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STATUTORY INSTRUMENTS

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**1994 No. 3144**

**MEDICINES**

**The Medicines for Human Use (Marketing  
Authorisations Etc.) Regulations 1994**

*Made - - - - 8th December 1994*  
*Laid before Parliament 9th December 1994*  
*Coming into force - - 1st January 1995*

The Secretary of State, in exercise of the powers conferred by section 2(2) of the European Communities Act 1972<sup>(1)</sup>, being designated for the purpose of that section in relation to medicinal products<sup>(2)</sup>, hereby makes the following Regulations:

**Citation, commencement and interpretation**

1.—(1) These Regulations may be cited as the Medicines for Human Use (Marketing Authorisations Etc.) Regulations 1994 and shall come into force on 1st January 1995—

- (a) in the case of all of these Regulations, immediately after the coming into force of Council Regulation (EEC) No. 2309/93<sup>(3)</sup> and Council Directive 93/39/EEC<sup>(4)</sup>; and also
- (b) in the case of paragraphs 4, 5 and 6 of Schedule 7, immediately after the coming into force of the Marketing Authorisations for Veterinary Medicinal Products Regulations 1994<sup>(5)</sup>.

(2) In these Regulations:

“the Act” means the Medicines Act 1968<sup>(6)</sup>; “the Community” means the European Community;

“Community marketing authorization” means a marketing authorization granted by the European Commission under Council Regulation (EEC) No. 2309/93<sup>(7)</sup>;

“the EMEA” means the European Agency for the Evaluation of Medicinal Products established by Council Regulation (EEC) No. 2309/93;

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(1) 1972 c. 68.

(2) See The European Communities (Designation) Order 1972 (S.I.1972/1811).

(3) OJ No. L214, 24.8.93, p.1.

(4) OJ No. L214, 24.8.93, p.22.

(5) S.I. 1994/

(6) 1968 c. 67. Relevant amendments were made by the Prescription by Nurses Act 1992 (c. 28), section 1 and S.I. 1977/1050, 1983/1724, 1992/604, 605 and 3271 and 1993/834.

(7) OJ No. L214, 24.8.93, p.1.

“parallel import” means the import into the United Kingdom from another Member State of the Community of a medicinal product for human use in respect of which there has been granted a Community marketing authorization or a marketing authorization by another Member State of the Community and which has no difference having therapeutic effect from a medicinal product in respect of which a marketing authorization has previously been granted in the United Kingdom;

“the relevant Community provisions” means the provisions of—

Council Directive [65/65/EEC](#)(8);

Council Directive [75/318/EEC](#)(9);

Chapters I to II and V to VI of Council Directive [75/319/EEC](#)(10) and any Regulation adopted by the Commission under Article 15 of that Directive;

Council Directive [89/342/EEC](#)(11);

Council Directive [89/343/EEC](#)(12);

Council Directive [89/381/EEC](#)(13);

Council Directive [92/26/EEC](#)(14);

Council Directive [92/27/EEC](#)(15);

Council Directive [92/73/EEC](#)(16);

Regulation ([EEC](#)) No. [2309/93](#)(17) and any Regulations adopted by the Commission under Article 15.4 or 22.1 of that Regulation,

as they have effect on the day these Regulations come into force;

“relevant medicinal product” means a medicinal product for human use to which Chapters II to V of Council Directive [65/65/EEC](#) apply, and accordingly includes the industrially produced medicinal products mentioned in Article 2.2 of that Directive; and

“United Kingdom marketing authorization” means a marketing authorization granted by the licensing authority under these Regulations.

(3) For the purposes of the definition of “relevant medicinal product” in paragraph (2) a medicinal product which is a herbal remedy is not industrially produced if—

- (a) it is, or is to be, sold or supplied in circumstances to which either section 12(1) of the Act or Article 2 of the Medicines (Exemptions from Licences) (Special and Transitional Cases) Order 1971(18) relate and has been manufactured or assembled only for sale or supply in those circumstances; or

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(8) OJ No. L22, 9.2.65, p.369/65. The Directive was amended by Directives [75/319/EEC](#) (OJ No. L147, 9.6.75, p.13); [83/570/EEC](#) (OJ No. L332, 28.11.83, p.1); [87/21/EEC](#), (OJ No. L15, 17.1.87, p.36), [89/343/EEC](#) (OJ No. L142, 25.5.89, p.16) and [93/39/EEC](#) (OJ No. L214, 24.8.93, p.22).

(9) OJ No. L147, 9.6.75, p.1. The Directive was amended by Directives [89/341/EEC](#) (OJ No. L142, 25.5.89, p.11), [91/507/EEC](#) (OJ No. L270, 26.9.91, p.32) and [93/39/EEC](#) (OJ No. L214, 24.8.93, p.22).

(10) OJ No. L147, 9.6.75, p.13. The Directive was amended by Directives [83/570/EEC](#) (OJ No. L332, 28.11.83, p.1), [89/341/EEC](#) (OJ No. L142, 25.5.89, p.11) and [93/39/EEC](#) (OJ No. L214, 24.8.1993, p.22); see also Directives [89/342/EEC](#) (OJ No. L142, 25.5.89, p.14), [89/343/EEC](#) (OJ No. L142, 25.5.89, p.16) and [89/381/EEC](#) (OJ No. L181, 28.6.89, p.44), which extend the provisions of Directives [65/65/EEC](#) and [75/319/EEC](#) to vaccines, toxins or serums and allergens, radiopharmaceuticals and products derived from human blood or human plasma.

(11) OJ No. L142, 25.5.89, p.14.

(12) OJ No. L142, 25.5.89, p.16.

(13) OJ No. L181, 28.6.89, p.44.

(14) OJ No. L113, 30.4.92, p.5.

(15) OJ No. L113, 30.4.92, p.8.

(16) OJ No. L297, 13.10.92, p.8.

(17) OJ No. L214, 24.8.93, p.1.

(18) S.I. [1971/1450](#). The relevant amending instruments are S.I. [1972/1200](#) and [1989/1184](#) and [2323](#).

- (b) the process to which the plant or plants are subjected in producing the product consists only of drying, crushing or comminuting, and the product is, or is to be, sold or supplied only as provided by section 12(2) of the Act.
- (4) Except where the contrary intention appears—
  - (a) any reference in these Regulations to a marketing authorization includes a reference both to a United Kingdom marketing authorization (including a product licence having effect as such an authorization) and to a Community marketing authorization;
  - (b) any reference in these Regulations to the variation of a marketing authorization includes a reference to a change in the requirements for labels or package leaflets; and
  - (c) any reference in these Regulations to an application for the grant or renewal of a marketing authorization is a reference to an application made after the coming into force of these Regulations.
- (5) Expressions used in these Regulations which are also used in any of the relevant Community provisions shall, except where the contrary intention appears, and except in the case of ‘clinical trial’, have the same meaning as they have there, and related expressions shall be construed accordingly.
- (6) Subject to paragraph (5), section 11 of the Interpretation Act 1978(19) shall apply for the interpretation of these Regulations as if they were made in the exercise of a power conferred by the Act.
- (7) In these Regulations—
  - (a) any reference to a numbered regulation or to a numbered Schedule is a reference to the regulation or Schedule to these Regulations bearing that number; and
  - (b) any reference in a regulation or Schedule to a numbered paragraph is a reference to the paragraph of that regulation or Schedule bearing that number.

### **Responsibility for Member States' functions under the Regulations and Directives**

2.—(1) In so far as they relate to relevant 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.

### **Marketing authorizations for relevant medicinal products**

3.—(1) Except in accordance with any exception or exemption set out in the relevant Community provisions and subject to paragraphs 1 and 3 of Schedule 1—

- (a) no relevant medicinal product shall be placed on the market; and
- (b) no such product shall be distributed by way of wholesale dealing,

unless a marketing authorization in respect of that product has been granted in accordance with the relevant Community provisions by the licensing authority or the European Commission, 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.

