STATUTORY INSTRUMENTS

1994 No. 105

MEDICINES

The Medicines (Homoeopathic Medicinal Products for Human Use) Regulations 1994

Made - - - -	*19th January 1994*
Laid before Parliament	*24th January 1994*
Coming into force - -	*14th February 1994*

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

PART I

GENERAL

Citation, commencement and interpretation

1.—(1) These Regulations may be cited as the Medicines (Homoeopathic Medicinal Products for Human Use) Regulations 1994 and shall come into force on 14th February 1994.

(2) In these Regulations:

"the Act" means the Medicines Act 1968(**3**);

"the Board" means the Advisory Board on the Registration of Homoeopathic Products(**4**);

"certificate of registration" means a certificate for the purposes of these Regulations;

"homoeopathic medicinal product" means a medicinal product (which may contain a number of principles) prepared from products, substances or compositions called homoeopathic stocks in accordance with a homoeopathic manufacturing procedure described by the European Pharmacopoeia or, in the absence thereof, by any pharmacopoeia used officially in a member State;

(**1**) 1972 c. 68.
(**2**) S.I. 1972/1811.
(**3**) 1968 c. 67.
(**4**) The Board is established by S.I. 1994/102.

and any expression used in these Regulations which is defined in the Act shall bear the meaning which it has in the Act.

(3) In these Regulations—

(a) any reference to doing anything in accordance with a certificate of registration shall be construed in the same way as a reference to doing anything in accordance with a licence under Part II of the Act is to be construed by section 132(3) of the Act (general interpretation provisions);

(b) any reference to the holder of a certificate of registration shall be construed as a reference to the holder of such a certificate which is for the time being in force; and

(c) any reference to placing a product on the market shall be construed in accordance with Council Directive 92/73/EEC(**5**).

Application

2. These Regulations shall apply to homoeopathic medicinal products for human use other than those prepared in accordance with a magistral or officinal formula as defined in Article 1(4) and (5) of the 1965 Directive(**6**) or which satisfy the criteria laid down in Article 2(4) of that Directive.

Placing on the market

3. A certificate of registration shall authorise the placing on the market of a homoeopathic medicinal product to which these Regulations apply.

PART II

CERTIFICATES OF REGISTRATION

Application for certificate

4.—(1) An application for a certificate of registration shall be made in writing to the licensing authority and shall be accompanied by the material and information specified in Schedule 1 to these Regulations.

(2) An application for such a certificate may relate to a series of homoeopathic medicinal products derived from the same homoeopathic stock or stocks.

Determination of application for certificate

5.—(1) In dealing with an application for a certificate of registration, the licensing authority shall, in respect of any product to which the application relates, take due account of any registration granted by any member State other than the United Kingdom in accordance with Article 7 of Council Directive 92/73/EEC and of any authorisation granted by any such member State in accordance with Article 9 of that Directive.

(2) On an application for a certificate of registration, the licensing authority may grant such a certificate, but shall, subject to paragraph (3) below, refuse to grant such a certificate where—

(a) the product is not for oral or external administration;

(**5**) OJ No. L297, 13.10.92, p.8.
(**6**) The definition of "the 1965 Directive", inserted into section 132(1) of the Act by regulation 3 of S.I. 1992/3271, is amended by S.I. 1994/101.

(b) a specific therapeutic indication appears on the labelling of the product or in any information relating thereto;

(c) the product does not have a sufficient degree of dilution to guarantee its safety;

(d) after verification of the material and information submitted in accordance with regulation 4(1) of these Regulations, the product proves to be harmful in the normal conditions of use, or the qualitative or quantitative composition of the product is not as declared; or

(e) the application does not comply with regulation 4(1) of these Regulations.

(3) Products shall not be considered to have a sufficient degree of dilution to guarantee their safety where they contain more than —

(a) one part per 10,000 of the mother tincture; or

(b) one hundredth of the smallest dose used in allopathy with regard to active principles whose presence in an allopathic medicinal product would require it to be sold by retail or supplied in circumstances corresponding to retail sale in accordance with a prescription given by a doctor.

