STATUTORY INSTRUMENTS

2005 No. 2750

The Medicines (Traditional Herbal Medicinal Products for Human Use) Regulations 2005

Citation, commencement and extent

1. These Regulations may be cited as the Medicines (Traditional Herbal Medicinal Products for Human Use) Regulations 2005 and shall come into force—

(a) except for the purposes of paragraphs 4(2)(a) and 8(a)(i) of Schedule 7 on 30th October 2005; and

(b) for the purposes of paragraphs 4(2)(a) and 8(a)(i) of Schedule 7 on 20th November 2005.

Interpretation

2.—(1) In these Regulations—

"the Act" means the Medicines Act 1968(**1**);

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

(a) in a case where—

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

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

that committee; and

(b) in any other case, the Commission;

"the 2001 Directive" means Directive 2001/83/EC of the European Parliament and of the Council on the Community code relating to medicinal products for human use(**2**) as amended by—

(c) 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(**3**),

(d) Commission Directive 2003/63/EC amending Directive 2001/83/EC on the Community code relating to medicinal products for human use(**4**),

(e) 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(**5**), and

(**1**) 1968 c. 67.
(**2**) OJNo. L311, 28.11.2001, p.67.
(**3**) OJ No. L33, 8.2.2003, p.30.
(**4**) OJ No. L159, 27.6.2003, p.46.
(**5**) OJ No. L136, 30.4.2004, p.85.

(f) 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(**6**);

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

"EC traditional herbal registration" means a traditional herbal registration granted by a competent authority of an EEA State in accordance with the simplified registration procedure for traditional herbal medicinal products set out in Chapter 2a of the 2001 Directive;

"licensing authority" shall be construed in accordance with section 6 of the Act;

"parallel import licence" means a traditional herbal registration granted by the licensing authority under these Regulations in respect of a traditional herbal medicinal product which is imported into the United Kingdom from another EEA state in accordance with the rules of Community law relating to parallel imports;

"the relevant Community provisions" means the provisions of the 2001 Directive which apply to traditional herbal medicinal products and to traditional herbal registrations;

"traditional herbal registration" means a registration granted by the licensing authority under these Regulations and includes a parallel import licence.

(2) Expressions used in these Regulations which are also used in the 2001 Directive shall have the same meaning as they have there and related expressions shall be construed accordingly.

(3) Subject to paragraph (2), section 11 of the Interpretation Act 1978(**7**) shall apply for the interpretation of these Regulations as if they were made in the exercise of a power conferred by the Act.

(4) Any reference in these Regulations to an application that is signed includes a reference to an application that is signed with an electronic signature.

Responsibility for Member States' functions in relation to traditional herbal medicinal products

3.—(1) In so far as they relate to traditional herbal medicinal products 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 relevant Community provisions 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.

Traditional herbal registrations for traditional herbal medicinal products

4.—(1) Except in accordance with any exception or exemption set out in the relevant Community provisions and subject to paragraphs 2, 4 and 5 of Schedule 1—

(a) no traditional herbal medicinal product shall be placed on the market; and

(b) no such product shall be distributed by way of wholesale dealing,

unless a traditional herbal registration in respect of that product has been granted in accordance with the relevant Community provisions by the licensing authority and is for the time being in force in accordance with those provisions.

(**6**) OJ No. L136, 30.4.2004, p.34.
(**7**) 1978 c. 30.

(2) Schedule 1 shall have effect for the purpose of making certain exceptions or exemptions from paragraph (1), and for imposing certain obligations in connection with such exceptions and exemptions.

Applications for the grant or renewal of a traditional herbal registration

5.—(1) Every application for the grant or renewal of a traditional herbal registration shall be made in writing in accordance with the relevant Community provisions, subject to the rules of Community law relating to parallel imports, and the applicant shall comply with so much of the relevant Community provisions as contain requirements for applications as are applicable to the application or the consideration of it.

(2) Every application shall be made in writing, shall be signed by or on behalf of the applicant and shall, unless the licensing authority otherwise direct, be accompanied by any fee which may be payable in connection with that application.

(3) One copy of the application and of any accompanying material shall be supplied to the licensing authority in the English language and where the application or any accompanying material has been translated from another language, one copy of the application or the accompanying material, as the case may be, shall also be supplied in the original language.

(4) An application for the grant of a traditional herbal registration shall include a statement indicating—

(a) whether the herbal medicinal product is one that should be available—

(i) only from a pharmacy; or

(ii) on general sale; and

(b) what, if any, provisions of the traditional herbal registration are proposed concerning the method of sale or supply of the product (including, in particular, any proposed restrictions affecting the circumstances of the use or promotion of the product).

(5) The applicant for the grant or renewal of a traditional herbal registration must be established in the Community.