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(19) 1978, c. 30.

#### **Applications for the grant, renewal or variation of a United Kingdom marketing authorization**

4.—(1) Every application for the grant, renewal or variation of a United Kingdom marketing authorization for a relevant medicinal product shall be made in accordance with the relevant Community provisions, subject to any provision of Community law affecting parallel imports, and the applicant shall comply with so much of the relevant Community provisions as impose obligations on applicants 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) In the case of an application for the grant of a marketing authorization, twenty-six copies, or such lesser number as the licensing authority may direct, of each 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, also one copy of the application or the accompanying material, as the case may be, in the original language.

(4) In the case of an application for the renewal of a marketing authorization, three copies of each application and of any accompanying material shall be supplied to the licensing authority, but in all other respects the applicant shall comply with the provisions of paragraph (3).

(5) An application for the grant of a marketing authorization shall include a statement indicating

- (a) whether the relevant medicinal product is one that should be available—
  - (i) only on prescription;
  - (ii) only from a pharmacy; or
  - (iii) on general sale; and
- (b) what, if any, provisions of the authorization 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).

(6) For the purposes of point 8(a)(iii) of the second paragraph of Article 4 of the 1965 Directive, the period of 10 years there mentioned (period during which essentially similar products must have been on the market) shall apply to all relevant medicinal products.

(7) An applicant shall not be entitled by virtue of point 8(a) of the second paragraph of Article 4 of the 1965 Directive to omit to provide any particulars or results if proper consideration of the application without them could not be carried out without prejudicing any rights which arise under any law relating to the protection of industrial and commercial property and which are enforceable in the United Kingdom.

(8) The applicant for the grant or renewal of a United Kingdom marketing authorization must be established in the Community.

(9) An application for the renewal of a marketing authorization shall be made not later than 3 months before the date on which the existing authorization expires.

#### **Consideration, and grant or refusal, of an application for, or for renewal or variation of, a United Kingdom marketing authorization.**

5.—(1) The licensing authority shall consider every application for the grant, renewal or variation by them of a marketing authorization in accordance with the relevant Community provisions, and shall grant, renew or vary, or refuse to grant, renew or vary the authorization in accordance with those provisions.

(2) The licensing authority shall publish in the Gazette<sup>(20)</sup> notice of every authorization granted by them.

(3) 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 marketing authorization.

(4) A marketing authorization shall, unless previously renewed or revoked, be valid for the period (not exceeding five years) specified in it beginning with the date on which it is granted, but where an application for the renewal of such an authorization is made in accordance with Article 10 of the 1965 Directive the marketing authorization shall remain in force pending the decision of the licensing authority on that application.

### **Revocation, suspension or variation of a United Kingdom marketing authorization or the suspension of the use or marketing of medicinal products.**

6.—(1) The licensing authority may and, where appropriate shall, subject to and in accordance with the relevant Community provisions, revoke, suspend or vary a marketing authorization for a relevant 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 marketing authorization for a relevant 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 authorization 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 authorization 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 or the provisions of Council Regulation (EEC) No. 2309/93, the licensing authority or the European Commission revoke or suspend a marketing authorization, 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 authorization, 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 marketing authorization 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 (otherwise than on the application of the holder) or suspension of a

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<sup>(20)</sup> See The Medicines Act 1968, section 132(1) for a definition of “the Gazette”.

marketing authorization, and for notifying the holder of that authorization in accordance with the preceding provisions of this regulation.

(8) The licensing authority shall publish in the Gazette notice of every decision by them to revoke an authorization.

### **Obligations of holders of marketing authorizations, and offences by holders of marketing authorizations and other persons**

7.—(1) Every holder of a United Kingdom marketing authorization for a relevant medicinal product shall comply with all obligations which relate to him by virtue of the relevant Community provisions (apart from Regulation (EEC) No. 2309/93) including, in particular, obligations relating to providing or updating information, to making changes, to applying to vary the authorization, to pharmacovigilance, and to labels and package leaflets.

(2) The holder of a marketing authorization 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 authorization 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 marketing authorization shall keep such documents as will facilitate the withdrawal or recall from sale or supply of any relevant medical product to which the authorization relates.

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

(5) 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.

(6) The holder of a marketing authorization granted or renewed after the coming into force of these Regulations must be established in the Community.

### **Control of retail sale of supply of relevant medicinal products**

8.—(1) Paragraphs (2) or (3) applies where a Community marketing authorization for a relevant medicinal product is subject to any condition or restriction which attaches to the authorization under Article 9.3(b) of Council Regulation (EEC) No. 2309/93.

(2) If the condition or restriction is to the effect that the product is to be sold or supplied only in accordance with a prescription given by a person who, in relation to the product, is an appropriate practitioner for the purposes of section 58 of the Act, the appropriate Ministers shall, subject to Article 3.4 of Council Directive 92/26/EEC (power to waive the application of the other provisions of that Article), give effect to the condition or restriction—

- (a) by exercising their powers under section 58 or 60 of the Act; or
- (b) where it appears to them that such an exercise would not be immediately practicable, by means of a written direction addressed to the holder of the authorization.

(3) If the condition or restriction is not to that effect, the appropriate Ministers shall give effect to it—

- (a) by the exercise of any other statutory power available to them for that purpose; or

(b) if there is no such power, by means of a written direction addressed to the holder of the authorization.

(4) Except as provided by paragraph (2), the appropriate Ministers shall not exercise their powers under section 58(1) or, subject to paragraph (5), section 60 of the Act in relation to any relevant medicinal product for which a Community marketing authorization has been granted.

(5) Paragraph (4) does not prevent the appropriate Ministers from exercising their powers under section 60 of the Act for the purposes mentioned in subsection (2) of that section.

### **Consequential and other amendments of the Act and the Medicines Act 1971**

**9.—(1)** —Sections 3 and 4 of the Act shall have effect as if any reference to the Act included a reference to these Regulations.

(2) Section 7 of the Act (dealing with medicinal products and product licences) shall not apply in relation to relevant medicinal products.

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

(4) Section 58A of the Act (requirement to specify certain products for human use as prescription-only products) shall have effect as if in subsection (1)—

- (a) the reference to section 58(1) of the Act included a reference to section 60(1) of the Act;
- (b) the reference to a product licence included a reference to a marketing authorization;
- (c) the reference to the descriptions or classes specified for the purposes of section 58 of the Act included a reference to the descriptions or classes specified in regulations under section 60 of the Act.

(5) Section 59 of the Act (special provisions in relation to new medicinal products) shall have effect as if—

- (a) any reference to a product licence granted under Part II of the Act included a reference to a marketing authorization granted under these Regulations; and
- (b) any reference to a product licence included a reference to such an authorization.

(6) 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 marketing authorization.

(7) Section 92 of the Act (scope of Part VI) shall have effect as if—

- (a) any reference in subsection (4) to a licence under Part II of the Act included a reference to a marketing authorization; and
- (b) the reference in that subsection to being engaged, in relation to medicinal products of the description in question, in any such activities as are referred to in that subsection included a reference to being engaged in putting medicinal products of that description on the market.

(8) Section 103 of the Act (construction of references to specified publications) shall have effect as if any reference in subsection (2) to a licence granted under the Act included a reference to a marketing authorization.

(9) The following provisions of the Act, namely—

- (a) the provisions amended by paragraphs (3) to (8); and
- (b) the other provisions of Parts III, VI and VII of the Act,

shall have effect as if all relevant medicinal products were medicinal products for the purposes of the Act (whether or not they would otherwise be so).

(10) In relation to any medicinal product to which section 58A of the Act applies by virtue of paragraph (4) and in respect of which a Community marketing authorization has been granted—

- (a) that section shall have effect as if subsections (3) and (4) were omitted;
- (b) section 58 of the Act (medicinal products on prescription only) shall have effect as if subsection (6) were omitted;
- (c) section 60 of the Act (restricted sale, supply and administration of certain medicinal products) shall have effect as if subsection (7) were omitted;
- (d) each of those sections shall have effect subject to the provisions of paragraph (4) of regulation 8 above; and
- (e) section 129 of the Act (orders and regulations) shall have effect as if subsection (6) were omitted.

