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STATUTORY INSTRUMENTS

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**2012 No. 1916**

**The Human Medicines Regulations 2012**

**PART 13**

**Packaging and leaflets**

**CHAPTER 1**

*Requirements for packaging and package leaflets relating to medicinal products*

**Packaging requirements: general**

**257.**—(1) The information specified in Part 1 of Schedule 24 must appear—

- (a) on the outer packaging of a medicinal product; and
- (b) on the immediate packaging of the product, unless paragraph (2) or (3) applies to the packaging.

(2) This paragraph applies to immediate packaging if the packaging is in the form of a blister pack and is placed in outer packaging which complies with the requirements of Part 1 of Schedule 24.

(3) This paragraph applies to immediate packaging if the packaging is too small to display the information required by Part 1 of Schedule 24.

(4) The information specified in Part 2 of Schedule 24 must appear on immediate packaging to which paragraph (2) applies.

(5) The information specified in Part 3 of Schedule 24 must appear on immediate packaging to which paragraph (3) applies.

(6) Information included on the packaging of a product in accordance with this regulation, regulation 261 and Schedule 24 must be easily legible, comprehensible and indelible.

(7) Nothing in this regulation or Schedule 24 applies to a registrable homoeopathic medicinal product.

**Packaging requirements: specific provisions**

**258.**—(1) In addition to other information required by this Part, the information specified in Part 1 of Schedule 25 must appear on the outer packaging, or, if there is no outer packaging, on the immediate packaging of a medicinal product sold or supplied in accordance with a prescription given by a person who is an appropriate practitioner for the purposes of regulation 214(3) to (6), whether or not the medicinal product in question is a prescription only medicine.

(2) The requirements of paragraph 4 or 6 of Schedule 25, as the case may be, are satisfied in relation to a package containing a number of packages of medicinal products of the same description if the information specified in paragraph 4 or 6 of that Schedule is shown on one or more of those packages.

(3) The information specified in Part 2 of that Schedule must appear on a package which contains a number of packages of medicinal products of the same description, other than special medicinal products, for the purpose of transport, delivery or storage.

(4) But paragraph (3) does not apply to a packing case, crate or other covering used solely for the purposes of transport or delivery of packages of medicinal products, each of which is labelled in accordance with the other requirements of this Part.

(5) In addition to the other information required by this Part, the information specified in Parts 3 and 4 of Schedule 25 must appear on the outer packaging and the immediate packaging of products of the kind specified in those Parts of that Schedule.

(6) Nothing in this regulation or Schedule 25 requires information to appear on—

- (a) a package containing a medicinal product where part of the package is transparent or open, provided that the information required by this regulation and that Schedule is clearly visible through the transparent or open part of the package;
- (b) a paper bag or similar wrapping in which a package that contains a medicinal product and bears information in accordance with the requirements of this regulation and that Schedule is placed at the time of sale or supply;
- (c) a package enclosing a package of a medicinal product for export;
- (d) an ampoule or other container of not more than 10 millilitres' nominal capacity which is enclosed in a package on which information appears in accordance with the requirements of this regulation and that Schedule; or
- (e) a blister pack or similar packaging enclosed in a package on which information appears in accordance with the requirements of Parts 3 and 4 of Schedule 25.

(7) Nothing in this regulation or Schedule 25 applies to a medicinal product—

- (a) which is an anti-viral medicine in the form of a solution to be used for the treatment of a child under the age of one year;
- (b) on the container of which appears—
  - (i) the name of the person to whom the product is to be administered,
  - (ii) the date on which the product is sold or supplied, and
  - (iii) the necessary instructions for proper use; and
- (c) which is sold or supplied for the purpose of treating a disease which is—
  - (i) a serious risk to human health, or potentially a serious risk to human health, and
  - (ii) pandemic or imminently pandemic.

(8) Nothing in this regulation or Schedule 25 applies to a traditional herbal medicinal product or a registrable homoeopathic medicinal product.

