

2005 No. 2750

MEDICINES

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

Made - - - - - 6th October 2005

Laid before Parliament 7th October 2005

Coming into force

*Except for the purposes of paragraphs 4(2)(a) and 8(a)(i)
of Schedule 7 30th October 2005*

*For the purposes of paragraphs 4(2)(a) and 8(a)(i) of
Schedule 7 20th November 2005*



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of Schedule 7 30th October 2005*

*For the purposes of paragraphs 4(2)(a) and 8(a)(i) of
Schedule 7 20th November 2005*

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

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^(c);

“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

(a) S.I. 1972/1811.
(b) 1972 c.68.
(c) 1968 c.67.

(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(a) 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(b),

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

(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(d), and

(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(e);

“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(f) 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.

(a) OJ No. L311, 28.11.2001, p.67.

(b) OJ No. L33, 8.2.2003, p.30.

(c) OJ No. L159, 27.6.2003, p.46.

(d) OJ No. L136, 30.4.2004, p.85.

(e) OJ No. L136, 30.4.2004, p.34.

(f) 1978 c.30.

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.

(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(a) 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(b) (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(c) (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
- (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).

(a) 1968 c.29.

(b) 1971 c.69; section 1 was amended by section 21(1) of the Health and Medicines Act 1988 (c.49).

(c) 1987 c.43.

6th October 2005

Warner
Minister of State,
Department of Health

SCHEDULE 1

Regulation 4(2)

EXEMPTIONS AND EXCEPTIONS FROM THE PROVISIONS OF REGULATION 4

Interpretation

1. In this Schedule—

“first level nurse” means a person registered in Sub-Part 1 of the Nurses’ Part of the professional register;

“professional register” means the register maintained by the Nursing and Midwifery Council under article 5 of the Nursing and Midwifery Order 2001(a);

“registered midwife” means a person registered in the Midwives’ Part of the professional register;

“relevant register” means—

- (a) in relation to a first level nurse or registered midwife, the professional register,
- (b) in relation to a pharmacist, the register maintained in pursuance of section 2(1) of the Pharmacy Act 1954 or the register maintained in pursuance of Articles 6 and 9 of the Pharmacy (Northern Ireland) Order 1976, and
- (c) in relation to a person whose name is registered in the part of the register maintained by the Health Professions Council in pursuance of article 5 of the Health Professions Order 2001(b) relating to—
 - (i) chiropodists and podiatrists;
 - (ii) physiotherapists;
 - (iii) radiographers: diagnostic or therapeutic,that register;

“supplementary prescriber” means—

- (a) a first level nurse,
- (b) a pharmacist,
- (c) a registered midwife, or
- (d) a person whose name is registered in the part of the register maintained by the Health Professions Council in pursuance of article 5 of the Health Professions Order 2001 relating to—
 - (i) chiropodists and podiatrists;
 - (ii) physiotherapists;
 - (iii) radiographers: diagnostic or therapeutic,

(a) S.I. 2002/253.
(b) S.I. 2002/254.

against whose name is recorded in the relevant register, an annotation or entry signifying that he is qualified to order drugs, medicines and appliances as a supplementary prescriber.

2. Regulation 4(1) shall not apply to a traditional herbal medicinal product supplied in response to a bona fide unsolicited order, formulated in accordance with the specification of a doctor, dentist or supplementary prescriber and for use by his individual patients on his direct personal responsibility, in order to fulfil the special needs of those patients, but such supply shall be subject to the conditions specified in paragraph 3.

3. The conditions mentioned in paragraph 2 are that—

- (a) the traditional herbal medicinal product is supplied to a doctor, dentist or supplementary prescriber or for use in a registered pharmacy, a hospital or a health centre under the supervision of a pharmacist, in accordance with paragraph 2;
- (b) no advertisement or representation relating to the traditional herbal medicinal product is issued with a view to it being seen generally by the public in the United Kingdom and that no advertisement relating to that product, by means of any catalogue, price list or circular letter is issued by, at the request or with the consent of, the person selling that product by retail or by way of wholesale dealing or supplying it in circumstances corresponding to retail sale, or the person who manufactures it, and that the supply is in response to a bona fide unsolicited order;
- (c) the manufacture or assembly of the traditional herbal medicinal product is carried out under the supervision of such staff and such precautions are taken as are adequate to ensure that the product is of the character required by and meets the specifications of the doctor, dentist or supplementary prescriber who requires it;
- (d) written records as to the manufacture or assembly in accordance with sub-paragraph (c) are made and maintained and are available to the licensing authority or the enforcement authority on request by them or either of them;
- (e) if the traditional herbal medicinal product is manufactured or assembled in the United Kingdom, or imported into the United Kingdom from a third country, the product—
 - (i) is manufactured, assembled or imported by the holder of a manufacturer's licence which relates specifically to the manufacture, assembly or import of traditional herbal medicinal products to which paragraph 2 applies; or
 - (ii) has been manufactured, assembled or imported as an investigational medicinal product by the holder of a manufacturing authorization granted by the licensing authority for the purposes of regulation 36 of the Medicines for Human Use (Clinical Trials) Regulations 2004(a); and
- (f) the traditional herbal medicinal product is distributed by way of wholesale dealing by the holder of a wholesale dealer's licence.

4.—(1) Subject to the following sub-paragraphs, regulation 4(1) shall not apply to anything done—

- (a) in relation to England and Wales, by a doctor or dentist which relates to a traditional herbal medicinal product specially prepared by him, or to his order, for administration—
 - (i) to one or more patients of his, or
 - (ii) where that doctor or dentist is a member of a group of doctors or dentists working together to provide primary medical or general services to one or more patients of any other doctor or dentist of that group,and consists of procuring the manufacture or assembly of a stock of the product with a view to administering the product to such patients;

(a) S.I. 2004/1031.

- (b) in relation to Scotland and Northern Ireland, by a doctor or dentist which relates to a traditional herbal medicinal product specially prepared by him, or to his order, for administration—
 - (i) to one or more patients of his, or
 - (ii) where that doctor or dentist is a member of a group of doctors or dentists working together to provide general medical or dental services to one or more patients of any other doctor or dentist of that group,and consists of procuring the manufacture or assembly of a stock of the product with a view to administering the product to such patients; or
- (c) in a registered pharmacy, a hospital or health centre and is done there by or under the supervision of a pharmacist, and consists of procuring the manufacture or assembly of a stock of traditional herbal medicinal products with a view to dispensing them in accordance with paragraph 2.