(11) The provisions of the Trade Description Act 1968<sup>(21)</sup> shall apply to the application of a trade description to goods subject to a marketing authorization 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.

(12) Section 1 of the Medicines Act 1971<sup>(22)</sup> (fees payable for purposes of Part II of the Act) shall have effect as if—

- (a) in subsection (1), 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 marketing authorization or for the variation or renewal of such an authorization; and
- (b) in subsection (2)(b), any reference to a licence under Part II of the Act included a reference to a marketing authorization under these Regulations.

(13) Section 19 of the Consumer Protection Act 1987<sup>(23)</sup> (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 relevant medicinal product in respect of which a United Kingdom marketing authorisation under these Regulations or a Community marketing authorisation is for the time being in force.

(14) Section 1 of the Food Safety Act 1990<sup>(24)</sup> (meaning of “food” and other basic expressions) shall have effect as if in paragraph (d)(i) of subsection (2), the reference to medicinal products within the meaning of the Medicines Act 1968 in respect of which product licences within the meaning of that Act are for the time being in force, included a reference to relevant medicinal products in respect of which United Kingdom marketing authorizations under these Regulations or Community marketing authorizations are for the time being in force.

### **Application of enforcement provisions of the Act**

**10.**—(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

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<sup>(21)</sup> 1968 c. 29; section 2(5) was amended by the Medicines Act 1968, Schedule 5, paragraph 16.

<sup>(22)</sup> 1971 c. 69.

<sup>(23)</sup> 1987 c. 43.

<sup>(24)</sup> 1990 c. 16.

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

**Other Schedules to have effect**

**11.** The following Schedules shall have effect, namely Schedule 5 (labels), Schedule 6 (transitional provisions) and Schedule 7 (consequential amendments to regulations).

Signed by authority of the Secretary of State for Health

8th December 1994

*Tom Sackville*  
Parliamentary Under Secretary of State,  
Department of Health

## SCHEDULE 1

Regulation 3(2)

## EXEMPTIONS AND EXCEPTIONS FROM THE PROVISIONS OF REGULATION 3

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

2. The conditions mentioned in paragraph 1 are that—

- (a) the relevant medicinal product is supplied to a doctor or dentist or for use in a registered pharmacy, a hospital or a health centre under the supervision of a pharmacist, in accordance with paragraph 1;
- (b) no advertisement or representation relating to the relevant 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 sale or supply is in response to a bona fide unsolicited order;
- (c) the manufacture or assembly of the relevant 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 or dentist 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) the relevant medicinal product is manufactured, assembled or imported by the holder of an authorization referred to in Article 16 of Council Directive [75/319/EEC](#) which relates specifically to the manufacture, assembly or import of relevant medicinal products to which paragraph 1 applies; and
- (f) the relevant medicinal product is distributed by way of wholesale dealing by the holder of a wholesale dealer's licence.

3.—(1) Subject to the following sub-paragraphs, regulation 3(1) shall not apply to anything done

- (a) by a doctor or dentist which relates to a relevant medicinal product specially prepared by him, or to his order, for administration to one or more patients of his or, 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
- (b) 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 relevant medicinal products with a view to dispensing them in accordance with paragraph 1.

(2) The exemption conferred by sub-paragraph (1) shall not apply to procuring the manufacture of relevant 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 relevant medicinal products to which paragraph 1 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 relevant medicinal products in excess of a total of 5 litres of fluid and 2.5 kilograms of solids of all relevant medicinal products to which that sub-paragraph relates.

4.—(1) Regulation 3(1) shall not apply to the placing on the market by way of supplying of any relevant medicinal product to which this paragraph relates if the conditions of sub-paragraph (3) are satisfied.

(2) The relevant medicinal products to which this paragraph relates are relevant medicinal products which are for use by being administered to one or more human beings and which may be lawfully sold by retail or supplied in circumstances corresponding to retail sale, otherwise than in accordance with a prescription by a doctor or dentist.

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

- (a) that the relevant 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 relevant 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 relevant 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 relevant 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 sale or supply is in response to a bona fide unsolicited order;
- (e) that the relevant medicinal product is prepared by or under the supervision of a pharmacist; and
- (f) that the relevant medicinal product is manufactured by the holder of a manufacturer's licence which relates specifically to the manufacture of relevant medicinal products to which paragraph 1 applies.

5.—(1) Regulations 3(1) shall not apply to a radiopharmaceutical for human use<sup>(25)</sup> —

- (a) which is prepared at the time at which it is intended to be administered; and
- (b) which is prepared, in accordance with the manufacturer's instructions and by the person by whom it is to be administered, exclusively from a kit, generator or precursor (or from more than one of these) in respect of which a marketing authorization is in force; and
- (c) the administration of which is not or will not be a contravention of regulation 2 of the Medicines (Administration of Radioactive Substances) Regulations 1978<sup>(26)</sup>.

(2) In this paragraph—

“generator” means any system incorporating a fixed parent radionuclide from which is produced a daughter radionuclide which is to be removed by elution or by any other method and is to be used in a radiopharmaceutical;

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<sup>(25)</sup> See article 2 of Council Directive 89/343/EEC.

<sup>(26)</sup> S.I. 1978/1006.

“kit” means any preparation to be reconstituted or combined with radionuclides in a final radiopharmaceutical, usually prior to its administration;

“precursor” means a radionuclide produced for the radio-labelling of another substance prior to its administration, other than a radionuclide which is incorporated in or produced from a generator or is included in a radiopharmaceutical;

“radiopharmaceutical” means any relevant medicinal product which when ready for use contains one or more radionuclides included for a medicinal purpose.

6. Any person who sells or supplies a relevant medicinal product in accordance with any of paragraphs 1 to 4 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 5(3) and 6(7)

### PROCEDURAL PROVISIONS RELATING TO THE GRANT, REVOCATION AND SUSPENSION OF UNITED KINGDOM MARKETING AUTHORIZATIONS

#### **Interpretation**

1. In this Schedule—
- “appropriate committee” has the meaning assigned to it by section 4(6) of the Act;
- “authorization” means a United Kingdom marketing authorization; and
- “the time allowed” means the period of twenty-eight days or such extended period as the licensing authority may in any particular case allow.

#### *Scope and application of the procedural provisions*

- 2.—(1) Subject to paragraphs 3 and 4 below, this Schedule applies to any application for the grant or renewal of a marketing authorization for a relevant medicinal product where, throughout the period beginning with the date on which the application is made and ending with the date on which the licensing authority give a decision on the application, either—
- (a) there is no other marketing authorization in force in respect of the product anywhere in the Community; or
  - (b) any day in that period falls within the period beginning with 1st January 1995, and ending with 31st December 1997.

(2) Subject to paragraphs 3 and 4 below, this Schedule also applies to every proposal to revoke, vary or suspend an authorization for a relevant medicinal product where there is no such other authorization in force at the time of the proposal.

3. This Schedule shall cease to apply if at any time the matter is, by virtue of any relevant Community provision, referred to the Committee for Proprietary Medicinal Products for the application of the procedure laid down in Article 13 of Council Directive [75/319/EEC](#).

4. This Schedule does not apply—

- (a) if the licensing authority make a decision in relation to the application in accordance with Article 7.2 of the 1965 Directive (suspension of detailed examination of an application under active examination in another Member State); or
- (b) the application or proposal relates to the renewal or variation of a marketing authorization which has been granted in accordance with the provisions of Chapter III of Council Directive [75/319 EEC](#) or which has been granted by Member States in accordance with Article 4 of Council Directive [87/22/EEC](#) before 1st January 1995; or
- (c) to the variation of an authorization on the application of holder.