(4) The licensing authority shall not refuse to grant a certificate of registration on the ground set out in paragraph (2)(c) or (d) above except after consultation with the Board.

(5) Subject to paragraph (6) below, the licensing authority shall take all appropriate measures to ensure that the procedure for determining an application for a certificate of registration is completed within 120 days of the date of submission of the application by the applicant.

(6) The time limit referred to in paragraph (5) above may be extended for a further 90 days where the applicant is notified that the time is to be so extended, in writing, prior to the expiry of that time limit.

Grant of a certificate

6. Where a certificate of registration is granted—

(a) the appropriate Ministers shall determine which, if any, of their powers under sections 51(1) (general sale lists) and 58(1) (medicinal products on prescription only) of the Act they propose to exercise in respect of that product; and

(b) the licensing authority shall publish the decision to grant the certificate in the Gazette.

Requirements in respect of controls

7. The holder of a certificate of registration shall be responsible for furnishing to the licensing authority, on request, details of controls carried out on the finished product and, where applicable, on the ingredients of that product and of the controls carried out at an intermediate stage of the manufacturing process, in each case in accordance with the methods notified to the licensing authority at the time the certificate was applied for.

Duration and renewal of certificates

8.—(1) A certificate of registration shall, unless previously revoked, expire at the end of the period of five years beginning with the date on which it was granted or the date from which it was last renewed, as the case may be.

(2) A certificate which has not been revoked may, on the application of the holder of the certificate, be renewed by the licensing authority for five years from the date on which it would otherwise expire.

(3) An application for renewal of a certificate shall be made, in writing, no later than three months before the date of expiry of that certificate.

(4) The provisions of regulation 5 of these Regulations shall apply in relation to applications for the renewal of certificates of registration as they apply to applications for such certificates and any reference in that regulation to the grant of or the refusal to grant a certificate shall be construed as a reference to its renewal or to a refusal to renew it, as the case may be.

Suspension and revocation

9.—(1) Subject to paragraph (2) below, the licensing authority shall suspend a certificate of registration for such period as it may determine, or shall revoke a certificate, where —

(a) the product to which the certificate relates proves to be harmful in the normal conditions of use;

(b) the qualitative or quantitative composition of such product is not as declared; or

(c) any of the material or information provided in accordance with regulation 4(1) of these Regulations proves to be incorrect.

(2) Except in the interests of safety, where the licensing authority propose to suspend a certificate of registration with immediate effect, they shall not do so on the ground set out in paragraph (1)(a) or (b) above, except after consultation with the Board.

(3) The licensing authority shall publish any decision to revoke a certificate of registration in the Gazette.

Withdrawal from the market

10.—(1) Subject to paragraph (3) below, the holder of a certificate of registration shall withdraw from the market all products to which that certificate relates within the time and for the period specified in any written notice issued by the licensing authority for the purpose of this regulation.

(2) A notice referred to in paragraph (1) above may be issued on one or more of the following grounds—

(a) that the product to which the certificate relates proves to be harmful in the normal conditions of use;

(b) that the qualitative and quantitative composition of the product is not as declared;

(c) that details of the controls referred to in regulation 7 of these Regulations have not been furnished to the licensing authority pursuant to a request under that regulation; or

(d) that a requirement or obligation upon the holder of a manufacturer's licence or upon the holder of a manufacturing authorisation granted by the competent authority of a member State other than the United Kingdom relating to the product or, where the product has been imported, but was not consigned from a member State, a requirement or obligation on the holder of a wholesale dealer's licence, has not been met.

(3) The licensing authority may order the holder of the certificate of registration to withdraw from the market specified batches only of a product to which a notice under paragraph (1) above applies.

(4) A notice under paragraph (1) above shall be served on the holder of the relevant certificate and shall specify the grounds for the issue of the notice.

Variation of certificates

11. The licensing authority may, on the application of the holder of a certificate of registration, vary the provisions of the certificate in accordance with any proposals contained in the application

which relate to a change to the certificate which does not require, in their opinion, medical, scientific or pharmaceutical assessment.

