2003 No. 2317

MEDICINES

The Medicines (Child Safety) Regulations 2003

Made - - - - -	*6th September 2003*
Laid before Parliament	*10th September 2003*
Coming into force - -	*1st October 2003*

As respects England, Scotland and Wales, the Secretary of State concerned with health in England and, as respects Northern Ireland, the Department of Health, Social Services and Public Safety, acting jointly, in exercise of the powers conferred upon them by sections 87(1), 88(1) and (2), 91(2) and 129(5) of the Medicines Act 1968(**a**), or, as the case may be, the powers conferred by the said provisions and now vested in them(**b**), and of all other powers enabling them in that behalf, after consulting, pursuant to section 129(6) of that Act, such organisations as appear to them to be representative of interests likely to be substantially affected by these Regulations, and after taking into account, pursuant to section 129(7) of that Act, the advice of the Medicines Commission, hereby make the following Regulations:—

Citation, commencement and interpretation

1.—(1) These Regulations may be cited as the Medicines (Child Safety) Regulations 2003 and shall come into force on 1st October 2003.

(2) In these Regulations—

"European Economic Area" means the European Economic Area created by the Agreement on the European Economic Area signed at Oporto on 2nd May 1992, as adjusted by the Protocol signed at Brussels on 17th March 1993;

"first level nurse" means a person registered in Parts 1, 3, 5, 8, 10, 11, 12, 13, 14 or 15 of the professional register;

"nurse prescriber" means a person—

(a) who is a first level nurse, and

(b) against whose name is recorded in the professional register an annotation signifying that he is qualified to order drugs, medicines and appliances.

"placed on the market" has the same meaning as in regulation 3 of the Medicines for Human Use (Marketing Authorisations Etc.) Regulations 1994(**c**);

"professional register" means the register maintained by the Nursing and Midwifery Council(**d**) pursuant to paragraph 10 of Schedule 2 to the Nursing and Midwifery Order 2001(**e**);

(**a**) 1968 c. 67; the expression "the appropriate Ministers" in sections 87(1) and 88(1) of that Act, which is relevant to the powers being exercised in the making of these Regulations, is defined in section 1(2) of that Act.

(**b**) In the case of the Secretary of State concerned with health in England, by virtue of articles 2(1) and 5 of, and the Schedule to, S.I. 1999/3142; and in the case of the Department of Health, Social Services and Public Safety, the powers vested in the Minister in charge of that Department by virtue of section 95(5) of, and paragraph 10 of Schedule 12 to, the Northern Ireland Act 1998 (c. 47) may now be exercised by the Department by virtue of section 1(8) of, and paragraph 4(1)(b) of the Schedule to, the Northern Ireland Act 2000 (c. 1).

(**c**) S.I. 1994/3144; to which there are amendments which are not relevant to this definition.

(**d**) *See* article 3 of the Nursing and Midwifery Order 2001, S.I. 2002/253.

(**e**) S.I. 2002/253.

"relevant medicinal products" means medicinal products for human use consisting of or containing aspirin, paracetamol or more than 24mg of elemental iron which are in the form of tablets, capsules, pills, lozenges, pastilles, suppositories or oral liquids, except for—

(a) effervescent tablets containing not more than 25 per cent of aspirin or paracetamol by weight;

(b) medicinal products in sachets or other sealed containers which hold only one unit dose;

(c) medicinal products which are not intended for—

(i) retail sale (including sale by a retail pharmacy business), or

(ii) supply (including supply in pursuance of a prescription) in circumstances corresponding to retail sale;

(d) medicinal products which are for exportation only;

"relevant register" means—

(a) in relation to a first level nurse, the professional register, and

(b) in relation to a pharmacist, the register maintained in pursuance of section 2(1) of the Pharmacy Act 1954(**a**) or the register maintained in pursuance of articles 6 and 9 of the Pharmacy (Northern Ireland) Order 1976(**b**);

"supplementary prescriber" means—

(a) a first level nurse, or

(b) a pharmacist,

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

"United Kingdom marketing authorization" has the meaning given in regulation 1(2) of the Medicines for Human Use (Marketing Authorisations Etc.) Regulations 1994(**c**).

Child resistant containers for relevant medicinal products

2.—(1) Subject to regulation 3, the sale or supply of relevant medicinal products otherwise than in containers that are both opaque or dark tinted and child resistant is prohibited.