*Requirement to consult the appropriate committee or the Medicines Commission*

5. The licensing authority shall not, at any time while this Schedule applies, refuse to grant or renew the authorization applied for, or revoke, vary (other than on the application of the holder) or (subject to paragraph 13 below) suspend the relevant authorization on grounds other than those relating to the accuracy or completeness of an application, except after consultation with the appropriate committee or, if for the time being there is no such committee, the Medicines Commission.

*Provisional opinion against authorization*

6.—(1) Where the appropriate committee or the Medicines Commission are consulted under paragraph 5 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 authorization; 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 authorization ought to be revoked, varied or suspended,

the committee or Medicines Commission shall notify the applicant or holder accordingly.

(2) A person who has been notified in accordance with sub-paragraph (1) above may within the time allowed after the giving of the notification give notice of his wish to make written or oral representations to the appropriate committee or the Medicines Commission, as the case may be, and the committee or Medicines Commission, having given him an opportunity to make written or oral representations, shall take into account such representations as are made.

(3) The appropriate committee or the Medicines Commission shall report their findings and advice to the licensing authority together with the reasons for their advice and the licensing authority shall take the report into account in deciding whether to grant the authorization, or to continue with the proposal to refuse to renew or to revoke, vary or suspend it.

### *Licensing Authority's decision*

7.—(1) In the case of an application for the grant of an authorization the licensing authority shall then (subject to the following provisions of this Schedule) either grant or refuse the application and may grant it with provisions otherwise than in accordance with the application.

(2) In the case of an application of the renewal of an authorization the licensing authority shall either renew the authorization (whether or not in accordance with the application) or decide that it is still minded to refuse it.

(3) In the case of a proposal to revoke, suspend or vary an authorization the licensing authority shall decide whether or not to proceed further with the proposal.

(4) The licensing authority shall give notice to the applicant or holder of the advice given to it by the appropriate committee or the Medicines Commission, of the reasons for that advice, and of its decision made in accordance with sub-paragraphs (1), (2) or (3) above.

### **Confirmation or alteration of the decision after taking into account the advice of the Medicines Commission**

8.—(1) If a person is dissatisfied with the decision as notified to him under paragraph 7, and he has not made representations to the Medicines Commission under paragraph 6, he may give notice to the licensing authority of his wish to make written or oral representations to the Medicines Commission.

(2) On receipt of a notice under sub-paragraph (1) above the licensing authority shall arrange for the person who gave it to be heard by the Medicines Commission or, as the case may be, for his written representations to be considered by them.

(3) After considering the representations (oral or written) the Medicines Commission shall report their findings and advice, and the reasons for their advice, to the licensing authority who shall take it into account in deciding whether to confirm or alter its decision under paragraph 7.

(4) The licensing authority shall give notice to the applicant or holder of the Medicines Commission's advice and of the reasons for it, and of the confirmation or alteration of its decision under paragraph 7.

### *Person appointed to hear representations*

9. If the licensing authority—

- (a) determine an application in a way which differs from the advice of the Medicines Commission under paragraph 6, or propose to refuse to renew or propose to revoke, vary or suspend a marketing authorization against such advice, or propose not to alter their decision or propose to continue with their proposal following the advice of the Medicines Commission under paragraph 8; or
- (b) where there has been no hearing before, and no representations have been made or referred to, the Medicines Commission, determine an application, or propose to refuse to renew or propose to revoke, vary or suspend a marketing authorization, in a way which differs from the advice of the appropriate committee under paragraph 6; or
- (c) in the absence of any such advice as is mentioned in either of the preceding sub-paragraphs, determine an application, or propose to refuse to renew or to revoke, vary or suspend a marketing authorization, in a way which differs from the advice given by the appropriate committee or the Medicines Commission; or
- (d) propose, on grounds not relating to safety, quality or efficacy—
  - (i) not to grant or renew an authorization;
  - (ii) to grant or renew an authorization otherwise than in accordance with the application;
 or

(iii) to revoke, vary or suspend an authorization,

the licensing authority (in any case where a decision on the application has not already been made, before determining the application) shall notify the applicant or holder accordingly.

**10.** Any notification given under paragraph 9—

- (a) in a case falling within sub-paragraph (a), (b) or (c) of that paragraph, shall state the advice of the Medicines Commission or of the appropriate committee and the reasons stated by the Medicines Commission or the committee for giving that advice;
- (b) in a case falling within sub-paragraph (d) of that paragraph (whether it also falls within any of the other sub-paragraphs of that paragraph or not), shall include a statement of the proposals of the licensing authority and of the reasons for them.

*Right to be heard by a person appointed or to make further representations*

**11.** A person to whom notification has been given under paragraph 9 may, within the time allowed after the notification was given, give notice of his wish to appear before and be heard by a person appointed for the purpose by the licensing authority, or of making representations in writing to the licensing authority with respect to the decision or proposal referred to in the notification.

**12.—(1)** Where the applicant or holder gives notice under paragraph 11 of his wish to appear before and be heard by a person appointed for the purpose by the licensing authority, the licensing authority shall make that appointment and—

- (a) the person so appointed shall not, except with the consent of the applicant or holder, be an officer or servant of any of the Ministers specified in paragraphs (a) and (b) of section 1(1) of the Act;
- (b) if the applicant or holder so requests, the hearing shall be in public; and
- (c) if the applicant or holder so requests, the licensing authority shall furnish to him a copy of the report of the person so appointed.

(2) The licensing authority shall take into account the report of the person appointed and decide whether to renew the authorization, revoke, vary or suspend the authorization or confirm or alter its decision, as the case may be.

*Cases where suspension is to have immediate effect*

**13.** Paragraph 5 shall not apply to the suspension of an authorization (whether or not it applies to any existing proposal to suspend or revoke the authorization) where it appears to the licensing authority that, in the interests of safety, it is necessary to suspend the authorization with immediate effect for a period not exceeding three months, but where the licensing authority, by virtue of this paragraph, so suspends an authorization it shall report the suspension forthwith to the appropriate committee or, if for the time being there is no such committee, the Medicines Commission.

**14.** If after suspending an authorization with immediate effect by virtue of paragraph 13, it appears to the licensing authority that, or the appropriate committee or the Medicines Commission advise that, the authorization ought to be further suspended or revoked the licensing authority shall proceed in accordance with the applicable provisions of this Schedule (including paragraph 13).

## SCHEDULE 3

Regulation 7 (4)

## OFFENCES, PENALTIES ETC.

*Offences*

1. Any person who, in breach of the relevant Community provisions or of these Regulations, places a relevant medicinal product on the market without holding a Community or United Kingdom marketing authorization in respect of that product, or otherwise than in accordance with the terms of such an authorization, 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 relevant medicinal product, or who has in his possession a relevant 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 marketing authorizations, any holder of a marketing authorization for a relevant medicinal product who contravenes any condition of the authorization shall be guilty of an offence.

4. Where the use, supply or marketing of a relevant medicinal product is suspended in accordance with regulation 6 or Council Regulation (EEC) No. 2309/93, 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.

5. Any person who is or, immediately before its revocation or suspension, was the holder of a marketing authorization who fails to comply with a notice given to him under regulation 6(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.

6. Any holder of a marketing authorization who fails promptly to—

- (a) update information concerning the product or any connected matter as required by Article 4 of the 1965 Directive or Article 6 of Council Regulation (EEC) No. 2309/93; or
- (b) 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 9a of the 1965 Directive or Article 15.1 of Council Regulation (EEC) No. 2309/93; or
- (c) introduce any changes or make any amendments that may be required in accordance with those Articles; or
- (d) provide information to the EMEA, the Commission or the licensing authority as required by Article 15.2 of Council Regulation (EEC) No. 2309/93; or
- (e) submit any application to the licensing authority or the Community to make any changes or variation as required by Article 9a of the 1965 Directive or Article 15.3 of Council Regulation (EEC) No. 2309/93,

shall be guilty of an offence.

