STATUTORY INSTRUMENTS

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, **[**[F1]regulation 257C where the product is for sale or supply in Great Britain only,**]** 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.

[[F2](8) Nothing in this regulation applies to the outer or immediate packaging of an advanced therapy medicinal product for sale or supply in Great Britain only.**]**

Textual Amendments

F1 Words in reg. 257(6) inserted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **198(2)** (as amended by S.I. 2020/1488, reg. 1, **Sch. 2 para. 152(a)**); 2020 c. 1, **Sch. 5 para. 1(1)**

F2 Reg. 257(8) inserted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **198(3)** (as amended by S.I. 2020/1488, reg. 1, **Sch. 2 para. 152(b)**); 2020 c. 1, **Sch. 5 para. 1(1)**

[F3Packaging Requirements: medicinal products required to bear safety features

257A.—(1) The information specified in paragraph 18A of Schedule 24 must not be removed or covered, either fully or partially, **[**F4from a product to which Article 54a of the 2001 Directive applies**]** unless the following conditions are met—

(a) a person who is the holder of a manufacturer's licence verifies, prior to partially or fully removing or covering the features, that the medicinal product concerned is authentic and that it has not been tampered with;

(b) the holder of the manufacturer's licence replaces the features with ones which are equivalent as regards the possibility to verify the authenticity, identification and to provide evidence of tampering of the medicinal product; and

(c) the replacement of the features is conducted in accordance with the applicable principles and guidelines for good manufacturing practice set out in the Good Manufacturing Practice Directive.

(2) For the purposes of paragraph (1)(b), the features shall be considered equivalent if they—

(a) comply with the requirements set out in Commission Regulation 2016/161; and

(b) are equally effective in enabling the verification of authenticity and identification of the medicinal product and in providing evidence of tampering with the medicinal product.

(3) In performing the activities referred to in paragraph (1), the holder of a manufacturer's licence shall be regarded as a producer for the purposes of the Consumer Protection Act 1987.**]**

Textual Amendments

F3 Regs. 257A, 257B inserted (9.2.2019) by The Human Medicines (Amendment) Regulations 2019 (S.I. 2019/62), regs. 1, **11** and regs. 257A, 257B inserted (N.I.) (9.2.2019) by The Human Medicines (Amendment) Regulations 2019 (S.R. 2019/10), regs. 1, **11**

F4 Words in reg. 257A inserted (31.12.2020) by S.I. 2019/775, **reg. 199** (as substituted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 153**)

[F3Transitional Arrangements

257B. The information specified in paragraph 18A of Schedule 24 does not need to appear on the packaging of a medicinal product released for sale or distribution before 9 February 2019, unless the product **[**F5is one to which Article 54a of the 2001 Directive applies and**]** has been repackaged or relabelled after that date.**]**

Textual Amendments

F3 Regs. 257A, 257B inserted (9.2.2019) by The Human Medicines (Amendment) Regulations 2019 (S.I. 2019/62), regs. 1, **11** and regs. 257A, 257B inserted (N.I.) (9.2.2019) by The Human Medicines (Amendment) Regulations 2019 (S.R. 2019/10), regs. 1, **11**

F5 Words in reg. 257B inserted (31.12.2020) by S.I. 2019/775, **reg. 199A** (as substituted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 153**)

[F6Packaging requirements: advanced therapy medicinal products

257C.—(1) The information specified in Part 4 of Schedule 24 must appear—

(a) on the outer packaging of an advanced therapy medicinal product for sale or supply in Great Britain only (other than an exempt advanced therapy medicinal product); and

(b) on the immediate packaging of that product, unless paragraph (2) or (3) applies to the packaging.

(2) This paragraph applies to the 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 4 of Schedule 24.

(3) This paragraph applies to immediate packaging if the packaging is too small to display the information required by Part 4 of Schedule 24.

(4) The information specified in Part 5 of Schedule 24 must appear on immediate packaging to which paragraph (2) or (3) applies.

Textual Amendments

F6 Regs. 257C-257E inserted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **200** (as amended by S.I. 2020/1488, reg. 1, **Sch. 2 para. 154**); 2020 c. 1, **Sch. 5 para. 1(1)**

Guidance as to packaging and package leaflets

257D.—(1) The licensing authority may publish guidance on packaging and package leaflets applicable to products for sale or supply in the whole United Kingdom or parts of the United Kingdom, as appropriate.

(2) Guidance published under paragraph (1) may, in particular, include—

(a) the wording of certain special warnings for certain categories of medicinal products;

(b) the particular information needs relating to products that are a pharmacy medicine;

(c) the legibility of particulars on the labelling and package leaflet;

(d) the methods of identification and authentication of medicinal products;

(e) the list of excipients which must feature on the labelling of medicinal products and the way in which these excipients must be indicated.