### **Packaging requirements: information for blind and partially sighted patients**

**259.**—(1) The name of a medicinal product must also be expressed in Braille format on the outer packaging of the product (or, if there is no outer packaging, on the immediate packaging of the product).

(2) The holder of a marketing authorisation, Article 126a authorisation or traditional herbal registration for a medicinal product must ensure that the package leaflet is made available on request in formats suitable for blind and partially-sighted persons.

(3) Nothing in this regulation applies to a registrable homoeopathic medicinal product.

### **Package leaflets**

**260.**—(1) A package leaflet for a medicinal product must—

- (a) be drawn up in accordance with the summary of the product characteristics; and
- (b) contain all the information specified in Schedule 27 in the order specified in that Schedule.

(2) A package leaflet must be included in the packaging of a medicinal product unless all the information required by Part 1 of Schedule 27 (and, where the product contains paracetamol, the information required by Part 2 of that Schedule) is conveyed on the outer packaging or the immediate packaging of the product.

(3) A package leaflet relating to a medicinal product must be legible, clear and easy to use, and the applicant for, or holder of, a marketing authorisation, Article 126a authorisation or traditional herbal registration relating to the product must ensure that target patient groups are consulted in order to achieve this.

(4) Regulation (5) applies in a case where a package leaflet is not provided under paragraph (2) because all the information required by Schedule 27 is conveyed on the outer packaging or the immediate packaging of the product.

(5) Where this paragraph applies, any requirement of these Regulations that is expressed by reference to a package leaflet shall be taken to refer to the outer packaging or, as the case may be, the immediate packaging of the product.

(6) Nothing in this regulation or Schedule 27 applies to a registrable homoeopathic medicinal product.

### **Use of pictures and symbols etc**

**261.**—(1) The outer packaging and the package leaflet of a medicinal product may include—

- (a) symbols, diagrams or pictures designed to clarify information mentioned in Part 1 of Schedule 24 or in Schedule 27; and
- (b) other information, compatible with the summary of the product characteristics, which is useful to the patient.

(2) Symbols, diagrams, pictures or additional information included in accordance with this regulation must not include any element of a promotional nature.

(3) Nothing in this regulation applies to a registrable homoeopathic product.

### **Labelling requirements for radionuclides**

**262.**—(1) Where a medicinal product contains radionuclides—

- (a) the carton and the container of the product must be labelled in accordance with the regulations for the safe transport of radioactive materials laid down by the International Atomic Energy Agency; and
- (b) the labelling on the shielding and the vial must comply with the remaining provisions of this regulation.

(2) The label on the shielding must—

- (a) include the information specified in Part 1 of Schedule 24;
- (b) explain in full the codings used on the vial;
- (c) indicate, where necessary, for a given time and date, the amount of radioactivity per dose or per vial; and
- (d) indicate the number of capsules or, for liquids, the number of millilitres per container.

- (3) The label on the vial must include—
- (a) the name or code of the medicinal product, including the name or chemical symbol of the radionuclide;
  - (b) the batch identification and expiry date of the product;
  - (c) the international symbol for radioactivity;
  - (d) the name and address of the manufacturer; and
  - (e) the amount of radioactivity; as mentioned in paragraph 2(c).

### **Leaflets relating to radionuclides**

- 263.**—(1) The licensing authority must ensure that a detailed instruction leaflet is enclosed with—
- (a) radiopharmaceuticals;
  - (b) radionuclide generators;
  - (c) radionuclide kits; or
  - (d) radionuclide precursors.
- (2) The leaflet must include the information specified in Schedule 27.
- (3) The leaflet must also include—
- (a) any precautions to be taken by the user and the patient during the preparation and administration of the medicinal product; and
  - (b) special precautions for the disposal of the packaging and its unused contents.

### **Homoeopathic medicines**

**264.**—(1) The outer packaging and immediate packaging and, where a package leaflet is included, the package leaflet of a homoeopathic medicinal product must clearly include the words “homoeopathic medicinal product”.