7. Any person responsible for placing on the market a relevant medicinal product authorized by the Community or by the licensing authority who, at any time, does not have at his disposal an appropriately qualified person responsible for pharmacovigilance as required by Chapter 3 of Title II of Council Regulation (EEC) No. 2309/93 or Chapter Va of Council Directive 75/319/EEC shall be guilty of an offence.

**8.** Any person responsible for placing a relevant 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 Chapter 3 of Title II of Council Regulation (EEC) No. 2309/93 or Chapter Va of Council Directive 75/319/EEC, shall be guilty of an offence.

**9.** Any person responsible for placing a relevant medicinal product on the market who fails to make or maintain a detailed record of any suspected adverse reaction as required by Chapter 3 of Title II of Council Regulation (EEC) No. 2309/93, or Chapter Va of Council Directive 75/319/EEC shall be guilty of an offence.

**10.** Any person who, while employed or engaged as an appropriately qualified person responsible for pharmacovigilance for the purposes of Chapter 3 of Title II of Council Regulation (EEC) No. 2309/93, or Chapter Va of Council Directive 75/319/EEC 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 relevant medicinal product is answered fully and promptly,

as required by any provision of any such Chapter, shall be guilty of an offence.

**11.** Any holder of a marketing authorization who sells or supplies or procures the sale or supply of a relevant medicinal product to which the authorization 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 Council Directive 92/27/EEC or of Schedule 5 to these Regulations, shall be guilty of an offence.

**12.** Where, in relation to a relevant 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 Council Directive 92/27/EEC or Schedule 5, any person, other than the holder of the marketing authorization 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.

**13.** 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. Penalties

#### *Penalties*

**14.** 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

**15.**—(1) Where an offence is committed under any of paragraphs 8, 9 or 10 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.

**16.** Where the holder of a marketing authorization 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 authorization, it shall be a defence for him to prove—

- (a) that he had communicated the provisions relating to the authorization 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 has not been complied with.

## SCHEDULE 4

Regulation 10(2)(a)

### MODIFICATIONS OF ENFORCEMENT PROVISIONS OF THE ACT

- 1.** In section 107 of the Act (validity of decisions and proceedings relating thereto)—
  - (a) in subsection (1), the reference to Part II of the Act shall include a reference to these Regulations and the reference to a licence shall include a reference to a marketing authorization;
  - (b) in subsections (2)(a) and (3)(b), any reference to the Act shall include a reference to these Regulations; and
  - (c) in subsection (4), any reference to a licence shall include a reference to a marketing authorization.
- 2.** In section 108 of the Act (enforcement in England and Wales)—
  - (a) in subsection (1), the reference to the Act shall include a reference to these Regulations and the relevant Community provisions; and
  - (b) in subsection (2)(c), the reference to sections 93 and 94 of the Act shall include a reference to these Regulations and those provisions.
- 3.** In section 109 of the Act (enforcement in Scotland), in subsection (1), the reference to the Act shall include a reference to these Regulations and the relevant Community provisions.
- 4.** In section 110 of the Act (enforcement in Northern Ireland), in subsection (1), the reference to the Act shall include a reference to these Regulations and the relevant Community provisions.
- 5.** In section 111 of the Act (rights of entry)—
  - (a) in subsection (1), the first reference to the Act shall include a reference to these Regulations and the relevant Community provisions;
  - (b) in subsection (2), the first reference to the Act shall include a reference to these Regulations and Council Regulation (EEC) No. 2309/93; and
  - (c) in subsection (3), any reference to a licence under Part II of the Act shall include a reference to a marketing authorization.

6. In section 112 of the Act (power to inspect, take samples and seize goods and documents)—
  - (a) in subsection (1), the first reference to the Act shall include a reference to these Regulations and Council Regulation (EEC) No. 2309/93;
  - (b) in subsection (4), any reference to the Act shall include a reference to these Regulations;
  - (c) in subsections (5) and (9), any reference to the Act shall include a reference to these Regulations and Council Regulation (EEC) No. 2309/93; and
  - (d) in subsection (7), any reference to a licence under Part II of the Act shall include a reference to a marketing authorization.
7. In section 118 of the Act (restrictions on disclosure of information), in subsection (1), the second reference to the Act shall include a reference to these Regulations and Council Regulation (EEC) No. 2309/93.
8. In section 119 of the Act (protection for officers of enforcement authorities), any reference to the Act shall include a reference to these Regulations and Council Regulations (EEC) No. 2309/93.
9. In section 121 of the Act (contravention due to default of other person)—
  - (a) in subsections (1) and (2), any reference to the Act shall include a reference to these Regulations; and
  - (b) in subsection (4), the reference to sections 63 to 65, 85 to 90 and 93 to 96 of the Act shall include a reference to paragraphs 11 and 12 of Schedule 3 to these Regulations.
10. In section 122 of the Act (warranty as a defence)—
  - (a) in subsection (1), the reference to the Act shall include a reference to these Regulations; and
  - (b) in subsection (2), the reference to sections (b) 63(b), sections 64 and 65, sections 85 to 88 and section 90 of the Act shall include a reference to paragraphs 11 and 12 of Schedule 3 to these Regulations.
11. In section 124 of the Act (offences by bodies corporate), in subsection (1), the reference to the Act shall include a reference to these Regulations.
12. In section 125 of the Act (prosecutions)—
  - (a) in subsections (1) to (3), any reference to the Act shall include a reference to these Regulations; and
  - (b) in subsections (4) and (6), the second reference to the Act shall include a reference to these Regulations.
13. In section 127 of the Act (service of documents), the reference to the Act shall include a reference to these Regulations and Council Regulation (EEC) No. 2309/93.
14. In Schedule 3 to the Act (sampling), in paragraph 1(1), the first reference to the Act shall include a reference to these Regulations and Council Regulation (EEC) No. 2309/93.

## SCHEDULE 5

Regulation 11

### LABELS

#### *Interpretation*

1. In this Schedule, unless the context otherwise requires—

“dispensed relevant medicinal product” means a relevant medicinal product prepared or dispensed in accordance with a prescription given by a practitioner;

“relevant medicinal product on a general sale list” means a relevant medicinal product of a description, or falling within a class, specified in an order under section 51 of the Act which is for the time being in force;

“requirements” includes restrictions;

“retail sale” has the same meaning as in section 131 of the Act; and

“supply in circumstances corresponding to retail sale” has the same meaning as in section 131 of the Act.

### *Introductory*

2. The requirements of this Schedule supplement those of Council Directive [92/27/EEC](#) relating to:

- (a) special warnings necessary for particular medicinal products;
- (b) the legal status for supply to the patient, in accordance with Council Directive [92/26/EEC](#);
- (c) identification and authenticity.

### *Dispensed relevant medicinal products*

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

- (a) the name of the person to whom the product is to be administered;
- (b) the name and address of the person who sells or supplies the product;
- (c) the date on which the product is dispensed;
- (d) where the relevant medicinal product has been prescribed by a practitioner, such of the following particulars as he may request—
  - (i) the name of the relevant medicinal product or its common name;
  - (ii) directions for use of the relevant medicinal product; and
  - (iii) precautions relating to the use of the relevant 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 relevant 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 relevant 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.

### *Delivery and storage*

4.—(1) Subject to the following provisions of this Schedule, where for the purposes of transport, delivery or storage a number of packages of relevant medicinal products all of the same description, not being relevant medicinal products to which paragraph 1 of Schedule 1 applies, are enclosed in a package, such package shall be labelled to show the following particulars—

- (a) any special requirements for the storage and handling of the product;
- (b) the expiry date of the product; and
- (c) the manufacturer's batch number.

(2) Sub-paragraph (1) does not apply to any package in the form of a packing case, crate or other covering used solely for the purposes of transport or delivery (but not storage) of containers and packages of relevant medicinal products each of which is labelled in accordance with the provisions of this Schedule.

