6.2003, p.46.
(**21**) OJ No. L136, 30.4.2004, p.85.
(**22**) OJ No. L136, 30.4.2004, p.34.
(**23**) OJ No. L 297, 13.10.1992, p.8.
(**24**) *See* articles 1(5), 13 to 16, 53, 68, 69, 85, 100, 119 and 124.

Directive 2001/83/EC has now been amended by Directive 2004/27/EC(**25**). Regulations 5, 7, 9 and 10 to 18 and provisions in regulations 2, 6, 8, 20 and 21 in part implement the changes made by Directive 2004/27/EC.

Regulations 2, 5, 6, 13, 14, 16, 17 and 18 make changes necessitated by the extension of the mutual recognition procedure and decentralised procedure set out in Article 28 of Directive 2001/83/EC to homoeopathic medicinal products registered under the simplified scheme. In particular new capital fees for decentralised procedure and incoming and outgoing mutual recognition applications are introduced by regulations 17 and 18 which amend Schedule 2 to the Homoeopathic Regulations and insert new Schedule 2A respectively.

Regulation 9 amends regulation 8 of the Homoeopathic Regulations dealing with renewal of certificates of registration in order to implement the changes to Article 24 of Directive 2001/83/EC and the insertion of Article 23a.

Regulation 10 makes provision for the licensing authority to revoke, suspend or compulsorily vary a certificate of registration, if this is in accordance with the provisions of Directive 2001/83/EC, as required by Article 116 of the Directive.

Regulations 7, 8, 11 and 12 contain consequential amendments.

Regulations 8(3) and 20 insert a new Schedule 6 to the Homoeopathic Regulations which sets out offences for breaches of the Homoeopathic Regulations. The Schedule contains some new offences introduced to implement changes to Directive 2001/83/EC but also includes offences that were previously applied by virtue of sections 7 and 45 of the Medicines Act 1968 (the "Act") as applied to homoeopathic medicinal products. Regulation 21 inserts Schedule 1 which amends section 7 of the Act so that this section no longer applies to medicinal products to which the Homoeopathic Regulations apply.

Regulations 15 and 20 also insert a new Schedule 7 to the Homoeopathic Regulations which provides that the requirement introduced by Directive 2004/27/EC for the name of a homoeopathic medicinal product to be in Braille format on the label, and the changes made to what information may be on the label of a product with a certificate of registration, shall not apply until 30th October 2010 for products granted a certificate of registration before 30th October 2005.

Regulation 19 and in part regulations 6, 9, 10 and 20 make provision for the procedures on applications for, and decisions in respect of, certificates of registration, in particular for consultation of a committee established under the Act, or the Commission on Human Medicines. Changes to the procedures have been made as a consequence of amendments made by the Medicines (Advisory Bodies) Regulations 2005(**26**) which amend the Act to, amongst other things, abolish the Medicines Commission.

Regulations 3, 4 and provisions in regulation 2 correct minor errors and omissions in the Homoeopathic Regulations.

Regulation 21 and Schedule 1 amend the Medicines (Labelling) Regulations 1976 and the Medicines (Leaflets) Regulations 1977 so that these Regulations do not apply to homoeopathic medicinal products to which the Homoeopathic Regulations apply. The Medicines (Advisory Board on the Registration of Homoeopathic Products) Order 1995 is amended to change the definition of a homoeopathic medicinal product (amended by Directive 2004/27/EC), to remove the reference to Directive 92/74/EEC (this Directive which related to veterinary medicinal products has been repealed), and to extend the remit of the Advisory Board on the Registration of Homoeopathic Products to include consideration of proposals to compulsorily vary a certificate of registration.

A Regulatory Impact Assessment in relation to these Regulations, and a Transposition Note in relation to the implementation of Directive 2004/27/EC, have been placed in the libraries of both

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(**25**) Directive 2004/27/EC of the European Parliament and of the Council amending Directive 2001/83/EC on the Community code relating to medicinal products for human use, OJ No. L136, 30.4.2004, p.34.
(**26**) S.I. 2005/1094.

Houses of Parliament and copies may be obtained from the Medicines and Healthcare products Regulatory Agency, Market Towers, 1 Nine Elms Lane, London SW8 5NQ.