(2) The outer packaging and immediate packaging and, where a package leaflet is included, the package leaflet of a registrable homoeopathic medicinal product must also include the information specified in paragraph (1) and Part 1 of Schedule 28 and no other information (unless paragraph (5) or (6) applies).

(3) Regulation (4) applies in a case where a package leaflet is not included with a registrable homoeopathic medicinal product.

(4) Unless the context requires otherwise, any requirement of these Regulations that is expressed by reference to a package leaflet shall be taken to refer to—

- (a) the outer packaging or the immediate packaging of the product; or
- (b) in a case to which paragraph (5) or paragraph (6) applies, the outer packaging of the product.

(5) Where the immediate packaging of a registrable homoeopathic medicinal product is in the form of a blister pack and is placed in outer packaging which complies with the requirements of this regulation and Part 1 of Schedule 28, the immediate packaging must include the information specified in this regulation and Part 2 of Schedule 28.

(6) Where the immediate packaging of a registrable homoeopathic medicinal product is too small to display the information required by Part 1 of Schedule 28, the immediate packaging must include the information specified in this regulation and Part 3 of Schedule 28.

### **Additional requirements for traditional herbal medicinal products**

**265.**—(1) Schedule 29 imposes additional requirements in relation to traditional herbal medicinal products.

- (2) Nothing in this regulation or Schedule 29 requires information to appear on—
- (a) a package containing a traditional herbal medicinal product where part of the package is transparent or open, provided that the information required by this regulation and that Schedule is clearly visible through the transparent or open part of the package;
  - (b) a paper bag or similar wrapping in which a package that contains a traditional herbal medicinal product and bears information in accordance with the requirements of this regulation and that Schedule is placed at the time of sale or supply;
  - (c) a package enclosing a package of a traditional herbal medicinal product for export;
  - (d) an ampoule or other container of not more than 10 millilitres' nominal capacity which is enclosed in a package on which information appears in accordance with the requirements of this regulation and that Schedule; or
  - (e) a blister pack or similar packaging, enclosed in a package labelled in accordance with the requirements of this regulation and that Schedule.

### **Language requirements etc**

**266.**—(1) Information given in accordance with the requirements of this Part must be given in English unless either or both of paragraphs (2) and (3) applies.

(2) This paragraph applies in the case of a medicinal product that has been designated as an orphan medicinal product under Regulation (EC) No. 141/2000 of the European Parliament and of the Council of 16 December 1999 on orphan medicinal products<sup>(1)</sup> where—

- (a) any information specified in paragraph (1) is given in a language of an EEA State other than English; and
- (b) the licensing authority accedes to a reasoned request that the information need not be given in English.

(3) This paragraph applies in the case of a product for which the licensing authority grants an Article 126a authorisation where the licensing authority decides that the information need not be given in English.

(4) In a case where paragraph (5) applies, the licensing authority may grant either or both of—

- (a) an exemption from the obligation that certain particulars should appear on the outer and immediate packaging and in the package leaflet of the medicinal product in accordance with this Part; and
- (b) a full or partial exemption from the obligation that the information included on the outer and immediate packaging and in the package leaflet for the product must be given in English in accordance with paragraph (1).

(5) This paragraph applies—

- (a) when a medicinal product is not intended to be delivered directly to the patient; or
- (b) where there are severe problems in respect of the availability of the medicinal product.

(6) The licensing authority may make the grant of an exemption in accordance with paragraph (4) subject to measures that it considers necessary to safeguard human health

(7) Information given in English in accordance with this regulation may be given in several languages in addition to English, provided that the same particulars appear in all the languages used.

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(1) OJ No L 18, 22.1.2000, p.1, as amended by Regulation (EC) No 596/2009 (OJ No L 188, 18.7.2009, p.14.