### *Relevant medicinal products on a general sale list*

5.—(1) Subject to the following provisions of this Schedule, where a relevant medicinal product on a general sale list, not being a dispensed relevant medicinal product, is sold by retail, or supplied in circumstances corresponding to retail sale or by means of an automatic machine or is in the possession of any person for the purpose of such sale or supply, every container and every package immediately enclosing a container of such product, being a product described in any of the following sub-paragraphs, shall be labelled to show the words and particulars set out in such sub-paragraph or sub-paragraphs—

- (a) if the product contains aloxiprin, aspirin or paracetamol, the words “If symptoms persist consult your doctor” and, except where the product is for external use only, the recommended dosage;
- (b) if the product contains aloxiprin, the words “Contains an aspirin derivative”;
- (c) if the product contains aspirin, except where the product is for external use only or where the name of the product includes the word “aspirin” and appears on the container or package, the words “Contains aspirin”;
- (d) if the product contains paracetamol, except where the name of the product includes the word “paracetamol” and appears on the container or package, the words “Contains paracetamol”;
- (e) if the product contains paracetamol, the words “Do not exceed the stated dose”;

(2) Where a container or package is required by this paragraph to show—

- (a) words set out in more than one of sub-paragraphs (b), (c) and (d) of sub-paragraph (1), there may be substituted for those words other words showing that the product contains more than one of the substances aloxiprin, aspirin and paracetamol and naming the substances so contained, except that in the case of aloxiprin the words “aspirin derivative” shall appear and the word “aloxiprin” need not appear;
- (b) words set out in one or more of those sub-paragraphs, such words shall appear in a prominent position and shall be within a rectangle within which there shall be no other matter of any kind, except that where words set out in more than one of the said sub-paragraphs appear on the container or package then any of them may together be within a rectangle within which there shall be no other matter of any kind.

(3) Where a container or package is required to be labelled to show the words “Do not exceed the stated dose”, such words shall appear adjacent to either the directions for use, where such directions appear on the container or package, or the recommended dosage, where such recommendation appears on the container or package.

(4) Where a container or package is required to be labelled to show the words “Do not exceed the stated dose”, such words shall not be required to be shown if, by virtue of paragraph 6, the words set out in head (a) of sub-paragraph (2) of that paragraph are required to be, and are, shown.

(5) Without prejudice to the operation of sub-paragraph (1), where a relevant medicinal product, not being a dispensed medicinal product, is—

- (a) sold by retail; or
- (b) supplied in circumstances corresponding to retail sale; or
- (c) in the possession of a person for the purpose of such sale or supply; or
- (d) sold by way of wholesale dealing,

then, if the product is a product referred to in regulation 8 of the Medicines (Sale or Supply) (Miscellaneous Provisions) Regulations 1980<sup>(27)</sup> which is not presented for sale in the manner described in relation to that product in that regulation, every container and every package immediately enclosing a container of that relevant medicinal product shall be labelled to show the capital letter “P” within a rectangle within which there shall be no other matter of any kind.

*Relevant medicinal products not on a general sale list*

6.—(1) Subject to the following provisions of this Schedule, where a relevant 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—

- (a) shall be labelled in accordance with the provisions of paragraph 5 as if such provisions applied to such containers and packages as they apply to containers and packages of relevant medicinal products on a general sale list;
- (b) shall, if the product is described in any head of sub-paragraph (2), be labelled to show the words and particulars set out in that head, except that where words set out in more than one of heads (a), (b) and (c) of that sub-paragraph appear on the container or package then the word “Warning” need not appear more than once, and where the product is a dispensed relevant medicinal product then the words set out in those heads need not appear;
- (c) shall, unless any of the provisions of paragraph 7 apply to such container or package or the product is a dispensed relevant medicinal product, be labelled to show the capital letter “P” within a rectangle within which there shall be no other matter of any kind.

(2) The descriptions and words referred to in sub-paragraph (1) are—

- (a) if the product would be subject to restrictions imposed under section 58 of the Act but for an exemption from any such restrictions conferred by an order made under that section by reason of the proportion or level in such product of any substance, except where the product is for external use only or contains any of the substances described in head (c) of this sub-paragraph the words “Warning. Do not exceed the stated dose”;
- (b) if the product is for the treatment of asthma or other conditions associated with bronchial spasm or contains ephedrine or any of its salts, except where the product is for external use only, the words “Warning. Asthmatics should consult their doctor before using this product”;
- (c) if the product contains an antihistamine or any of its salts or molecular compounds, except where the product is for external use only or where the marketing authorization contains no warning relating to the sedating effect of the product in use, the words “Warning. May cause drowsiness. If affected do not drive or operate machinery. Avoid alcoholic drink”;

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(27) S.I. 1980/1923. The relevant amending instruments are S.I. 1982/28, 1990/1124 and 1994/2411.

- (d) if the product is embrocation, liniment, lotion, liquid antiseptic or other liquid preparation or gel and is for external use only, the words “For external use only”;
- (e) if the product contains hexachlorophane, either the words “Not to be used for babies” or a warning that the product is not to be administered, except on medical advice, to a child under two years.

(3) The requirement of sub-paragraph (1)(c) shall apply to every container and every package immediately enclosing a container of a relevant medicinal product which is sold by way of wholesale dealing and which is not a relevant medicinal product on a general sale list.

(4) Where a container or package is required by this paragraph to be labelled to show any of the words or particulars specified in heads (a) to (e) of sub-paragraph (2), such words or particulars shall be within a rectangle within which there shall be no other matter of any kind, except that where words or particulars set out in more than one head of that sub-paragraph appear on the container or package then any of them may be together within a rectangle within which there shall be no other matter of any kind.

#### *Prescription only relevant medicinal products*

7. Subject to the following provisions of this Schedule, every container and every package immediately enclosing a container of a relevant medicinal product which is subject to restrictions imposed under section 58(1) of the Act (relevant medicinal products on prescription only) shall, if the product is described in heads (d) or (e) of sub-paragraph (2) of paragraph 6, be labelled to show the words and particulars set out in that head and shall, except where the product is sold by retail or supplied in circumstances corresponding to retail sale or is the subject of an exemption, by virtue of the provisions of section 58(4)(a), from any of the restrictions imposed by section 58(2) of the Act, be labelled to show the letters “POM” in capital letters within a rectangle within which there shall be no other matter of any kind.

#### *Exemptions*

8. 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 relevant 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 relevant medicinal product labelled in accordance with the provisions of this Schedule is placed when such relevant medicinal product is sold by retail or supplied in circumstances corresponding to retail sale; or
- (c) any container or package immediately enclosing the container of a relevant medicinal product which is for export;
- (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 those provisions of paragraphs 5 to 7 which apply to such package;
  - (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 relevant medicinal product and such container is immediately enclosed in a package which is labelled in accordance with those provisions of paragraphs 5 to 7 which apply to such package;

- (iii) where the package immediately enclosing such a container as is described in head (ii) above is itself in the form of a bubble, blister or other sealed unit as is mentioned in that head and is part of a continuous series comprising a sheet or strip of like packages and is required to be labelled to show any of the words, particulars or letters referred to in paragraphs 5 to 7, such requirements shall be deemed to have been complied with if the said words, particulars or letters, as the case may be, are displayed at frequent intervals on the said sheet or strip of such packages.

## SCHEDULE 6

Regulation 11

### TRANSITIONAL PROVISIONS

**1.** If on 1st January 1995 there is in force in relation to a medicinal product for human use to which these Regulations apply a product licence granted under Part II of the Act, that product licence shall have effect from that date as if it were a marketing authorization granted under these Regulations.

**2.** Accordingly any right conferred or obligation imposed by these Regulations shall be conferred or imposed on the holder of such a product licence, except that the provisions of regulation 7(6) (which requires the holder of a marketing authorization to be established in the Community) and the provisions of Schedule 5 (labels) shall not apply.