(2) The exemption conferred by sub-paragraph (1) shall not apply to procuring the manufacture of traditional herbal medicinal products unless those products are to be manufactured by the holder of a manufacturer's licence which relates specifically to the manufacture or assembly of traditional herbal medicinal products to which paragraph 2 applies.

(3) The exemption conferred by sub-paragraph (1) shall not apply to anything done by a doctor or dentist in relation to a stock held by him of such traditional herbal medicinal products in excess of a total of 5 litres of fluid and 2.5 kilograms of solids of all traditional herbal medicinal products to which that sub-paragraph relates.

5.—(1) Regulation 4(1) shall not apply to the placing on the market by way of supplying of any traditional herbal medicinal product to which this paragraph relates if the conditions of sub-paragraph (2) are satisfied.

(2) The conditions referred to in sub-paragraph (1) are—

- (a) that the traditional herbal medicinal product is sold or supplied to a person exclusively for use by him in the course of a business carried on by him for the purposes of administering it or causing it to be administered to one or more human beings otherwise than by selling it;
- (b) that, if sold or supplied through the holder of a wholesale dealer's licence, the traditional herbal medicinal product is sold or supplied to such a person, and for such use by him, as is described in head (a) above;
- (c) that, where the manufacture or assembly of the traditional herbal medicinal product is procured, it is procured by such a person, and for such use by him, as is described in head (a) above;
- (d) that no advertisement or representation relating to the traditional herbal medicinal product is issued with a view to it being seen generally by the public in the United Kingdom and that no advertisement relating to that product, by means of any catalogue, price list or circular letter, is issued by, at the request or with the consent of, the person selling that product by retail or by way of wholesale dealing or supplying it in circumstances corresponding to retail sale, or the person who manufactures it, and that the supply is in response to a bona fide unsolicited order;
- (e) that the traditional herbal medicinal product is prepared by or under the supervision of a pharmacist; and
- (f) that the traditional herbal medicinal product is manufactured by the holder of a manufacturer's licence which relates specifically to the manufacture of traditional herbal medicinal products to which paragraph 2 applies.

6. Any person who sells or supplies a traditional herbal medicinal product in accordance with any of paragraphs 2 to 5 shall maintain, and keep for a period of at least 5 years, a record showing—

- (a) the source from which that person obtained that product;

- (b) the person to whom and the date on which the sale or supply was made;
- (c) the quantity of each sale or supply;
- (d) the batch number of the batch of that product from which the sale or supply was made; and
- (e) details of any suspected adverse reaction to the product so sold or supplied of which he is aware.

7. A person required to maintain the records mentioned in paragraph 6 shall—

- (a) notify the licensing authority of any suspected adverse reaction such as is mentioned in head (e) of that paragraph which is a serious adverse reaction; and
- (b) make available for inspection at all reasonable times by the licensing authority the records mentioned in that paragraph.

SCHEDULE 2

Regulations 6(2), 7(7)

PROCEDURAL PROVISIONS RELATING TO THE GRANT, RENEWAL, VARIATION, REVOCATION AND SUSPENSION OF TRADITIONAL HERBAL REGISTRATIONS

PART 1

INTERPRETATION AND APPLICATION

Interpretation

1. In this Schedule—

“active ingredient from a new source” means an active ingredient in respect of which the application names as manufacturer a manufacturer not previously named as the manufacturer of that active ingredient included in a medicinal product in respect of which a marketing authorization (other than a product licence of right) or a traditional herbal registration has previously been granted;

“complex variation application” means an application by a traditional herbal registration holder to vary a traditional herbal registration which relates to a change in the formulation of a medicinal product comprising one or more of the following changes—

- (a) a change in that product’s active ingredients which involves the addition of one or more active ingredients which are active ingredients from a new source;
- (b) a change in that product’s excipients which involves the addition of one or more TSE risk excipients from a new source; or
- (c) a change which involves the addition of one or more vitamins or minerals which are vitamins or minerals from a new source where no European Pharmacopoeia certificate of suitability covering those vitamins or minerals has been submitted with the application;

“new excipient” means any ingredient of a medicinal product, other than an active ingredient, that has not previously been included in a medicinal product which is intended to be administered by the same route of administration as the product in question and in respect of which a marketing authorization (other than a product licence of right) or a traditional herbal registration has previously been granted, except that—

- (a) in the case of a medicinal product intended to be administered orally, the expression does not include any ingredient specified in any enactment (including an enactment comprised in subordinate legislation or in any Directive, Regulation or Decision of the European Community) as an approved ingredient or additive in food or in a food product; and

- (b) in the case of a medicinal product intended for external use only, the expression does not include any ingredient specified in any enactment (including an enactment comprised in subordinate legislation or in any Directive, Regulation or Decision of the European Community) as an approved ingredient or additive in a cosmetic product;

“new excipient variation application” means an application, other than a complex variation application, by a traditional herbal registration holder to vary a traditional herbal registration which relates to a change in the formulation of the medicinal product to add a new excipient;

“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;

“TSE risk excipient from a new source” means an excipient which has been manufactured from raw materials of ruminant origin or which has had raw materials of ruminant origin used in its manufacture and in respect of which—

- (a) the application names as manufacturer a manufacturer not previously named as the manufacturer of that excipient included in a medicinal product in respect of which a marketing authorization (other than a product licence of right) or a traditional herbal registration has previously been granted; and
- (b) no European Pharmacopoeia certificate of suitability covering the excipient has been submitted with the application;

“vitamin or mineral from a new source” means a vitamin or mineral in respect of which the application names as manufacturer a manufacturer not previously named as the manufacturer of that vitamin or mineral included in a medicinal product in respect of which a marketing authorization (other than a product licence of right) or a traditional herbal registration has previously been granted.

Scope and application of this Schedule

2. Subject to paragraphs 6 and 7, Part 2 applies to—

- (a) any application for the grant of a traditional herbal registration for a traditional herbal medicinal product except one made pursuant to the procedure in Article 28 of the 2001 Directive;
- (b) any application to renew a traditional herbal registration for a traditional herbal medicinal product; and
- (c) any proposal to revoke, vary or suspend a traditional herbal registration for a traditional herbal medicinal product, other than a variation on the application of the holder of that traditional herbal registration.