PART III

FEES

Application

12. No fee shall be payable under this Part of these Regulations in connection with an application for the grant or variation of a certificate of registration where the application therefor is made at the specific written invitation of the licensing authority.

Fees for applications for certificates

13. Subject to regulation 17 of these Regulations, in respect of an application for the grant of a certificate of registration pursuant to regulation 4 of these Regulations there shall be payable by the applicant the fee specified in Schedule 2 to these Regulations in connection with that application.

Fees for variations of certificates

14. In respect of an application for the variation of a certificate of registration pursuant to regulation 11 of these Regulations, there shall be payable by the applicant a fee of £90.

Fees payable by holders of certificates

15.—(1) Subject to paragraph (2) below, there shall be payable by the holder of a certificate of registration a fee of £15 in respect of each fee period during any part of which the certificate is in force.

(2) No fee shall be payable under paragraph (1) above in respect of the fee period during which a certificate of registration is first granted.

(3) For the purposes of this regulation, "fee period" means the period beginning with the coming into force of these Regulations and ending on 31st March 1994 and subsequently, the period beginning with the first day of April in any year and ending with the last day of March in the following year.

Time for payment of fees

16.—(1) Any fee to which regulation 13 or 14 of these Regulations refers shall be payable to the licensing authority at the time the application for grant or variation of the certificate of registration is made.

(2) Any fee to which regulation 15 of these Regulations refers shall be payable to the licensing authority on the first day of the fee period to which it relates.

Refund or waiver of fees

17. The licensing authority shall, in the circumstances and to the extent provided in Schedule 3 to these Regulations, refund or waive payment of any fee or part of a fee to which regulation 13 of these Regulations refers.

Civil proceedings to recover unpaid fees

18. All unpaid sums due by way of, or on account of, any fees payable under these Regulations shall be recoverable as debts due to the Crown.

PART IV

APPLICATION OF PROVISIONS OF THE ACT

Application of the Act to certificates of registration

19.—(1) Subject to paragraph (2) below, the provisions of the Act specified in column 1 of Schedule 4 to these Regulations and any other provisions of the Act which relate to those provisions shall have effect in relation to certificates of registration as they have effect in relation to product licences.

(2) Where for any provision specified in column 1 of that Schedule there is a corresponding entry in column 2 of that Schedule, that provision shall, in its application to certificates of registration, have effect subject to the modifications specified in that entry and as though every reference in that provision —

(a) to a product licence or to a licence under Part II of the Act were a reference to a certificate of registration;

(b) to any other of those provisions were to that other provision as applied (with or without modifications) by these Regulations.

Signed by authority of the Secretary of State for Health

Tom Sackville
Parliamentary Under Secretary of State
Department of Health

19th January 1994

SCHEDULE 1

Regulation 4(1)

ACCOMPANYING MATERIAL AND INFORMATION FOR APPLICATIONS FOR CERTIFICATES OF REGISTRATION

1. The name or corporate name of and the permanent address of—

(a) the person responsible for placing the product on the market in the United Kingdom,

(b) the manufacturers and the sites involved in the different stages of the manufacture of the product (including the manufacturer of the finished product and the manufacturers of the homoeopathic stock or stocks), and

(c) where relevant, the importer of the product.

2. Details of the scientific name or other name given in a pharmacopoeia of the homoeopathic stock or stocks.

3. A statement of the various routes of administration, pharmaceutical forms and degree of dilution to be registered.

4. A dossier describing how the homoeopathic stock or stocks is or are obtained and controlled and justifying its or their homoeopathic nature.

5. A manufacturing and control file for each pharmaceutical form and a description of the method of dilution and potentization.

6. A copy of the manufacturer's licence or corresponding authorisation granted by a member State other than the United Kingdom in respect of the product.

7. Copies of any registrations or authorisations obtained for the same product in member States other than the United Kingdom.