(3) Until such time as the licensing authority publishes guidance under paragraph (1), any guidance published by the Commission pursuant to Article 65 of the 2001 Directive, insofar as that guidance was in force immediately before IP completion day, continues to apply as if it had been published by the licensing authority under paragraph (1).

Textual Amendments

F6 Regs. 257C-257E inserted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **200** (as amended by S.I. 2020/1488, reg. 1, **Sch. 2 para. 154**); 2020 c. 1, **Sch. 5 para. 1(1)**

Regulation-making power as to certain forms of labelling

257E. The Ministers may by regulations require the use of certain forms of labelling of a medicinal product in order to make it possible to ascertain—

(a) the price of the medicinal product;

(b) any reimbursement conditions of the National Health Service;

(c) the legal status for supply to the patient in accordance with regulation 5 (classification), insofar as not already provided for in Schedule 25;

(d) authenticity and identification of the medicinal product in accordance with Article 54a(5) of the 2001 Directive.**]**

Textual Amendments

F6 Regs. 257C-257E inserted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **200** (as amended by S.I. 2020/1488, reg. 1, **Sch. 2 para. 154**); 2020 c. 1, **Sch. 5 para. 1(1)**

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 **[**F7UK marketing authorisation, EU 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.

Textual Amendments

F7 Words in reg. 259(2) substituted (31.12.2020) by S.I. 2019/775, **reg. 202** (as amended by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 156**)

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.

[F8(1A) If the medicinal product is an advanced therapy medicinal product for sale or supply in Great Britain only (other than an exempt advanced therapy medicinal product), the package leaflet must contain the information specified in Part 3 of Schedule 27 in the order specified in that Part.**]**

(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) **[**F9, or where the product is an advanced therapy medicinal product for sale or supply in Great Britain only, the information specified in Part 3 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 **[**F10UK marketing authorisation, EU 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.

Textual Amendments

F8 Reg. 260(1A) inserted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **203(2)** (as amended by S.I. 2020/1488, reg. 1, **Sch. 2 para. 157(a)**); 2020 c. 1, **Sch. 5 para. 1(1)**

F9 Words in reg. 260(2) inserted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **203(3)** (as amended by S.I. 2020/1488, reg. 1, **Sch. 2 para. 157(b)**); 2020 c. 1, **Sch. 5 para. 1(1)**

F10 Words in reg. 260(3) substituted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **203(4)** (as amended by S.I. 2020/1488, reg. 1, **Sch. 2 para. 157(c)**); 2020 c. 1, **Sch. 5 para. 1(1)**

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 [M1] 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.

Marginal Citations

M1 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 **[**[F11]UK**]** 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 **[**F11UK**]** 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 **[**F11UK**]** 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 **[**F11UK**]** 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 **[**F11UK**]** 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.

Textual Amendments

F11 Word in reg. 267 inserted (31.12.2020) by S.I. 2019/775, **reg. 206** (as amended by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 160**)

Enforcement and offences

Offence relating to packaging and package leaflets [F12in Great Britain]: holder of authorisation etc

268.—(1) This regulation applies to the holder of a **[**F13UKMA(UK), UKMA(GB)**]**, 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 **[**F14, in Northern Ireland**]**, 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 F15... or **[**F16regulation 50C(4), 50D(8) or 58A(2)(b)**]**; or

(b) the product is not accompanied by a package leaflet when one is required by virtue of this Part.

Textual Amendments

F12 Words in reg. 268 heading inserted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), **reg. 207(1A)** (as amended by S.I. 2020/1488, reg. 1, **Sch. 2 para. 161(a)**); 2020 c. 1, **Sch. 5 para. 1(1)**

F13 Words in reg. 268(1) substituted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), **reg. 207(2)(a)** (as amended by S.I. 2020/1488, reg. 1, **Sch. 2 para. 161(b)**); 2020 c. 1, **Sch. 5 para. 1(1)**

F14 Words in reg. 268(1) inserted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), **reg. 207(2)(b)** (as amended by S.I. 2020/1488, reg. 1, **Sch. 2 para. 161(b)**); 2020 c. 1, **Sch. 5 para. 1(1)**

F15 Words in reg. 268(2)(a) omitted (31.12.2020) by virtue of The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **207(3)(b)**; 2020 c. 1, Sch. 5 para. 1(1)

F16 Words in reg. 268(2)(a) substituted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **207(3)(a)**; 2020 c. 1, Sch. 5 para. 1(1)