3. Subject to paragraphs 6 and 7, Part 3 applies to any application to vary a traditional herbal registration for a traditional herbal medicinal product which is a complex or a new excipient variation application.

4. Subject to paragraphs 6 and 7, Part 4 applies where the licensing authority propose to refer an application for the grant of a traditional herbal registration for a traditional herbal medicinal product to the Committee for Herbal Medicinal Products in accordance with Article 16c(4) of the 2001 Directive.

5. Subject to paragraphs 6 and 7, Part 5 applies where—

- (a) an applicant for a traditional herbal registration for a traditional herbal medicinal product, or for the variation or renewal of such a traditional herbal registration; or
- (b) the holder of a traditional herbal registration for a traditional herbal medicinal product,

gives notice under paragraphs 12, 17 or 20 of his wish to appear before or be heard by a person appointed by the licensing authority.

6. This Schedule shall cease to apply if at any time the relevant matter is, by virtue of any relevant Community provision, referred to the Committee for Herbal Medicinal Products for the application of the procedure laid down in Articles 32 to 34 of the 2001 Directive.

7. This Schedule does not apply—

- (a) if an application relates to a traditional herbal medicinal product in respect of which either of the conditions set out in Article 16d(1) are fulfilled and—
 - (i) the licensing authority declines to assess the application because an application for an EC traditional herbal 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
 - (ii) the licensing authority rejects the application where the traditional herbal medicinal product in question has an EC traditional herbal registration in another EEA State and the application has not been submitted in accordance with Article 28(1) and (2) of the 2001 Directive;
- (b) if the application or proposal relates to the renewal, revocation, suspension or variation of a traditional herbal registration which has been granted—
 - (i) in accordance with the provisions of Title III, Chapter 4 of the Directive; or
 - (ii) which has not been so granted, but which has been subject to the procedure laid down in Articles 32 to 34 of the Directive following a referral under Article 30 or 31 of that Directive, unless the procedure was limited to certain specific parts of the traditional herbal registration; or
- (c) if the licensing authority refuse to grant the traditional herbal registration applied for following a referral to the Committee for Herbal Medicinal Products in accordance with Article 16c(4) where the Committee for Herbal Medicinal Products has not supported the grant of the application.

PART 2

PROCEDURES RELATING TO GRANT, RENEWAL, COMPULSORY VARIATION, REVOCATION OR SUSPENSION OF TRADITIONAL HERBAL REGISTRATIONS

Requirement to consult the appropriate committee

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

- (a) refuse to grant or renew the traditional herbal registration applied for; or
- (b) revoke, vary or (subject to paragraph 13 of this Schedule) suspend a traditional herbal registration,

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

Provisional opinion against traditional herbal registration

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

- (a) may be unable to advise the licensing authority to grant or renew the traditional herbal 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 traditional herbal 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

10.—(1) After receiving the report of the appropriate committee pursuant to paragraph 9(8) the licensing authority shall—

- (a) decide whether to refuse to grant or renew the traditional herbal 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 traditional herbal 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

11.—(1) If—

- (a) the appropriate committee was consulted pursuant to paragraph 8;
- (b) the committee did not give a provisional opinion under paragraph 9(1); and
- (c) the licensing authority propose—
 - (i) to determine the application in a way which differs from the advice of the committee,
 - (ii) to revoke, vary or suspend a traditional herbal registration against such advice, or
 - (iii) on grounds not relating to safety, quality or efficacy—

- (aa) not to grant or renew a traditional herbal registration,
- (bb) to grant or renew a traditional herbal registration otherwise than in accordance with an application, or
- (cc) to revoke, vary or suspend a traditional herbal registration,

the licensing authority shall notify the applicant or holder accordingly.

(2) If—

- (a) the appropriate committee has not been consulted pursuant to paragraph 8; and
- (b) the licensing authority propose, on grounds not relating to safety, quality or efficacy—
 - (i) not to grant or renew a traditional herbal registration,
 - (ii) to grant or renew a traditional herbal registration otherwise than in accordance with an application, or
 - (iii) to revoke, vary or suspend a traditional herbal 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

12.—(1) Subject to sub-paragraph (4), a person to whom a notification has been given under paragraph 10(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 11(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 9(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

13.—(1) Paragraph 8 shall not apply to the suspension of a traditional herbal registration (whether or not it applies to any existing proposal to suspend or revoke the traditional herbal registration) where it appears to the licensing authority that, in the interests of safety, it is necessary to suspend the traditional herbal registration with immediate effect for a period not exceeding three months.

(2) Where the licensing authority so suspend a traditional herbal registration they shall report the suspension forthwith to the appropriate committee.

14. If, after suspending a traditional herbal registration with immediate effect by virtue of paragraph 13—

- (a) it appears to the licensing authority; or
- (b) the appropriate committee advise,

that the traditional herbal 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 13).

PART 3

VARIATION OF TRADITIONAL HERBAL REGISTRATION ON APPLICATION OF HOLDER

Hearing before appropriate committee

15.—(1) If the licensing authority decide, on grounds relating to safety, quality or efficacy—

- (a) to refuse to grant a complex variation application or a new excipient variation application; or
- (b) to grant it otherwise than in accordance with the application,

they shall notify the applicant accordingly.

(2) A person who has been notified in accordance with sub-paragraph (1) may, within the time allowed, give notice to the licensing authority of his wish to make written or oral representations to the appropriate committee.

(3) On receipt of a notice under sub-paragraph (2), the licensing authority shall inform the appropriate committee and the committee shall give the applicant an opportunity to make such representations in accordance with sub-paragraphs (4) to (7).

(4) Subject to sub-paragraph (5), the applicant 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 (1), or within such shorter period as the licensing authority may specify in the notification referred to in sub-paragraph (1).

(5) If the applicant 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 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 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 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 section; and
- (b) report their findings and advice to the licensing authority, together with the reasons for their advice.

Licensing authority decision

16.—(1) After receiving the report of the appropriate committee, the licensing authority shall—

- (a) confirm or alter their decision; and

- (b) take the report into account before doing so.
- (2) The licensing authority shall notify the applicant 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.