8. One or more specimens of mock-ups of the sales presentation of the product to be registered.

9. Data concerning the stability of the product.

SCHEDULE 2

Regulation 13

FEES FOR APPLICATIONS FOR THE GRANT OF CERTIFICATES OF REGISTRATION

1. Subject to paragraph 2, where an application for the grant of a certificate of registration relates to—

(a) a single product; or

(b) a series of products being a number of dilutions of a homoeopathic stock or stocks, each dilution having the same pharmaceutical form,

the fee shall be £500.

2. Where an application for the grant of a certificate of registration relates to —

(a) a single product (other than a sterile product); or

(b) a series of products (other than sterile products) being a number of dilutions of a homoeopathic stock or stocks,

in respect of which a certificate has already been granted at the time of receipt of the application to the person making the application, the fee shall be £350.

SCHEDULE 3

Regulation 17

REFUND OR WAIVER OF FEES

1. Subject to paragraph 2, where an application for the grant of a certificate of registration is withdrawn before determination by the licensing authority, the following percentage of the fee otherwise payable under regulation 13 of these Regulations in connection with that application shall be refunded or, if it has not yet been paid, shall be waived:

(a) if the application has been received but no medical, scientific or pharmaceutical assessment thereof has begun, 90 per cent.;

(b) if medical, scientific or pharmaceutical assessment has begun but has not been completed, 50 per cent.

2. If an application for the grant of a certificate is withdrawn either after medical, scientific and pharmaceutical assessment has been completed or following consideration of that application by the Board, no refund or waiver of the fee payable under regulation 13 of these Regulations in connection with that application shall be made.

SCHEDULE 4

Regulation 19

APPLICATION OF PROVISIONS OF THE ACT

(1) Provision of the Medicines Act 1968	(2) Modification
section 6	as though in subsection (1) for "this Part of this Act" there were substituted "Part II of the Medicines (Homoeopathic Medicinal Products for Human Use) Regulations 1994"; as though "licences and" were omitted; and as though after "certificates" there were inserted "of registration"; as though in subsection (2) for "this Act" there were substituted "the Medicines (Homoeopathic Medicinal Products for Human Use) Regulations 1994"
section 21	as though in subsections (1), (2) and (3), "or the Commission" and "or Commission", in any place where those words appear, were omitted; as though in subsection (1) for "subsection (3) of section 20 of this Act" there were substituted "regulation 5(2) of the Medicines (Homoeopathic Medicinal Products for Human Use) Regulations 1994"; as though for the word "licence" in both places where it appears there were substituted "certificate of registration"; and as though for "that subsection" there were substituted "regulation 5(2) of the Medicines

(1) Provision of the Medicines Act 1968	(2) Modification
	(Homoeopathic Medicinal Products for Human Use) Regulations 1994"; as though in subsections (3) and (4) for "licence"(in any place where it appears) there were substituted "certificate of registration"; as though in subsection (4) ", in a case where the applicant has not been heard by, or made representations to, the Commission under subsection (1) of this section" were omitted and as though for "he" in the first place where it appears, there were substituted "the applicant"; as though in paragraph (a) of subsection (5), "subsection (2) or" were omitted; as though for paragraph (d) of subsection (5) there were substituted "propose on grounds not relating to safety or quality to refuse to grant the certificate"
section 22	as though in subsection (1) for "licence under this Part of this Act" there were substituted "certificate of registration"; as though in subsection (2) "or propose to grant a licence otherwise than in accordance with the application" were omitted and for "licence" there were substituted "certificate of registration"
section 23	as though in subsection (1) "to the provisions of this Part of this Act relating to clinical trials and medicinal tests on animals and" were omitted; as though subsection (4) were omitted
section 29	as though in subsection (1) for "section 28 of this Act" there were substituted "regulation 9 of the Medicines (Homoeopathic Medicinal Products for Human Use) Regulations 1994"; and as though in subsection (2) for ", revoke or vary", in both places in which they appear, there were substituted "or revoke" and for ", revocation or variation" there were substituted "or revocation" and as though for "licence" (in any place where it appears) there were substituted "certificate of registration"