**Submission of mock-ups of packaging and leaflets to licensing authority**

**267.**—(1) At the time when a person applies for a marketing authorisation, Article 126a authorisation, certificate of registration or traditional herbal registration for a medicinal product, the person must submit to the licensing authority—

- (a) one or more mock-ups of the outer packaging and immediate packaging proposed for the product; and
- (b) a draft package leaflet.

(2) If the application is for a marketing authorisation, Article 126a authorisation or traditional herbal registration, the person must also provide to the licensing authority the results of assessments of the packaging and package leaflet carried out in co-operation with target patient groups.

(3) The licensing authority must refuse the application for a marketing authorisation, Article 126a authorisation, certificate of registration or traditional herbal registration if—

- (a) the packaging or the package leaflet does not comply with the requirements of this Part; or
- (b) (in relation to an application for a marketing authorisation, Article 126a authorisation or traditional herbal registration) the information on the packaging or the package leaflet does not accord with the particulars listed in the summary of the product characteristics.

(4) If the holder of a marketing authorisation, Article 126a authorisation, certificate of registration or traditional herbal registration for a product wishes to make changes to the packaging or the package leaflet (other than a change connected with the summary of the product characteristics), the proposed change must be submitted to the licensing authority in accordance with paragraph (5).

(5) In the circumstances in paragraph (4) the holder must submit to the licensing authority such of the following as are affected by the proposed change—

- (a) one or more mock-ups of the outer packaging and immediate packaging of the product showing the proposed change; and
- (b) a draft package leaflet showing the proposed change.

(6) If the licensing authority has not refused a proposed change within the period of 90 days beginning with the date of the submission, the applicant may make the change.

*Enforcement and offences***Offence relating to packaging and package leaflets: holder of authorisation etc**

**268.**—(1) This regulation applies to the holder of a marketing authorisation, Article 126a authorisation, certificate of registration or traditional herbal registration for a medicinal product who sells or supplies, offers to sell or supply, or possesses for the purpose of sale or supply, a medicinal product to which the authorisation, certificate or registration relates.

(2) A person to whom this regulation applies is guilty of an offence if—

- (a) a package or package leaflet relating to the product does not comply with the applicable requirements of this Part or Article 28 or 32 of the Paediatric Regulation; or
- (b) the product is not accompanied by a package leaflet when one is required by virtue of this Part.

**Offences relating to packaging and package leaflets: other persons**

**269.**—(1) This regulation applies to a person, other than the holder of a marketing authorisation, Article 126a authorisation, certificate of registration or traditional herbal registration for a medicinal

product, who, in the course of a business sells or supplies, or offers to sell or supply the product, or possesses the product for the purpose of sale or supply.

(2) A person to whom this regulation applies is guilty of an offence if the person sells or supplies, or offers to sell or supply, the product, or possesses the product for the purpose of sale or supply, knowing or having reasonable cause to believe—

- (a) that a package or package leaflet relating to the medicinal product does not comply with the applicable requirements of this Part or Article 28 or 32 of the Paediatric Regulation; or
- (b) that the product is not accompanied by a package leaflet when one is required by virtue of this Part.

### **Non-compliance with requirements of this Part**

**270.**—(1) If the holder of a marketing authorisation, Article 126a authorisation, certificate of registration or traditional herbal registration fails to comply with a requirement imposed by this Part in relation to a medicinal product, the licensing authority may give a notice to the holder requiring compliance within three months or such other period (which may be less than three months) as may be specified in the notice.

(2) If the holder fails to comply with the notice, the licensing authority may suspend the marketing authorisation, Article 126a authorisation, certificate of registration or traditional herbal registration until the holder complies with the requirements of this Part.

(3) A person who fails to comply with a notice under this regulation is guilty of an offence.

### **Offences: penalties**

**271.** A person who is guilty of an offence under regulation 268, 269 or 270 is liable—

- (a) on summary conviction to a fine not exceeding the statutory maximum; or
- (b) on conviction on indictment, to a fine, to imprisonment for a term not exceeding two years, or to both.