Right to be heard by a person appointed

17.—(1) Subject to sub-paragraph (2), if the licensing authority notify the applicant of the authority's decision—

- (a) to refuse the application; or
- (b) to grant it otherwise than in accordance with the application,

the applicant 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) Sub-paragraph (1) shall not apply where—
 - (a) the person had not made any representations in accordance with paragraph 15(4) to (7); and
 - (b) the decision of the licensing authority was in accordance with the advice of the appropriate committee.

PART 4

REFERRAL TO THE COMMITTEE FOR HERBAL MEDICINAL PRODUCTS IN ACCORDANCE WITH ARTICLE 16C(4) OF THE 2001 DIRECTIVE

Hearing before appropriate committee

18.—(1) If the licensing authority propose to refer an application for a traditional herbal registration to the Committee for Herbal Medicinal Products in accordance with Article 16c(4) of the 2001 Directive they shall notify the applicant accordingly.

(2) A person who has been notified in accordance with sub-paragraph (1) may, within the time allowed, give notice to the licensing authority of his wish to make written or oral representations to the appropriate committee.

(3) On receipt of a notice under sub-paragraph (2), the licensing authority shall inform the appropriate committee and the committee shall give the applicant an opportunity to make such representations in accordance with sub-paragraphs (4) to (7).

- (4) Subject to sub-paragraph (5), the applicant 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 (1), or within such shorter period as the licensing authority may specify in the notification referred to in sub-paragraph (1).

(5) If the applicant 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 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 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 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 section; and
 - (b) report their findings and advice to the licensing authority, together with the reasons for their advice.

Licensing authority decision

- 19.—(1) After receiving the report of the appropriate committee, the licensing authority shall—
- (a) decide whether to proceed with their proposal; and
 - (b) take the report into account before doing so.
- (2) The licensing authority shall notify the applicant 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.

Right to be heard by a person appointed

20.—(1) Subject to sub-paragraph (2), if the licensing authority notify the applicant of the authority's decision to refer the application to the Committee for Herbal Medicinal Products as proposed, the applicant 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) Sub-paragraph (1) shall not apply where—
- (a) the person had not made any representations in accordance with paragraph 18(4) to (7); and
 - (b) the decision of the licensing authority was in accordance with the advice of the appropriate committee.

PART 5

HEARING BEFORE PERSON APPOINTED

Hearing before person appointed

21.—(1) If an applicant or holder of a traditional herbal registration gives notice under paragraphs 12, 17 or 20 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 refer the application to the Committee for Herbal Medicinal Products,
 - (iii) to grant or renew the traditional herbal registration,
 - (iv) to grant or renew the traditional herbal registration otherwise than in accordance with the application, or
 - (v) to revoke, vary or suspend the traditional herbal 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 refer the application to the Committee for Herbal Medicinal Products,
 - (iii) to grant or renew the traditional herbal registration,
 - (iv) to grant or renew the traditional herbal registration otherwise than in accordance with the application, or
 - (v) to revoke, vary or suspend the traditional herbal 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.

OFFENCES, PENALTIES ETC

Offences

1. Any person who, in breach of these Regulations, places a traditional herbal medicinal product on the market without holding a traditional herbal registration in respect of that product, or otherwise than in accordance with the terms of such a registration, 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 traditional herbal medicinal product, or who has in his possession a traditional herbal 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 traditional herbal registrations, any holder of a traditional herbal registration for a traditional herbal medicinal product who contravenes any condition of the registration shall be guilty of an offence.

4. Any person who is the holder of a traditional herbal registration who fails to implement an urgent safety restriction imposed on him by the licensing authority under regulation 8 shall be guilty of an offence.

5. Where the use, supply or marketing of a traditional herbal medicinal product is suspended in accordance with regulation 7, any person who sells, supplies or markets, or procures the sale, supply or marketing of, that product knowing, or having reasonable cause to believe, that such use, supply or marketing is suspended, shall be guilty of an offence.

6. Any person who is or, immediately before its revocation or suspension, was the holder of a traditional herbal registration who fails to comply with a notice given to him under regulation 7(5) (notice to take all reasonably practicable steps to publish information concerning revocation or suspension or to recover possession of products affected) shall be guilty of an offence.

7. Any holder of a traditional herbal 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) 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 of the 2001 Directive; or
- (d) submit any application to the licensing authority to make any changes or variation as required by that Article; or
- (e) notify the licensing authority if the traditional herbal 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 pursuant to regulation 9(4);

shall be guilty of an offence.

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

- (a) where the licensing authority have served a written notice on the holder under regulation 9(7) 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.

9. Any holder of a traditional herbal registration who fails to forward to the licensing authority any data requested by the authority pursuant to regulation 9(5)—

- (a) where the licensing authority have served a written notice on the holder under regulation 9(7) 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.

10. Any person who is the holder of a traditional herbal 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.

11. Any holder of a traditional herbal registration who communicates to the general public information relating to pharmacovigilance concerns about the product to which the registration relates without having previously communicated, or without simultaneously communicating, such information to the licensing authority shall be guilty of an offence.

12. Any holder of a traditional herbal registration who fails to ensure that information relating to pharmacovigilance concerns about the product to which the registration relates which he communicates to the general public or the licensing authority is presented objectively and is not misleading shall be guilty of an offence.

13. Any person responsible for placing on the market a traditional herbal medicinal product authorised by the licensing authority who, at any time, does not have at his disposal an appropriately qualified person responsible for pharmacovigilance as required by Title IX of the 2001 Directive shall be guilty of an offence.

14. Any person responsible for placing a traditional herbal medicinal product on the market who fails to report to the licensing authority any suspected adverse reaction, or to submit to the licensing authority any records of suspected adverse reactions as required by Title IX of the 2001 Directive, shall be guilty of an offence.

15. Any person responsible for placing a traditional herbal medicinal product on the market who fails to make or maintain a detailed record of any suspected adverse reaction as required by Title IX of the 2001 Directive shall be guilty of an offence.