**3.—(1)** Subject to sub-paragraph (2), any application for a product licence made before the date when these Regulations come into force but not then determined shall from that date be treated as an application for a marketing authorization, and the provisions of Schedule 2 shall apply accordingly.

(2) Where any act has been done in relation to an application to which sub-paragraph (1) applies before the date when these Regulations come into force, nothing in that sub-paragraph requires that act to be repeated.

**4.** The provisions of the Medicines (Labelling) Regulations 1976<sup>(28)</sup> and of the Medicines (Leaflets) Regulations 1977<sup>(29)</sup> (and subsequent regulations amending those Regulations) in so far as they relate to relevant medicinal products shall continue to have effect in relation to any relevant medicinal product in respect of which there is in force on the date these Regulations come into force a product licence under Part II of the Act, until the date when that licence is renewed.

**5.** Until 31st March 1995 the Medicines (Products for Human Use—Fees) Regulations 1991<sup>(30)</sup> shall have effect as if—

- (a) any reference to a product licence or to licences under Part II of the Act included a reference to a United Kingdom marketing authorization;
- (b) in regulation 2(1), the definition of “medicinal product” included a reference to a relevant medicinal product;
- (c) in regulation 7, the reference to an application under section 30 of the Act to vary a product licence included a reference to an application under regulation 4 above to vary a United Kingdom marketing authorization; and
- (d) in head 1(a)(i) in Column 1 of the Table in Part II of Schedule 1, paragraphs 2 and 2A of Part III of that Schedule and in the definition of “limited use drug” in paragraph 1 of Part I of Schedule 3, the references to paragraph 5 of Schedule 2 to the Applications

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<sup>(28)</sup> S.I. 1976/1726. The relevant amending instruments are S.I. 1977/996 and 2168, 1978/1140, 1981/1791, 1983/1729, 1985/1558 and 1992/3273.

<sup>(29)</sup> S.I. 1977/1055, amended by S.I. 1992/3274.

<sup>(30)</sup> S.I. 1991/1474. The relevant amending instruments are S.I. 1992/756 and 1994/691.

Regulations included references to section G of Part 4 of the Annex to Council Directive [75/318/EEC](#)**(31)**.

## SCHEDULE 7

Regulation 11

### CONSEQUENTIAL AMENDMENTS TO REGULATIONS

1. In the Medicines (Exemption from Licences) (Wholesale Dealing in Confectionery) Order 1975**(32)** after paragraph (2) of regulation 1 there shall be inserted the following paragraph—

“(2A) In this Order a reference to a medicinal product includes a reference to a relevant medicinal product within the meaning of the Medicines for Human Use (Marketing Authorizations Etc.) Regulations 1994, and a reference to a product licence includes a reference to a marketing authorization within the meaning of those Regulations.”.

2. In the Medicines (Child Safety) Regulations 1975**(33)** in sub-paragraph (d) of paragraph (3) of regulation 2, after the words “by virtue of the relevant product licence” there shall be inserted the words “or marketing authorization (within the meaning of the Medicines for Human Use (Marketing Authorizations Etc.) Regulations 1994)”.

3. In the Medicines (Labelling) Regulations 1976**(34)**—

- (a) for the heading to regulation 1 there shall be substituted the heading “Citation and scope”;
- (b) regulation 1 shall be re-numbered paragraph (1) of regulation 1; and
- (c) after that paragraph there shall be inserted the following paragraph—

“(2) Nothing in these Regulations applies to a medicinal product for human use to which the Medicines for Human Use (Marketing Authorizations Etc.) Regulations 1994 apply.”.

4. In the Medicines (Manufacturer’s Undertakings for Imported Products) Regulations 1977**(35)** for paragraph (1) of regulation 2 there shall be substituted the following paragraph—

“(1) In these Regulations, unless the context otherwise requires—

- (a) “medicinal product” includes a relevant medicinal product within the meaning of the Medicines for Human Use (Marketing Authorizations Etc.) Regulations 1994 and, where a product licence relates to any substance or article which is not a medicinal product, the substance or article to which the licence relates or is intended to relate;
- (b) “product licence” includes a marketing authorization within the meaning of the Medicines for Human Use (Marketing Authorizations Etc.) Regulations 1994; and
- (c) other expressions have the same meanings as in the Medicines Act 1968.”.

5. In the Medicines (Leaflets) Regulations 1977**(36)**

- (a) for the heading to regulation 1 there shall be substituted the heading “Citation, commencement and scope”;
- (b) regulation 1 shall be re-numbered paragraph (1) of regulation 1; and

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**(31)** The Annex to Council Directive [75/318/EEC](#) was replaced by Council Directive [91/507/EEC](#).

**(32)** S.I. [1975/762](#).

**(33)** S.I. [1975/2000](#). The relevant amending instruments are S.I. [1976/1643](#), [1987/877](#), and [1994/1402](#).

**(34)** S.I. [1976/1726](#). The relevant amending instruments are S.I. [1977/996](#), [1983/1729](#), [1988/1009](#) and [1992/3273](#).

**(35)** S.I. [1977/1038](#). The relevant amending instrument is S.I. [1992/2845](#).

**(36)** S.I. [1977/655](#).

(c) after that paragraph there shall be inserted the following paragraph—

“(2) Nothing in these Regulations applies to a medicinal product for human use to which the Medicines for Human Use (Marketing Authorizations Etc.) Regulations 1994 apply.”.

**6.** In the medicines (Fluted Bottles) Regulations 1978(**37**), in paragraph (g) of regulation 3, after the words “product licence,” there shall be inserted the words “a marketing authorization within the meaning of the Medicines for Human Use (Marketing Authorizations Etc.) Regulations 1994,”.

**7.** In the Importation of Animal Products and Poultry Products Order 1980(**38**), after the words “or the Marketing Authorisations for Veterinary Medicinal Products Regulations 1994” there shall be inserted the words “or the Medicines for Human Use (Marketing Authorizations Etc.) Regulations 1994”.

**8.** In the Medicines (Sale or Supply) (Miscellaneous Provisions) Regulations 1980(**39**), in sub-paragraph (a) of paragraph (1) of regulation 5, after the words “product licence” there shall be inserted the words “or the holder of a marketing authorization within the meaning of the Medicines for Human Use (Marketing Authorizations Etc.) Regulations 1994”.

**9.** In the Medicines (Pharmacy and General Sale) Exemption Order 1980(**40**)—

(a) in paragraph 11 of Column 1 of Schedule 1, after the words “Holders of product licences” there shall be inserted the words, “holders of marketing authorizations within the meaning of the Medicines for Human Use (Marketing Authorizations Etc.) Regulations 1994”; and

(b) in paragraph 11 of Column 2 of that Schedule, at the end there shall be added the words “or marketing authorizations”.

**10.** In the Health and Safety (Dangerous Pathogens) Regulations 1981(**41**), in regulation 2(1) in the definition of “listed pathogen”, after the words “marketing authorisation to which the Marketing Authorisations for Veterinary Medicinal Products Regulations 1984” there shall be inserted the words “or the Medicines for Human Use (Marketing Authorizations Etc.) Regulations 1994”.

**11.** In the Food Labelling Regulations 1984(**42**), in Column 2 of paragraph 7, at the end there shall be added the words “or a marketing authorization within the meaning of the Medicines for Human Use (Marketing Authorizations Etc.) Regulations 1994”.

**12.** In the Natural Mineral Waters Regulations 1985(**43**), in sub-paragraph (c) of paragraph (1) of regulation 3, at the end there shall be added the words “or a marketing authorization within the meaning of the Medicines for Human Use (Marketing Authorizations Etc.) Regulations 1994”.

**13.** In the Merchant Shipping (Medical Stores) Regulations 1986(**44**), in sub-paragraph (d) of paragraph (3) of regulation 6, after the words “product licence” there shall be inserted the words “or marketing authorization”.