(6) An application for the renewal of a traditional herbal registration shall be made not later than 6 months before the date on which the existing traditional herbal registration expires.

Consideration, and grant or refusal, of an application for, or for renewal or variation of, a traditional herbal registration

6.—(1) The licensing authority shall—

(a) consider every application for the grant, renewal or variation by them of a traditional herbal registration in accordance with the relevant Community provisions, and (where applicable) the rules of Community law relating to parallel imports, and

(b) grant, renew or vary, or refuse to grant, renew or vary the registration in accordance with those provisions and (where applicable) the rules of Community law relating to parallel imports.

(2) Schedule 2 shall have effect to regulate the procedure for receiving advice and representations before granting, renewing or varying, or refusing to grant, renew, or vary a traditional herbal registration, or after notification of a decision relating to an application to vary such a registration.

(3) A parallel import licence shall, unless previously renewed or revoked, be valid for the period specified in it, but where an application to renew it is made in accordance with regulation 5(6) it shall remain in force pending the decision of the licensing authority on that application.

(4) Subject to paragraph (6), a traditional herbal registration other than a parallel import licence shall, unless previously revoked, be valid for an unlimited period unless—

(a) it has not been renewed on the basis of a re-evaluation by the licensing authority of the risk-benefit balance in accordance with, and on the basis of the data set out in, Article 24(2) of the 2001 Directive; or

(b) it has been so renewed, but the licensing authority considers on justified grounds relating to pharmacovigilance that it should be subject to one additional renewal five years after the date of the first renewal, and it has not yet been subject to that additional renewal.

(5) Subject to paragraph (6), where, by reason of paragraph (4), a traditional herbal registration is not valid for an unlimited period, it shall, unless previously revoked, be valid for a period of five years beginning with the date on which it is granted or was renewed, whichever is the later, but where an application for its renewal is made in accordance with Article 24 of the 2001 Directive the traditional herbal registration shall remain in force pending the decision of the licensing authority on that application.

(6) A traditional herbal registration (other than a parallel import licence) shall cease to be valid if at any time after it is granted the medicinal product to which it relates is not placed on the market in the United Kingdom for a period of three consecutive years, unless an exemption is granted in accordance with Article 24(6) of the 2001 Directive.

(7) Each traditional herbal registration granted by the licensing authority shall be granted subject to a condition that the traditional herbal medicinal product to which the registration relates is to be available—

(a) only from a pharmacy; or

(b) on general sale.

Revocation, suspension or variation of a traditional herbal registration or the suspension of the use or marketing of traditional herbal medicinal products

7.—(1) The licensing authority may and, where appropriate shall, subject to and in accordance with the relevant Community provisions, revoke, suspend or vary a traditional herbal registration for a traditional herbal medicinal product.

(2) The licensing authority may and, where appropriate, shall, subject to paragraph (3) and subject to and in accordance with the relevant Community provisions, by notice in writing to the holder of a traditional herbal registration for a traditional herbal medicinal product, forthwith or from a date specified in the notice, suspend the use, supply or marketing within the United Kingdom of the product to which the registration relates for a period specified in the notice.

(3) In any case where the relevant Community provisions permit or require the suspension of the use, supply or marketing of a product until some decision or similar action is taken by the Community, the licensing authority may, instead of specifying a period in the notice, provide that the suspension is to apply until further notice.

(4) Where the licensing authority, in accordance with paragraph (3), include a provision that the suspension is to apply until further notice, they shall, where the effect of the Community decision or action is that the product may continue to be used or, as the case may be, marketed, in the United Kingdom, promptly give the holder of the registration written notice revoking the suspension forthwith or from such date specified in the notice as to comply with that decision or action.

(5) Where, under the preceding provisions of this regulation the licensing authority revoke or suspend a traditional herbal registration, or where the licensing authority suspend the use, supply or marketing of a product, or where the relevant Community provisions so permit or require, the licensing authority may and, where appropriate, shall give written notice to the person who is or,

immediately before its revocation or suspension, was the holder of the registration, requiring him to take all reasonably practicable steps to—

(a) inform wholesalers, retailers, medical practitioners, patients and others who may be in possession of relevant products of the revocation or suspension, the reasons for it, and the action (if any) to be taken to restrict or prevent further use, supply or marketing;

(b) withdraw from the market in the United Kingdom and recover possession of such products within the time and for the period specified in the notice.

(6) The licensing authority may require the holder of the traditional herbal registration to withdraw from the market in the United Kingdom specified batches only of a product to which a notice under paragraph (5) applies.

(7) Schedule 2 shall have effect to regulate the procedure for receiving advice and representations before revocation, variation or suspension of a traditional herbal registration, and for notifying the holder of that registration in accordance with the preceding provisions of this regulation.