16. Any person who, while employed or engaged as an appropriately qualified person responsible for pharmacovigilance for the purposes of Title IX of the 2001 Directive fails to—

- (a) establish or maintain a system for collecting and collating information about suspected adverse reactions;
- (b) prepare for the licensing authority a report on any such reactions; or
- (c) ensure that a request from the licensing authority for the provision of additional information necessary for the evaluation of the benefits and risks afforded by a traditional herbal medicinal product is answered fully and promptly; or
- (d) provide to the licensing authority any other information relevant to the evaluation of the benefits and risks afforded by a medicinal product, including appropriate information on post authorization safety studies,

as required by any provision of that Title, shall be guilty of an offence.

17.—(1) Any person who in the course of an application for the grant, renewal or variation of a traditional herbal registration for a traditional herbal medicinal product—

- (a) fails to provide to the licensing authority any information which is relevant to an evaluation of the safety, quality or efficacy of the traditional herbal medicinal product as required by point (7) or (11) of the introduction to Annex I to the 2001 Directive; or

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

shall be guilty of an offence.

(2) Any person who—

- (a) is responsible for placing a traditional herbal medicinal product on the market;
- (b) is the traditional herbal registration holder for a traditional herbal medicinal product; or
- (c) while employed or engaged as an appropriately qualified person responsible for pharmacovigilance for the purposes of Title IX of the 2001 Directive is required to provide information to the licensing authority about a traditional herbal medicinal product,

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

18. Any holder of a traditional herbal registration who sells or supplies or procures the sale or supply of a traditional herbal medicinal product to which the traditional herbal registration relates—

- (a) the labelling of which, or any package leaflet accompanying which, does not comply with; or
- (b) without a package leaflet required to be provided by virtue of,

the applicable requirements of Title V of the 2001 Directive or of Schedule 5 to these Regulations, shall be guilty of an offence.

19. Where, in relation to a traditional herbal medicinal product —

- (a) the labelling of the product, or any package leaflet accompanying the product, does not comply with; or
- (b) the product is not accompanied by a package leaflet required to be provided by virtue of,

the applicable requirements of Title V of the 2001 Directive or Schedule 5, any person, other than the holder of the traditional herbal registration for that product, who in the course of a business carried on by him, sells or supplies or procures the sale or supply of that product knowing, or having reasonable cause to believe, that the labelling does not so comply or, as the case may be, that the product is not so accompanied, shall be guilty of an offence.

20. Any person who fails to keep any record required under paragraph 6 of Schedule 1, or to give notice or make it available for inspection as and when required under paragraph 7 of that Schedule, shall be guilty of an offence.

21. Any person who—

- (a) sells or supplies a traditional herbal medicinal product in accordance with any of paragraphs 2 to 5 of Schedule 1; or
- (b) provides a specification for such a product for the purposes of paragraph 2 of that Schedule,

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

Penalties

22. 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

23.—(1) Where an offence is committed under any of paragraphs 14, 15, 16 or 17 by a person mentioned in those paragraphs who is acting as the employee or agent of another person, the employer or principal of that person shall be guilty of the same offence.

(2) Where a Scottish partnership is guilty of an offence under these Regulations in respect of any act or default which is shown to have been committed with the consent or connivance of, or to be attributable to any neglect on the part of, a partner in the partnership, he, as well as the partnership, shall be guilty of that offence and shall be liable to be proceeded against and punished accordingly.

24. Where the holder of a traditional herbal 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 registration, it shall be a defence for him to prove—

- (a) that he had communicated the provisions relating to the 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.

25.—(1) A person does not commit an offence under paragraphs 10, 17 or 21 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 4

Regulation 11(2)(a)

MODIFICATIONS OF ENFORCEMENT PROVISIONS OF THE ACT

1. In section 107 (validity of decisions and proceedings relating thereto)—

- (a) in subsection (1), for “Part II of this Act or of a Minister under section 75 of this Act, and the validity of any licence or certificate” substitute “the Herbal Regulations, and the validity of any registration”;
- (b) in subsections (2)(a) and (3)(b), for “this Act” substitute “the Herbal Regulations”;
- (c) in subsection (2)(b), for “this Act or of any regulations made under this Act” substitute “the Herbal Regulations”; and
- (d) in subsection (4), for “licence or certificate”, in each place those words appear, substitute “registration”.

2. In section 108 (enforcement in England and Wales)—

- (a) for subsection (1) substitute—

“(1) It shall be the duty of the Secretary of State to enforce in England, or to secure the enforcement in England of, the provisions of the Herbal Regulations.

(1A) It shall be the duty of the National Assembly of Wales to enforce in Wales, or to secure the enforcement in Wales of, the provisions of the Herbal Regulations.”; and

- (b) in subsection (2)(c) after “this Act”, in the second place those words appear, insert “or the Herbal Regulations”.

3. In section 109 (enforcement in Scotland), for subsections (1) to (3), substitute—

“(1) It shall be the duty of the Scottish Ministers to enforce in Scotland, or to secure the enforcement in Scotland of, the provisions of the Herbal Regulations.”.

4. For section 110 (enforcement in Northern Ireland) substitute—

“It shall be the duty of the Department for Health, Social Services and Public Safety to enforce in Northern Ireland, or to secure the enforcement in Northern Ireland of, the provisions of the Herbal Regulations.”.

5. In section 111 (rights of entry)—

- (a) in subsection (1)(a), for the words after “contravention” substitute “of any provisions of the Herbal Regulations, or”;
- (b) in subsection (1)(b), for “this Act or under any such regulations or order” substitute “those Regulations or any of the provisions of this Act applied by regulation 11 of those Regulations”;
- (c) in subsection (2)(a), for the words from “this Act or of any regulations” onwards substitute “the Herbal Regulations;”; and
- (d) in subsection (3)—
 - (i) for “licence or certificate under Part II of this Act” substitute “registration under the Herbal Regulations”, and
 - (ii) for “licence or certificate”, in the second place those words appear, substitute “registration”.