**14.** In the Trade Descriptions (Places of Production) (Marking) Order 1988(**45**), in article 1(2) (d) after the words “Marketing Authorisations for Veterinary Medicinal Products Regulations 1994” there shall be inserted the words “or the Medicines for Human Use (Marketing Authorizations Etc.) Regulations 1994”.

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(37) S.I. 1978/40.

(38) S.I. 1980/14. The relevant amending instrument is S.I. 1994/

(39) S.I. 1980/1923. The relevant amending instruments are S.I. 1982/28, 1990/1124 and 1992/2938.

(40) S.I. 1980/1924. The relevant amending instruments are S.I. 1982/27, 1989/1852 and 1994/2409.

(41) S.I. 1981/1011.

(42) S.I. 1984/1305, to which there are amendments not relevant to these Regulations.

(43) S.I. 1985/71. The relevant amending instruments are S.I. 1991/1476 and 1992/2596.

(44) S.I. 1986/144.

(45) S.I. 1988/1771.

**15. In the Medicines (Exemption from Licences) (Wholesale Dealing) Order 1990(46)—**

- (a) in paragraph (2) of regulation 1, after the definition of “intermediate feed” there shall be inserted the following definition—

““marketing authorization” has the same meaning as in the Medicines for Human Use (Marketing Authorizations Etc.) Regulations 1994;”;

- (b) in the definition of “medicinal product” in that paragraph, after head (c) there shall be inserted—

“(d) relevant medicinal products within the meaning of the Medicines for Human Use (Marketing Authorizations Etc.) Regulations 1994;”;

- (c) in paragraph (1) of regulation 2—

- (i) in sub-paragraph (a), after the words “product licence” (in both places where they occur) there shall be inserted the words “or marketing authorization”; and  
(ii) in sub-paragraph (b), after the words “product licence” (in both places where they occur) there shall be inserted the words “or marketing authorization”.

**16. In the Children’s Homes Regulations 1991(47), in paragraph (1) of regulation 2, in the definition of “medicinal product”, after the words “Medicines Act 1968” there shall be inserted the words “or a marketing authorization under Council Regulation (EEC) No. 2309/93 or the Medicines for Human Use (Marketing Authorizations Etc.) Regulations 1994”.**

**17. In the Medicines (Applications for Grant of Product Licences-Products for Human Use) Regulations 1993(48), after paragraph (1) of regulation 1 there shall be inserted the following paragraph—**

“(1A) Nothing in these Regulations applies to a medicinal product for human use to which the Medicines for Human Use (Marketing Authorizations Etc.) Regulations 1994 apply.”.

**18. In the Specified Animal Pathogens Order 1993(49), in sub-paragraph (a) of paragraph (2) of regulation 5, after the words “the Medicines Act 1968” there shall be inserted the words “or a marketing authorization has been granted under Council Regulation (EEC) No. 2309/93 or the Medicines for Human Use (Marketing Authorizations Etc.) Regulations 1994”.**

**19. In the Drinking Water in Containers Regulations 1994(50), in paragraph (b) of regulation 3, after the words “product licence within the meaning of that Act” there shall be inserted the words “or a marketing authorization within the meaning of the Medicines for Human Use (Marketing Authorizations Etc.) Regulations 1994”.**

**20. In the Medicines (Advertising) Regulations 1994(51)—**

- (a) in paragraph (1) of regulation 2, after the definition of “essential information” there shall be inserted the following definition—

““marketing authorization” means a marketing authorization granted by the European Commission under Council Regulation (EEC) No. 2309/93 or by the licensing authority under the Medicines for Human Use (Marketing Authorizations Etc.) Regulations 1994 and includes a product licence granted by the licensing authority under Part II of the Act;”;

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(46) S.I. 1990/566.

(47) S.I. 1991/1506.

(48) S.I. 1993/2538.

(49) S.I. 1993/3250.

(50) S.I. 1994/743.

(51) S.I. 1994/1932.

- (b) in paragraph (1) of regulation 3, for the words “product licence” there shall be substituted the words “marketing authorization”; and
- (c) in regulation 4 for the words “product licence” there shall be substituted the words “marketing authorization”;
- (d) in sub-paragraph (1) of paragraph (1) of regulation 9, for the words “product licence” there shall be substituted the words “marketing authorization”;
- (e) in regulation 12, for the words “product licence” there shall be substituted the words “marketing authorization”; and
- (f) in Schedule 2—
  - (i) in paragraph 1, for the word “licence” there shall be substituted the word “authorization”;
  - (ii) in paragraph 2, for the words “product licence” there shall be substituted the words “marketing authorization”; and
  - (iii) in paragraph 5, for the word “licence” there shall be substituted the word “authorization”; and

**21.** In the General Product Safety Regulations 1994<sup>(52)</sup>, in regulation 11(c)(ii)(aa), after the words “the provisions of the 1968 Act” there shall be inserted the words “or which are the subject of a marketing authorization within the meaning of the Medicines for Human Use (Marketing Authorizations Etc.) Regulations 1994”.

(b) regulation 1 shall be re-numbered paragraph (1) of regulation 1; and

(c) after that paragraph there shall be inserted the following paragraph—

“(2) Nothing in these Regulations applies to a medicinal product for human use to which the Medicines for Human Use (Marketing Authorizations Etc.) Regulations 1994 apply.”.

**22.** In the Medicines (Restrictions on the Administration of Veterinary Medicinal Products) Regulations 1994(b), in regulation 3(1)(b), after the words “a medicinal product licensed” there shall be inserted the words “or authorized in accordance with the Medicines for Human Use (Marketing Authorizations Etc.) Regulations 1994”.

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## EXPLANATORY NOTE

*(This note is not part of the Regulations)*

These Regulations implement for the United Kingdom, and in so far as they are concerned with medicinal products for human use, the Council Directives mentioned in regulation 1(2) in the definition of “relevant Community provisions”. They also contain provisions supplementing the provisions of Council Regulation (EEC) No. 2309/93. Both the Directives and the Regulation are concerned with the marketing of medicinal products.

The Regulations provide that the functions of a member state or the competent authority of a member State under the relevant Community provisions are, except as otherwise provided, to be performed

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<sup>(52)</sup> S.I. 1994/2328.

in the United Kingdom by the licensing authority (ie the Ministers in the United Kingdom concerned with health and agriculture— *see* sections 1 and 6 of the Medicines Act 1968) (regulation 2). They also provide that no medicinal product for human use which is subject to the relevant Community provisions may be placed on the market in the United Kingdom or be dealt with by way of wholesale dealing unless there is in force in respect of it a marketing authorization granted either by the European Commission or by the licensing authority (regulation 3).

Regulations 4 to 7 and Schedules 2 and 3 provide for the manner of making applications for the grant, renewal or variation of a United Kingdom marketing authorization, the procedure for the consideration of such an application, the revocation and suspension of a marketing authorization and the suspension of the use or marketing of medicinal products and the obligations of applicants for and holders of marketing authorizations. In particular regulation 7(4) and Schedule 3 create certain offences in connection with those obligations.

Regulation 8 is about the control of retail sale or supply of relevant medicinal products. Regulation 9 makes consequential and other amendments to the Medicines Acts 1968 and 1971.

Schedule 1 makes certain exceptions and exemptions from the requirement to hold a marketing authorization. Schedule 4 contains provisions applying with modifications the provisions of the Medicines Act 1968 about enforcement. Schedule 5 contains provisions about the labelling of medicinal products, Schedule 6 contains transitional provisions and Schedule 7 makes consequential amendments to other regulations.

An assessment of the cost to business of complying with these Regulations has been made, copies of which have been placed in the libraries of both Houses of Parliament and further copies of which may be obtained from the Medicines Control Agency, Department of Health, Room 1207, Market Towers, 1 Nine Elms Lane, London SW8 5NQ.