(1) Provision of the Medicines Act 1968	(2) Modification
section 44	as though in subsection (1) for "licence under this Part of this Act (including a licence of right) or for a clinical trial certificate or animal test certificate (including a certificate to which a person is entitled by virtue of section 37(4) of this Act" there were substituted "certificate of registration under the Medicines (Homoeopathic Medicinal Products for Human Use) Regulations 1994"; as though in subsection (2) for "licence under this Part of this Act" there were substituted "certificate of registration" and as though ", or of a clinical trial certificate or animal test certificate," were omitted; as though in subsection (3) the words from the beginning to "subsection (4) of this section," were omitted and as though "licence or" and "varied," were omitted; as though subsection (4) were omitted; as though in subsection (5) "other than a licence of right" were omitted and for "licence" (in both places where it appears) there were substituted the word "certificate"
section 45(**7**)	as though in subsection (1) before "section 8", for "," there were substituted "or" and as though ", section 31, section 32, section 34 or section 40" and "or animal feeding stuff" were omitted and as though for "any of those sections" there were substituted "either of those sections"; as though subsection (2) were omitted; as though in subsection (3) "or of a clinical trial certificate or animal test certificate" were omitted and, in paragraph (a), for "licence or certificate" there were substituted "certificate of registration"; as though subsections (4) and (5) were omitted;

(**7**) As regards subsection (8), see Magistrates' Courts Act 1980 (c. 43), section 32(2) and S.I. 1984/447. As regards subsection (9), see Criminal Justice Act 1982 (c. 48), sections 37, 38 and 46; S.I. 1984/447; and the Criminal Justice Act 1991 (c. 53), sections 17 and 18.

(1) Provision of the Medicines Act 1968	(2) Modification
	as though in subsection (8) for "(1) to (6)" there were substituted "(1), (3) and (6)"
section 46(**8**)	as though "or of a clinical trial certificate or animal test certificate" (wherever those words appear) were omitted; as though in subsection (1), for "any substance or article" to "product manufactured or assembled)" there were substituted "a medicinal product which has been manufactured or assembled"; and as though for "that licence or" there were substituted "that certificate"; as though in paragraph (a) of subsection (2) "applicable to them" were omitted; as though in paragraph (b) of subsection (2) "or certificate" were omitted
section 58A(**9**)	as though "and" were inserted at the end of subsection (1)(a) and subsection (1)(b) were omitted
section 59	as though in paragraph (c) of subsection (1) for "that licence" there were substituted "that certificate" and as though for subsection (3) where it first appears there were substituted "(2B)"
section 92	as though in paragraph (b) of subsection (4) for "licence" there were substituted "certificate" and has though for "subsection (3)" where those words first appear there were substituted "(2B)"
section 93	as though subsections (2), (4) and (10) were omitted and as though paragraph (b) of subsection (5) were omitted
section 94	as though in subsection (1) for "product licence under this Act" there were substituted "certificate of registration" and for "licence" in both places where it appears there were substituted "certificate of registration"
section 96	
section 97	

(**8**) Section 46 was amended by Schedule 1 to the Animal Health and Welfare Act 1984 (c. 26).
(**9**) Section 58A was inserted by regulation 2 of S.I. 1992/3271.

(1) Provision of the Medicines Act 1968	(2) Modification
section 107	as though in subsection (1) for "Part II of this Act" there were substituted "the Medicines (Homoeopathic Medicinal Products for Human Use) Regulations 1993" and as though "or of a Minister under section 75 of this Act" and "licence or"were omitted; as though in subsection (2) for "this Act" (in the first two places in which those words appear) there were substituted "the Medicines (Homoeopathic Medicinal Products for Human Use) Regulations 1994" and as though "or of any regulations made under this Act" were omitted; as though in subsection (4) "licence or" (wherever those words appear) were omitted
section 108(**10**)	as though at the end of subsection (1) there were inserted "and of the Medicines (Homoeopathic Medicinal Products for Human Use) Regulations 1994" as though in subsection (6), in paragraph (a) "40," and from "and of any regulations" to the end of the paragraph were omitted and as though paragraph (c) were omitted; as though in subsection (8) paragraph (b) were omitted; as though in subsection (11) paragraph (a) and, in paragraph (b), "in all other respects", were omitted
section 109(**11**)	as though at the end of subsection (1) there were inserted "and of the Medicines (Homoeopathic Medicinal Products for Human Use) Regulations 1994"
section 110(**12**)	as though at the end of subsection (1) there were inserted "and of the Medicines (Homoeopathic Medicinal Products for Human Use) Regulations 1994" and as though subsection (4) were omitted