6. In section 112 (power to inspect, take samples and seize goods and documents)—

- (a) in subsection (1), for the words before paragraph (a) substitute—

“For the purpose of ascertaining whether there is or has been a contravention of the Herbal Regulations, any person duly authorised in writing by an enforcement authority shall have a right to inspect—”;
- (b) in subsection (4)—
 - (i) for “offence under this Act is” substitute—

“offence—

 - (a) under the Herbal Regulations, or
 - (b) under section 114, 118 or 123 of this Act,

is”, and
 - (ii) for “under this Act”, in the second place those words appear, substitute “under those Regulations or under any of the provisions of this Act applied by regulation 11 of those Regulations”;
- (c) in subsection (5), for “this Act and any regulations or order made thereunder” substitute “the Herbal Regulations”;
- (d) in subsection (7)—
 - (i) for “a licence or certificate under Part II of this Act” substitute “a registration under the Herbal Regulations”, and
 - (ii) for “licence or certificate”, in the second place those words appear, substitute “registration”; and
- (e) in subsection (9), for “this Act”, in the second place those words appear, substitute “the Herbal Regulations”.

7. In section 115 (analysis of samples in other cases)—

- (a) in subsection (7), for “form prescribed by the Ministers” substitute “prescribed form”; and
- (b) omit subsection (9).

- 8.** In section 116 (liability to forfeiture under Customs and Excise Management Act 1979)—
- (a) for “this Act”, in both places those words appear, substitute “the Herbal Regulations”; and
 - (b) after subsection (3) insert—
 - “(4) In this section “the Ministers” means the Secretary of State and the Department for Health, Social Services and Public Safety, acting jointly.”.
- 9.** In section 118 (restrictions on disclosure of information), in subsection (1)(b), for “this Act” substitute “the Herbal Regulations or any provision of this Act applied by regulation 11 of those Regulations”.
- 10.** In section 119 (protection for officers of enforcement authorities)—
- (a) in subsection (1)—
 - (i) for “this Act”, in the first place those words appear, substitute “relevant legislation”, and
 - (ii) for “this Act”, in the second place those words appear, substitute “that legislation”;
 - (b) in subsection (2)—
 - (i) for “this Act”, in the first place those words appear, substitute “relevant legislation”, and
 - (ii) for “this Act”, in the second place those words appear, substitute “that legislation”;
 - (c) in subsection (3), for “this Act” substitute “relevant legislation”; and
 - (d) after subsection (3) insert—
 - “(4) In this section “relevant legislation” means—
 - (a) the Herbal Regulations, or
 - (b) any provision of this Act applied by regulation 11 of those Regulations.”.
- 11.** In section 121 (contravention due to default of other person)—
- (a) in subsection (1), for “to which this section applies constitutes an offence under this Act” substitute “of the Herbal Regulations constitutes an offence under those Regulations”;
 - (b) in subsection (2), for “this Act in respect of a contravention of a provision to which this section applies” substitute “the Herbal Regulations in respect of a contravention of a provision of those Regulations”; and
 - (c) Omit subsection (4).
- 12.** In section 122 (warranty as defence)—
- (a) in subsection (1), for “this Act in respect of a contravention of a provision to which this section applies” substitute “the Herbal Regulations”; and
 - (b) Omit subsection (2).
- 13.** In section 124 (offences by bodies corporate)—
- (a) in subsection (1), for “this Act” substitute “the Herbal Regulations, or under section 114, 118 or 123 of this Act,”; and
 - (b) after subsection (2) insert the following subsection—
 - “(2A) In subsections (1) and (2) of this section “body corporate” includes a Scottish partnership and “director”, in relation to such a partnership, includes any of its partners”.
- 14.** In section 125 (prosecutions)—
- (a) in subsections (1) and (2), for “under this Act” substitute “under the Herbal Regulations, or for an offence under section 114, 118 or 123 of this Act,”;
 - (b) omit subsection (3);

- (c) in subsection (4) after “this Act”, in the second place those words appear, insert “or under the Herbal Regulations”; and
- (d) omit subsections (6) and (7).

15. In section 127 (service of documents)—

- (a) for “any provision of this Act” substitute “relevant legislation”; and
- (b) at the end add—

“In this section “relevant legislation” means any provision of the Herbal Regulations or any provision of this Act applied by regulation 11 of those Regulations”.

16. In Schedule 3 (sampling)—

- (a) in paragraph 1(1)(a), for the words from “this Act or of any Regulations” onwards substitute “the Herbal Regulations, or”;
- (b) in paragraph 1(1)(b), for the words from “of their functions” onwards substitute “(in this Schedule referred to as “the relevant enforcement authority”) of their functions under those Regulations or under any provision of this Act applied by regulation 11 of those Regulations,”;
- (c) in paragraph 19(3), for “form prescribed by the Ministers” substitute “prescribed form”;
- (d) omit paragraph 20(2); and
- (e) in each of paragraphs 21 and 22, for “under this Act” substitute “under the Herbal Regulations, or under section 114, 118 or 123 of this Act,”.
- (f) in paragraph 24(1), for “under this Act,” substitute “under the Herbal Regulations, or under section 114, 118 or 123 of this Act,”.

SCHEDULE 5

Regulation 12

LABELS

Interpretation

1. In this Schedule—

“dispensed traditional herbal medicinal product” means a traditional herbal medicinal product prepared or dispensed in accordance with a prescription given by a practitioner; and
“requirements” includes restrictions.

Introductory

2. The requirements of this Schedule supplement those of Title V of the 2001 Directive relating to—

- (a) special warnings necessary for particular medicinal products;
- (b) the legal status for supply to the patient, in accordance with Title VI of the 2001 Directive;
- (c) identification and authenticity.

Dispensed traditional herbal medicinal products

3.—(1) Subject to the following provisions of this Schedule, where a traditional herbal medicinal product is a dispensed traditional herbal medicinal product the container of that product shall be labelled to show the following particulars—

- (a) where the traditional herbal medicinal product is for use by being administered to a particular human being, the name of the person to whom the traditional herbal medicinal product is to be administered;
- (b) the name and address of the person who sells or supplies the traditional herbal medicinal product;
- (c) the date on which the traditional herbal medicinal product is dispensed; and
- (d) where the traditional herbal medicinal product has been prescribed by a practitioner, such of the following particulars as he may request—
 - (i) the name of the traditional herbal medicinal product or its common name,
 - (ii) directions for use of the traditional herbal medicinal product, and
 - (iii) precautions relating to the use of the traditional herbal medicinal product,
 or where a pharmacist, in the exercise of his professional skill and judgement, is of the opinion that any of such particulars are inappropriate and has taken such steps as in all the circumstances are reasonably practicable to consult with the practitioner but has been unable to do so, particulars of the same kind as those requested by the practitioner as appear to the pharmacist to be appropriate.