## **CHAPTER 2**

### *Requirements relating to child safety*

### **Interpretation**

**272.** In this Chapter—

“appropriate practitioner” means any of the persons described as appropriate practitioners in relation to any prescription only medicine in regulation 214(3), (5) and (6);

“regulated medicinal product” means a medicinal product containing aspirin, paracetamol or more than 24mg of elemental iron, in the form of tablets, capsules, pills, lozenges, pastilles, suppositories or oral liquids, but does not include—

- (a) effervescent tablets containing not more than 25% of aspirin or paracetamol by weight;
- (b) medicinal products in sachets or other sealed containers which hold only one dose;
- (c) medicinal products which are not intended for retail sale or for supply in circumstances corresponding to retail sale; or
- (d) medicinal products which are for export only.

### **Child resistant containers for regulated medicinal products**

**273.**—(1) Regulated medicinal products sold or supplied otherwise than in accordance with regulation 274 may be sold only in containers which are—

- (a) opaque or dark tinted; and
- (b) child resistant.

(2) For the purposes of these Regulations, containers which are not reclosable are child resistant if they have been evaluated in accordance with, and comply with the requirements of—

- (a) British Standard EN 14375:2003 published by the British Standards Institution on 18th April 2005; or
- (b) any equivalent or higher technical specification for non-reclosable child resistant packaging recognised for use in the European Economic Area.

(3) For the purposes of these Regulations, containers which are reclosable are child resistant if they have been evaluated in accordance with, and comply with the requirements of—

- (a) British Standard EN ISO 8317:2004 published by the British Standards Institution on 11<sup>th</sup> May 2005; or
- (b) any equivalent or higher technical specification for reclosable child resistant packaging recognised for use in the European Economic Area.

### **Exemptions from regulation 273**

**274.**—(1) Regulation 273 does not apply to the retail sale, or supply in circumstances corresponding to retail sale, of regulated medicinal products in accordance with paragraph (2).

(2) Sale or supply is in accordance with this paragraph if the sale or supply is carried out—

- (a) by or under the supervision of a pharmacist;
- (b) on premises which are a registered pharmacy; and
- (c) either—
  - (i) in accordance with a prescription given by an appropriate practitioner where it is not reasonably practicable to provide the regulated medicinal products in containers that are both opaque or dark tinted and child resistant, or
  - (ii) at the request of a person who is aged 16 or over and specifically requests that the regulated medicinal products not be contained in a child resistant container.

(3) Regulation 273 also does not apply to the sale or supply of regulated medicinal products—

- (a) by a doctor or dentist to a patient, or the patient's carer, for the patient's use;
- (b) by a doctor or dentist to a person who is an appropriate practitioner, at the request of that person, for administration to a patient of that person; or
- (c) in the course of the business of a hospital or health centre, where the sale or supply is for the purposes of administration, whether in the hospital or health centre or elsewhere, in accordance with the directions of an appropriate practitioner.

### **Colouring of aspirin and paracetamol products for children**

**275.** The sale or supply of a medicinal product containing aspirin or paracetamol of any colour other than white is prohibited if—

- (a) it is a product for children aged 12 or under; and
- (b) in the case of paracetamol, it is in a solid form (including tablets, capsules, pills, lozenges, pastilles or suppositories).



## **Offences**

**276.**—(1) A person is guilty of an offence if, in the course of a business, the person sells or supplies, or possesses for the purposes of sale or supply—

- (a) a regulated medicinal product in a container which does not comply with the requirements of regulation 273, unless the sale or supply is or would be exempt from those requirements under regulation 274; or
  - (b) a medicinal product containing aspirin or paracetamol the sale or supply of which is prohibited under regulation 275.
- (2) A person guilty of an offence under this regulation is liable—
- (a) on summary conviction to a fine not exceeding the statutory maximum; or
  - (b) on conviction on indictment to a fine, to imprisonment for a term not exceeding 2 years, or to both.