(**10**) Section 108 was amended by the Local Government Act 1972 (c. 70), Schedule 30, the Animal Health and Welfare Act 1984 (c. 40), section 16 and Schedule 1, S.I. 1968/1699 and the Food Safety Act 1990 (c. 16), section 59(1) and Schedule 3.
(**11**) Section 109 was amended by Schedule 27 to the Local Government (Scotland) Act 1973 (c. 65) and by Schedule 3 to the Food Safety Act 1990.
(**12**) Section 110 was amended by S.R. & O. (N.I.) 1973/211.

(1) Provision of the Medicines Act 1968	(2) Modification
section 111	as though in paragraph (a) of subsection (1) after "any provisions of" there were inserted "the Medicines (Homoeopathic Medicinal Products for Human Use) Regulations 1994 or"; as though in subsection (3) for "licence or certificate under Part II of the Act" there were substituted "certificate of registration under the Medicines (Homoeopathic Medicinal Products for Human Use) Regulations 1994" and as though "licence or" were omitted
section 112	as though in subsection (7) for the words "licence or certificate under Part II of the Act" there were substituted "certificate of registration under the Medicines (Homoeopathic Medicinal Products for Human Use) Regulations 1994" and as though the words "licence or" were omitted
section 118	as though in paragraph (b) of subsection (1) for "this Act" there were substituted "the Medicines (Homoeopathic Medicinal Products for Human Use) Regulations 1994"
section 119	as though for "this Act" (in the first place in which those words appear) there were substituted "the Medicines (Homoeopathic Medicinal Products for Human Use) Regulations 1994" and in the other places in which they appear there were substituted "those Regulations"
section 121	as though in subsection (4) for "90" there were substituted "89"
section 122	as though in subsection (2) for "65," there were substituted "65 and" and as though "and section 90" were omitted
section 124	as though subsection (2) were omitted
section 126	as though in subsection (1) paragraph (a) were omitted; and as though "animal feeding stuff or" (in both places where those words appear) and "animal feeding stuffs or" were omitted; as though in subsection (2) "or animal feeding stuff" and "or of animal feeding stuffs" were omitted; as though in subsection (3) from ", to any of those provisions" to the end were omitted;

(1) Provision of the Medicines Act 1968	(2) Modification
	as though in subsection (4) ", or of so much of subsection (2) of section 90 of this Act as relates to leaflets" and "or of animal feeding stuffs in which medicinal products have been incorporated" were omitted; in paragraph (a) as though "or" were omitted; and as though paragraph (b) were omitted
section 127	as though for "this Act" there were substituted "the Medicines (Homoeopathic Medicinal Products for Human Use) Regulations 1994"
Schedule 2	as though for "the licence" or "licence" (wherever those words appear) there were substituted "certificate"; as though paragraph 1 were omitted; as though in paragraphs 2 and 4, "or the Commission" and "or Commission" (wherever those words appear) were omitted; as though in paragraph 2 for "the preceding paragraph" there were substituted "paragraph (2) of regulation 9 of the Medicines (Homoeopathic Medicinal Products for Human Use) Regulations 1994" and for ", revoked or varied" there were substituted "or revoked"; as though in paragraph 3 "or the Commission, as the case may be," were omitted; as though in paragraph 4 ", or to be varied so as to contain provisions specified in their advice" were omitted; as though in paragraph 5 as though ", in a case where the holder of the licence has not been heard by, or made representations to, the Commission under paragraph 2 of this Schedule" were omitted; as though in sub-paragraph (a) of paragraph 6 "paragraph 3 or" were omitted and as though in sub-paragraph (d) for ", revoke or vary" there were substituted "or revoke"; as though in paragraph 8 for "section 28 of this Act" there were substituted "paragraph (2) of regulation 9 of the Medicines (Homoeopathic Medicinal Products for Human Use) Regulations 1994"; as though sub-paragraph (a)