(2) Where the container of a dispensed traditional herbal medicinal product is enclosed in a package immediately enclosing that container the particulars set out in sub-paragraph (1) may be omitted from the container if that package is labelled to show such particulars.

(3) Where a number of containers or packages, or of containers and packages, of dispensed traditional herbal medicinal products all of the same description are enclosed in a package, sub-paragraph (1)(d) shall be deemed to have been complied with if such of the particulars referred to in that sub-paragraph as would, apart from this sub-paragraph, be required to be shown on each container or package, or on each container and package so enclosed, are shown on either one or more such containers or packages or such containers and packages as the case may be.

Traditional herbal medicinal products not on a general sale list

4. Subject to the following provisions of this Schedule, where a traditional herbal medicinal product to which any of the restrictions imposed by section 52 of the Act (sale or supply of medicinal products not on general sale list) apply is sold by retail, or supplied in circumstances corresponding to retail sale or is offered or exposed for sale by retail, every container and every package immediately enclosing a container of such a product shall unless the product is a dispensed traditional herbal medicinal product, be labelled to show the capital letter “P” within a rectangle within which there shall be no other matter of any kind.

Exemptions

- 5.—(1) Nothing in this Schedule shall require the labelling of—
- (a) any package in the form of a transparent wrapping or cover to a container and package of a traditional herbal medicinal product or any package the whole or part of which is transparent or open if the particulars shown on the labelled container enclosed in that package are clearly visible;
 - (b) any package in the form of a wrapping paper, paper bag or similar covering in which the container and package of a traditional herbal medicinal product labelled in accordance with the provisions of this Schedule is placed when such traditional herbal medicinal product is sold by retail or supplied in circumstances corresponding to retail sale;
 - (c) any container or package immediately enclosing the container of a traditional herbal medicinal product which is for export; or
 - (d) any container which is—
 - (i) an ampoule or other container of not more than 10 millilitres nominal capacity which is immediately enclosed in a package which is labelled in accordance with paragraph 4, or

- (ii) in the form of a wrapper consisting of paper, film, plastic material, metal foil or other sheet or strip material or in the form of a bubble, blister or other sealed unit consisting of such sheet or strip material, enclosing one or more dosage units of a traditional herbal medicinal product and such container is immediately enclosed in a package which is labelled in accordance with paragraph 4.

(2) Where any package immediately enclosing a container as is described in paragraph (1)(d)(ii) is—

- (a) itself in the form of a bubble, blister or other sealed unit as is mentioned in that paragraph;
- (b) part of a continuous series comprising a sheet or strip of like packages; and
- (c) required to be labelled to show the letter referred to in paragraph 4,

the requirement shall be deemed to have been complied with if the said letter is displayed at frequent intervals on the said sheet or strip of such packages.

SCHEDULE 6

Regulation 12

TRANSITIONAL PROVISION

1. The provisions of these Regulations shall not apply until 30th April 2011 to herbal medicinal products which were on the market in the United Kingdom on 30th April 2004 without a marketing authorization by virtue of section 12(2) of the Act.

SCHEDULE 7

Regulation 12

CONSEQUENTIAL AMENDMENTS TO ORDERS AND REGULATIONS

1. In the Medicines (Retail Sale or Supply of Herbal Remedies) Order 1977(a), after article 1 insert the following article—

“Application

1A. Nothing in this Order applies to a medicinal product for human use to which the Medicines (Traditional Herbal Medicinal Products for Human Use) Regulations 2005 apply.”.

2. In the Medicines (Sale or Supply) (Miscellaneous Provisions) Regulations 1980(b), in regulation 5 (restrictions on persons to be supplied with certain medicinal products), in paragraph (1)(a), after “Marketing Authorizations Etc.) Regulations 1994” insert “or the holder of a traditional herbal registration within the meaning of the Medicines (Traditional Herbal Medicinal Products for Human Use) Regulations 2005”.

3.—(1) The Medicines (Pharmacy and General Sale-Exemption) Order 1980(c) is amended as follows.

(2) In article 1 (citation, commencement and interpretation), in paragraph (2), after the definition of “supply” insert the following definition—

(a) S.I. 1977/2130.

(b) S.I. 1980/1923, paragraph (1) of regulation 5 was amended by S.I. 1994/3142 and 3144.

(c) S.I. 1980/1924; relevant amending instruments are S.I. 2000/1919 and 2003/697.

““traditional herbal registration” means a registration granted by the licensing authority under The Medicines (Traditional Herbal Medicinal Products for Human Use) Regulations 2005;”.

(3) In article 4A (exemption for the supply of medicinal products by national health service bodies)(a), in paragraph (2)(e), after “marketing authorization” insert “, a traditional herbal registration”.

(4) In article 4B (exemption for health professionals who supply medicinal products under a Patient Group Direction in order to assist doctors or dentists in providing national health services)(b), in paragraph (2)(f), after “marketing authorization” insert “, a traditional herbal registration”.

(5) In article 4C (exemption for the supply of medicinal products by independent hospitals, clinics and agencies)(c), in paragraph (2)(e), after “marketing authorization” insert “, a traditional herbal registration”.

(6) In article 4D (exemption for health professionals who supply medicinal products under a Patient Group Direction in order to assist the provision of health care by or on behalf of the police, the prison services or the armed forces)(d), in paragraph (2)(f), after “marketing authorization” insert “, a traditional herbal registration”.

4.—(1) The Medicines (Products Other Than Veterinary Drugs) (General Sale List) Order 1984(e) is amended as follows.

(2) In article 1 (citation, commencement and interpretation), in paragraph (2)(a)—

(a) in the definition of “marketing authorization”(f), after “Evaluation of Medicinal Products” insert “or by the European Medicines Agency under Regulation (EC) No. 726/2004 of the European Parliament and of the Council laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency(g)”; and

(b) after the definition of “product licence of right” insert the following definition—

““traditional herbal registration” means a registration granted by the licensing authority under the Medicines (Traditional Herbal Medicinal Products for Human Use) Regulations 2005; and”.