Urgent safety restrictions

8.—(1) The licensing authority may, subject to and in accordance with the relevant Community provisions, impose an urgent safety restriction on the holder of a traditional herbal registration.

(2) Where the licensing authority imposes an urgent safety restriction in accordance with paragraph (1), the holder of the traditional herbal registration shall—

(a) implement the restriction within a period specified by the licensing authority; and

(b) apply to vary the registration so as to take account of that safety restriction immediately and in any event not later than 15 days after the restriction was imposed.

Obligations of holders of traditional herbal registrations, and offences by holders of traditional herbal registrations and other persons

9.—(1) Every holder of a traditional herbal registration for a traditional herbal medicinal product shall comply with all obligations which relate to him by virtue of the relevant Community provisions including, in particular, obligations relating to providing or updating information, to making changes, to applying to vary the traditional herbal registration, to pharmacovigilance, and to labels and package leaflets.

(2) The holder of a traditional herbal registration shall maintain a record of reports of which he is aware of suspected adverse reactions in accordance with the relevant Community provisions which shall be open to inspection by a person authorised by the licensing authority, who may take copies of the record and, if the licensing authority so directs, the registration holder shall furnish the licensing authority with a copy of any such reports of which he has a record or of which he is or subsequently becomes aware.

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

(4) The holder of a traditional herbal registration shall notify the licensing authority if the medicinal product to which the registration relates has not been placed on the market in the United Kingdom for a period of three consecutive years.

(5) The holder of a traditional herbal registration shall, on request from the licensing authority, provide the licensing authority with data on the volume of sales of the medicinal product to which the registration relates.

(6) Schedule 3 shall have effect to create certain criminal offences in connection with the obligations of applicants for, and holders of, traditional herbal registrations and other persons arising under the relevant Community provisions.

(7) Where, by or under any provision of the relevant Community provisions 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.

Consequential and other amendments of the Act and other enactments

10.—(1) Section 7 of the Act (general provisions as to dealing with medicinal products) shall not apply in relation to traditional herbal medicinal products.

(2) Section 23 of the Act (special provisions as to effect of manufacturer's licence) shall have effect as if any reference in subsection (1) to a product licence included a reference to a traditional herbal registration.

(3) Section 56 of the Act (exemptions in respect of herbal remedies) shall not apply in relation to traditional herbal medicinal products.

(4) Section 61 of the Act (special restrictions on persons to be supplied with medicinal products) shall have effect as if the reference to a product licence included a reference to a traditional herbal registration.

(5) The provisions of the Trade Descriptions Act 1968(**8**) shall apply to the application of a trade description to goods subject to a traditional herbal registration in the same way as, by virtue of section 2(5)(b) of that Act, they apply to the application of a trade description to goods subject to any provision made under Part V of the Act.

(6) Section 1(1) of the Medicines Act 1971(**9**) (fees payable for purposes of Part II of the Act) shall have effect as if the reference to any application in pursuance of the Act for a licence under Part II of the Act or for the variation or renewal of such a licence included a reference to any application under these Regulations for a traditional herbal registration or for the variation or renewal of such a registration.

(7) Section 19 of the Consumer Protection Act 1987(**10**) (interpretation of Part II) shall have effect as if in subsection (1) in the definition of "licensed medicinal product", the reference to any medicinal product within the meaning of the Medicines Act 1968 in respect of which a product licence within the meaning of that Act is for the time being in force, included a reference to a traditional herbal medicinal product in respect of which a traditional herbal registration under these Regulations is for the time being in force.

Application of enforcement provisions of the Act

11.—(1) Subject to paragraph (2) below, the following provisions of Part VIII of the Act (which provide for enforcement of the Act), namely, sections 107 to 109, section 110 except subsection (4), sections 111 to 116, section 118, section 119, sections 121 to 127 and Schedule 3, shall apply for the purposes of these Regulations as they apply for the purposes of the Act.

(2) Those provisions as so applied shall have effect—

(a) with the modifications specified in Schedule 4 to these Regulations; and

(**8**) 1968 c. 29.
(**9**) 1971 c. 69; section 1 was amended by section 21(1) of the Health and Medicines Act 1988 (c. 49).
(**10**) 1987 c. 43.

(b) as if all traditional herbal medicinal products were medicinal products for the purposes of the Act (whether or not they would otherwise be so).

Other Schedules to have effect

12. The following Schedules shall have effect, namely Schedule 5 (labels), Schedule 6 (transitional provision) and Schedule 7 (consequential amendments to orders and regulations).

Signed by authority of the Secretary of State for Health

Warner
Minister of State,
Department of Health

6th October 2005