[F17Offence relating to packaging and package leaflets in Northern Ireland: holder of authorisation etc

268A.—(1) This regulation applies to the holder of a UKMA(UK), UKMA(NI), EU 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, in Northern Ireland, 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, Article 9 of Commission Regulation 2016/161 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.**]**

Textual Amendments

F17 Reg. 268A inserted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **207A** (as inserted by S.I. 2020/1488, reg. 1, **Sch. 2 para. 162**); 2020 c. 1, **Sch. 5 para. 1(1)**

Offences relating to packaging and package leaflets [F18in Great Britain]: other persons

269.—(1) This regulation applies to a person, other than the holder of a **[**F19UKMA(UK), UKMA(GB)**]**, certificate of registration or traditional herbal registration for a medicinal product, who, in the course of a business **[**F20carried on by that person,**]** sells or supplies, or offers to sell or supply the product, or possesses the product for the purpose of sale or supply **[**F21, in Great Britain**]**.

(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, **[**F22in Great Britain**]** 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 [F23]... or **[**[F24]regulation 50C(4), 50D(8) or 58A(2)(b)**]**; or

(b) that the product is not accompanied by a package leaflet when one is required by virtue of this Part.

Textual Amendments

F18 Words in reg. 269 heading inserted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), **reg. 208(1A)** (as amended by S.I. 2020/1488, reg. 1, **Sch. 2 para. 163(a)**); 2020 c. 1, **Sch. 5 para. 1(1)**

F19 Words in reg. 269(1) substituted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), **reg. 208(2)(a)** (as amended by S.I. 2020/1488, reg. 1, **Sch. 2 para. 163(b)**); 2020 c. 1, **Sch. 5 para. 1(1)**

F20 Words in reg. 269(1) inserted (E.W.S.) (1.7.2015) by The Human Medicines (Amendment) (No. 2) Regulations 2015 (S.I. 2015/903), regs. 1, **7** and words in reg. 269(1) inserted (N.I.) (1.7.2015) by The Human Medicines (Amendment) (No. 2) Regulations 2015 (S.R. 2015/259), regs. 1, **7**

F21 Words in reg. 269(1) inserted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), **reg. 208(2)(b)** (as amended by S.I. 2020/1488, reg. 1, **Sch. 2 para. 163(b)**); ; 2020 c. 1, **Sch. 5 para. 1(1)**

F22 Words in eg. 269(2) inserted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **208(2A)** (as amended by S.I. 2020/1488, reg. 1, **Sch. 2 para. 163(c)**); 2020 c. 1, **Sch. 5 para. 1(1)**

F23 Words in reg. 269(2)(a) omitted (31.12.2020) by virtue of The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **208(3)(b)**; 2020 c. 1, Sch. 5 para. 1(1)

F24 Words in reg. 269(2)(a) substituted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **208(3)(a)**; 2020 c. 1, Sch. 5 para. 1(1)

[[F25]**Offences relating to packaging and package leaflets in Northern Ireland: other persons**

269A.—(1) This regulation applies to a person, other than the holder of a UKMA(UK), UKMA(NI), EU marketing authorisation, Article 126a authorisation, certificate of registration or traditional herbal registration for a medicinal product, who, in the course of a business carried on by that person, sells or supplies, or offers to sell or supply the product, or possesses the product for the purpose of sale or supply in Northern Ireland.

(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, in Northern Ireland 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, Article 9 of Commission Regulation 2016/161 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.**]**

Textual Amendments

F25 Reg. 269A inserted (31.12.2020) by S.I. 2019/775, regs. 1, **208A** (as inserted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 164**)

Non-compliance with requirements of this Part

270.—(1) If the holder of a **[**F26UK marketing authorisation, EU 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 **[**F27UK marketing authorisation, EU 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.

Textual Amendments

F26 Words in reg. 270(1) substituted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **209** (as amended by S.I. 2020/1488, reg. 1, **Sch. 2 para. 165**); 2020 c. 1, **Sch. 5 para. 1(1)**

F27 Words in reg. 270(2) substituted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **209** (as amended by S.I. 2020/1488, reg. 1, **Sch. 2 para. 165**); 2020 c. 1, **Sch. 5 para. 1(1)**

Offences: penalties

271. A person who is guilty of an offence under regulation **[**F28268, 268A, 269, 269A**]** 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.

Textual Amendments

F28 Words in reg. 271 substituted (31.12.2020) by S.I. 2019/775, **reg. 209A** (as inserted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 166**)

Changes to legislation:
There are currently no known outstanding effects for the The Human Medicines Regulations 2012, CHAPTER 1.