STATUTORY INSTRUMENTS

2012 No. 1916

The Human Medicines Regulations 2012

PART 13

Packaging and leaflets

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

[[F1](b) any specification for non-reclosable child resistant packaging that the licensing authority is satisfied is of an equivalent or higher technical specification to that specified in sub-paragraph (a).**]**

(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 11th May 2005; or

[[F2](b) any specification for reclosable child resistant packaging that the licensing authority is satisfied is of an equivalent or higher technical specification to that specified in sub-paragraph (a).**]**

Textual Amendments

F1 Reg. 273(2)(b) substituted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **210(2)**; 2020 c. 1, Sch. 5 para. 1(1)

F2 Reg. 273(3)(b) substituted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **210(3)**; 2020 c. 1, Sch. 5 para. 1(1)

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.

Changes to legislation:
The Human Medicines Regulations 2012, CHAPTER 2 is up to date with all changes known to be in force on or before 16 September 2024. There are changes that may be brought into force at a future date. Changes that have been made appear in the content and are referenced with annotations.
View outstanding changes

Changes and effects yet to be applied to the whole Instrument associated Parts and Chapters:
Whole provisions yet to be inserted into this Instrument (including any effects on those provisions):

- Sch. 11 para. 1(1)(d)-(f) inserted by S.I. 2019/775 reg. 63(2)(a)(ii) (This amendment not applied to legislation.gov.uk. Reg. 63(2)(a)(ii) substituted immediately before IP completion day by S.I. 2019/1385, reg. 1, Sch. 1 para. 7(2))
- Sch. 24 para. 18B inserted by S.I. 2024/832 reg. 142(e)
- Sch. 24 Pt. 1 para. 23 words omitted by S.I. 2024/832 reg. 142(f)
- Sch. 33A para. 57A inserted by S.I. 2019/775, Sch. 7 (as amended) by S.I. 2019/1385 Sch. 1 para. 10(4) (This amendment not applied to legislation.gov.uk. Sch. 1 para. 10(3)(4) omitted immediately before IP completion day by virtue of S.I. 2020/1488, reg. 1, Sch. 3 para. 1(c))
- Sch. 33A para. 57(3) substituted by S.I. 2019/775, Sch. 7 (as amended) by S.I. 2019/1385 Sch. 1 para. 10(3)(b) (This amendment not applied to legislation.gov.uk. Sch. 1 para. 10(3)(4) omitted immediately before IP completion day by virtue of S.I. 2020/1488, reg. 1, Sch. 3 para. 1(c))
- Sch. 33A para. 57(2) words inserted by S.I. 2019/775, Sch. 7 (as amended) by S.I. 2019/1385 Sch. 1 para. 10(3)(a) (This amendment not applied to legislation.gov.uk. Sch. 1 para. 10(3)(4) omitted immediately before IP completion day by virtue of S.I. 2020/1488, reg. 1, Sch. 3 para. 1(c))
- Sch. 33B inserted by S.I. 2024/832 reg. 146
- reg. 3(12)(d)(ia) omitted by S.I. 2024/832 reg. 4(a)
- reg. 4(4)(d)(ia) omitted by S.I. 2024/832 reg. 5
- reg. 43(7)(b)(ii)(bb) words omitted by S.I. 2024/832 reg. 18(b)
- reg. 49(1ZA)-(1ZD) inserted by S.I. 2024/832 reg. 26(a)
- reg. 49(3ZA) inserted by S.I. 2024/832 reg. 26(d)
- reg. 51(9) words inserted by S.I. 2019/775, reg. 56 (as amended) by S.I. 2019/1385 Sch. 1 para. 5 (This amendment not applied to legislation.gov.uk. Sch. 1 paras. 2-6 omitted immediately before IP completion day by virtue of S.I. 2020/1488, reg. 1, Sch. 3 para. 1(a))
- reg. 52(1)(a)(i)(ii) and words substituted by S.I. 2019/775 reg. 57(2) (This amendment not applied to legislation.gov.uk. Reg. 57 substituted immediately before IP completion day by S.I. 2020/1488, reg. 1, Sch. 2 para. 42)
- reg. 53(2)-(2C) substituted for reg. 53(2) by S.I. 2019/775 reg. 58(3) (This amendment not applied to legislation.gov.uk. Reg. 58 substituted immediately before IP completion day by S.I. 2020/1488, reg. 1, Sch. 2 para. 43)
- reg. 53(2)(a) substituted by S.I. 2019/775, reg. 58(3) (as amended) by S.I. 2019/1385 Sch. 1 para. 6(2) (This amendment not applied to legislation.gov.uk. Sch. 1 paras. 2-6 omitted immediately before IP completion day by virtue of S.I. 2020/1488, reg. 1, Sch. 3 para. 1(a))
- reg. 55(1)(b)(iii)(bb) substituted by S.I. 2024/832 reg. 43(a)(ii)
- reg. 60A(10A) inserted by S.I. 2024/832 reg. 49(e)
- reg. 68(11H)-(A12) inserted by S.I. 2024/832 reg. 56(b)
- reg. 173(e) inserted by S.I. 2017/1322 Sch. 4 para. 2(2)(b) (This amendment not applied to legislation.gov.uk: superseded by S.I. 2018/121, reg. 2(4)(b)(i).)
- reg. 240(2A) words inserted by S.I. 2017/1322 Sch. 4 para. 2(3)(c) (This amendment not applied to legislation.gov.uk: superseded by S.I. 2018/121, reg. 2(4)(b)(ii).)
- reg. 240(6A) inserted by S.I. 2017/1322 Sch. 4 para. 2(3)(g) (This amendment not applied to legislation.gov.uk: superseded by S.I. 2018/121, reg. 2(4)(b)(ii).)

- reg. 257(9) inserted by S.I. 2024/832 reg. 110(c)
- reg. 257AA257AB inserted by S.I. 2024/832 reg. 111
- reg. 327(1)(c)(va) omitted by S.I. 2024/832 reg. 128(a)
- reg. 346(2)(c)(iia) omitted by S.I. 2024/832 reg. 132(b)
- reg. 346(2)(c)(iiia) omitted by S.I. 2024/832 reg. 132(b)
- reg. 346(2)(c)(iva) omitted by S.I. 2024/832 reg. 132(b)
- reg. 346(2)(c)(xviia) omitted by S.I. 2024/832 reg. 132(b)
- reg. 346(2)(c)(xxviiij) omitted by S.I. 2024/832 reg. 132(b)
- reg. 347B inserted by S.I. 2024/832 reg. 133