(1) Provision of the Medicines Act 1968	(2) Modification
	were omitted; and in sub-paragraph (b) for ", revoke or vary"there were substituted "or revoke", and for ", revocation or variation" there were substituted "or revocation"; as though in paragraphs 11, 13 and 14 for "paragraphs 1 to 9" there were substituted "paragraphs 2 to 9"; as though for paragraph 12 there were substituted "The licensing authority shall report the suspension forthwith to the appropriate committee."; as though in paragraph 13 for the words from the beginning to "the Commission" there were substituted "if the licensing authority are advised by the appropriate committee" and for ", or ought to be revoked or varied" there were substituted "or revoked"; as though paragraph 15 were omitted

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations implement in part Council Directive 92/73/EEC (OJ L297, 13.10.92, p.8) ("the Directive") which widens the scope of Directives 65/65/EEC (OJ No. 22, 9.2.1965, p.369/65) ("the 1965 Directive") and 75/319/EEC (OJ No. L147, 9.6.1975, p.13) ("the 1975 Directive") on the approximation of provisions laid down by law, regulation or administrative action relating to medicinal products and laying down additional provisions on homoeopathic medicinal products.

References to the 1965 Directive are brought in by Article 7(4) of the Directive and references to the 1975 Directive are brought in by Article 4 of the Directive.

These Regulations bring into operation, in respect of homoeopathic medicinal products for human use, the special, simplified registration procedure provided for in Article 7 of the Directive (excluding products defined in Article 1(4) and (5) of the 1965 Directive), or satisfying the criteria in Article 2(4) of that Directive (regulation 2).

Part II of the Regulations sets out the procedure for applying for certificates of registration (regulation 4, Schedule 1; Article 8 of the Directive) and for determining such applications (regulation 5(1), (2) and (3); Article 7(1) of the Directive and Article 5 of the 1965 Directive). It sets time limits for dealing with applications (regulation 5(4) and (5); Article 7 of the 1965 Directive) and specifies the conditions for suspension or revocation of certificates (regulation 9; Article 11 of

the 1965 Directive) and for withdrawal of products from the market (regulation 11; Article 28 of the 1975 Directive).

Part II also contains further provisions relating to the grant and revocation of certificates (regulation 6; Article 7(1) of the Directive, Article 12 of the 1965 Directive) and requirements in respect of controls (regulation 7; Article 27 of the 1975 Directive).

Regulation 8 provides for the expiry of certificates after five years and for their renewal (Article 10 of the 1965 Directive); and regulation 11 provides for the variation of certificates.

Part III of, and Schedule 2 to, these Regulations specify the fees payable in connection with applications for the grant of (regulation 13), or variations to (regulation 14), certificates and the fees payable in connection with the holding of certificates (regulation 15).

Regulation 16 and Schedule 3 provide as to time of payment of fees (regulation 16), refund and waiver of fees in specified circumstances (regulation 17) and recovery of unpaid fees (regulation 18).

Part IV of, and Schedule 4 to, these Regulations apply specified provisions of the Medicines Act 1968 to certificates of registration so as to apply provisions concerning the marketing of medicinal products under product licences. In particular, procedures identical to those set out in that Act apply where an application for the grant of a certificate is refused or where a certificate is suspended or revoked, and for enforcement of these Regulations.

Other parts of the Directive are implemented by the Medicines (Labelling and Leaflets) Amendment Regulations 1994 (S. I. 1994/104), the Medicines Act 1968 (Amendment) Regulations 1994 (S. I. 1994/101) and the Medicines (Standard Provisions for Licences and Certificates) Amendment Regulations 1994 (S. I. 1994/103).