(3) In article 2 (general sale list)—

(a) after paragraph (a) insert the following paragraph—

“(aa) medicinal products in respect of which a traditional herbal registration has been granted, which in the traditional herbal registration are classified as being general sale list medicines;”; and

(b) in paragraph (b) after “marketing authorization” insert “or traditional herbal registration”.

5. In the Dangerous Substances and Preparations (Safety) (Consolidation) Regulations 1994(h), in regulation 1 (citation, commencement and interpretation), in paragraph (2), in the definition of “medicinal product”, in paragraph (a), after sub-paragraph (i) insert the following sub-paragraph—

“(ia) in respect of which there is for the time being a traditional herbal registration granted under regulation 6 of the Medicines (Traditional Herbal Medicinal Products for Human Use) Regulations 2005, or”.

6. In the Medicines (Aristolochia and Mu Tong etc.) (Prohibition) Order 2001(a), in article 4 (Exceptions to the prohibitions imposed by articles 2 and 3), in paragraph (4), after “(Marketing

(a) Article 4A was inserted by article 2(c) of S.I. 2000/1919.

(b) Article 4B was inserted by article 2(c) of S.I. 2000/1919.

(c) Article 4C was inserted by article 3 of S.I. 2003/697.

(d) Article 4D was inserted by article 3 of S.I. 2003/697.

(e) S.I. 1984/769; relevant amending instrument is S.I. 2002/933.

(f) The definition of “marketing authorization” was inserted by article 2(a) of S.I. 2002/933.

(g) OJ No. L136, 30.4.2004, p.1.

(h) S.I. 1994/2844, regulation 1(2) was amended by S.I. 1996/2635 and 2004/1031.

Authorisations Etc.) Regulations 1994” insert “, a traditional herbal registration within the meaning of regulation 2(1) of the Medicines (Traditional Herbal Medicinal Products for Human Use) Regulations 2005”.

7. In the Medicines for Human Use (Kava-Kava) (Prohibition) Order 2002**(b)**, in article 3 (Exceptions to the prohibition imposed by article 2), in paragraph (d)—

(a) at the end of sub-paragraph (iii) insert “, or”; and

(b) after sub-paragraph (iii) insert the following sub-paragraph—

“(iv) a traditional herbal registration within the meaning given in regulation 2(1) of the Medicines (Traditional Herbal Medicinal Products for Human Use) Regulations 2005.”.

8. In the Unlicensed Medicinal Products for Human Use (Transmissible Spongiform Encephalopathies) (Safety) Regulations 2003**(c)**, in regulation 1 (citation, commencement and interpretation), in paragraph (2)—

(a) in the definition of “unlicensed product”—

(i) in sub-paragraph (a)(ii) after “Medicinal Products” insert “or under Regulation (EC) No. 726/2004 of the European Parliament and of the Council laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency”,

(ii) at the end of sub-paragraph (b) insert “or”, and

(iii) after sub-paragraph (b) insert the following sub-paragraph—

“(c) no traditional herbal registration has been granted by the licensing authority under the Medicines (Traditional Herbal Medicinal Products for Human Use) Regulations 2005;”; and

(b) in the definition of “the TSE Guideline” after “for human use” insert “as substituted by Commission Directive 2003/63/EC amending Directive 2001/83/EC on the Community code relating to medicinal products for human use”.

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations implement Directive 2004/24/EC of the European Parliament and of the Council amending, as regards traditional herbal medicinal products, Directive 2001/83/EC**(d)** on the Community code relating to medicinal products for human use**(e)** (the “2001 Directive”).

Directive 2004/24/EC amended the 2001 Directive to introduce a simplified registration procedure for the marketing of traditional herbal medicinal products for human use. These Regulations introduce a scheme of traditional herbal registrations (defined in Regulation 2).

Regulation 3 provides that the licensing authority established under section 6 of the Medicines Act 1968 (consisting of the Secretary of State for Health, the Secretary of State for Environment and Rural Affairs, and the Northern Ireland Department for Health, Social Services and Public Safety and the Northern Ireland Department for Agriculture and Rural Development) will perform the functions of the competent authority in relation to the provisions of the 2001 Directive which apply to traditional herbal medicinal products.

Regulation 4(1) requires all traditional herbal medicinal products placed on the market or distributed by wholesale dealing to be registered in accordance with these Regulations.

(a) S.I. 2001/1841.

(b) S.I. 2002/3170.

(c) S.I. 2003/1680, regulation 1(2) was amended by S.I. 2004/3224.

(d) Directive 2001/83/EC of the European Parliament and of the Council of 6th November 2001 on the Community code relating to medicinal products for human use, OJ L311, 28.11.2001, p 67.

(e) OJ No. L136, 30.4.2004, p.85.

Regulation 4(2) and Schedule 1 set out exemptions under which traditional herbal medicinal products may be supplied or administered without a traditional herbal registration provided the conditions set out in Schedule 1 are complied with. In particular, doctors, dentists and supplementary prescribers may prepare, or order to be prepared, traditional herbal medicinal products to be used by their individual patients.

Regulations 5 to 7 and Schedule 2 make provision for applications for the grant, renewal and variation of traditional herbal registrations, and for the licensing authority to revoke, vary or suspend traditional herbal registrations. In particular, Schedule 2 makes provision for reference to the appropriate committee of decisions to refuse traditional herbal registrations, proposals to refer applications in certain circumstances to the Committee for Herbal Medicinal Products, and to revoke, vary or suspend a registration.

Regulation 8 makes provision for the licensing authority to impose an urgent safety restriction on the holder of a traditional herbal registration.

Regulation 9 imposes obligations on the holders of traditional herbal registrations.

Regulations 9(6) and 11 and Schedules 3 and 4, make provision for enforcement and related matters, including powers of inspection, offences and penalties for breaches of the Regulations.

Regulation 12 and Schedule 5 impose labelling requirements for traditional herbal medicinal products which are prepared or dispensed in accordance with a prescription, or available only from a pharmacy.

Regulations 10 and 12 and Schedules 6 and 7, contain miscellaneous provisions for the consequential amendment of legislation and for transitional arrangements.

A Regulatory Impact Assessment in relation to these Regulations, and a Transposition Note in relation to the implementation of Directive 2004/24/EC, have been placed in the libraries of both 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.

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