(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 BS 8404 published by the British Standards Institution on 21st December 2001; 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 28317 published by the British Standards Institution on 15th February 1993, or

(b) any equivalent or higher technical specification for reclosable child resistant packaging recognised for use in the European Economic Area.

Exemptions from regulation 2

3.—(1) Regulation 2 shall not apply to the retail sale (including sale by a retail pharmacy business), or to the supply (including supply in pursuance of a prescription) in circumstances corresponding to retail sale, of relevant medicinal products by or under the supervision of a pharmacist on premises which are a registered pharmacy, if that sale or supply is—

(a) in accordance with a prescription given by a practitioner(**d**), supplementary prescriber or nurse prescriber ("prescriber"), and it is not possible to provide the relevant medicinal products so ordered in containers that are both opaque or dark tinted and child resistant; or

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(**a**) 1954 c. 61.
(**b**) S.I. 1976/1213 (N.I. 22).
(**c**) The relevant amending instrument is S.I. 2001/795.
(**d**) The expression "practitioner" is defined in section 132 of the Medicines Act 1968.

(b) at the request of a person, not being a child, who specifically requests that the relevant medicinal products not be contained in a child resistant container.

(2) Regulation 2 shall not apply to the sale or supply of relevant medicinal products—

(a) by a doctor or dentist to his—

(i) patient; or

(ii) patient's carer

in circumstances where the relevant medicinal products are for his patient;

(b) by a doctor or dentist to, and at the request of, another prescriber for administration to a particular patient of that other prescriber; or

(c) in the course of the business of a hospital or health centre, where the sale or supply is for the purpose of administration, whether in the hospital or health centre or elsewhere, in accordance with the directions of a prescriber.

Colouring of aspirin and paracetamol products for children

4.—(1) Subject to paragraph (2), the sale or supply of relevant medicinal products of any colour other than white is prohibited, if they are for administration exclusively to children.

(2) Paragraph (1) shall not apply to the sale or supply of relevant medicinal products consisting of or containing either paracetamol in oral liquid dosage form or more than 24mg of elemental iron.

Offences

5. Any person who contravenes section 87(2) of the Medicines Act 1968 by contravening any requirement imposed by these Regulations shall be guilty of an offence and shall be liable—

(a) on summary conviction to a fine not exceeding the statutory maximum; and

(b) on conviction on indictment to a fine or to imprisonment for a term not exceeding 2 years or both.

Transitional provisions

6.—(1) These Regulations shall not be applied in respect of relevant medicinal products consisting of or containing either paracetamol in oral liquid dosage form or more than 24mg of elemental iron if—

(a) in respect of those products, a United Kingdom marketing authorization was granted by the licensing authority before the coming into force of these Regulations;

(b) they were placed on the market before 1st October 2005; and

(c) their shelf life has not expired.

(2) Regulation 2(1) shall not be applied in respect of relevant medicinal products if—

(a) in respect of those products, a United Kingdom marketing authorization was granted by the licensing authority before the coming into force of these Regulations;

(b) they were placed on the market before 1st October 2005;

(c) their shelf life has not expired;

(d) they are in containers which are—

(i) in the form of sealed units consisting of sheet or strip material selected with a view to their resistance to opening by children; or

(ii) identical to containers which comply with the requirements of British Standard 6652 published on 30th September 1985, as amended and republished on 30th June 1989, and they—

(aa) have been certified by the British Standards Institution as complying with those requirements, or

(bb) are part of a series of containers in respect of which the licensing authority has been furnished with a report by the British Standards Institution to the effect that they comply with those requirements; and

(e) in the case of relevant medicinal products consisting of or containing aspirin or paracetamol, they are in containers which are opaque or dark tinted.

Revocation

7. The following provisions are hereby revoked—

(a) the Medicines (Child Safety) Regulations 1975(**a**);

(b) the Medicines (Child Safety) Amendment Regulations 1976(**b**);

(c) the Medicines (Child Safety) Amendment Regulations 1987(**c**);

(d) the Medicines (Child Safety) Amendment Regulations 1994(**d**); and

(e) paragraph 2 of Schedule 7 to the Medicines for Human Use (Marketing Authorisations Etc.) Regulations 1994(**e**).

Signed by authority of the Secretary of State for Health

Warner
Parliamentary Under Secretary of State,
6th September 2003 Department of Health

Sealed with the Official Seal of the Department of Health, Social Services and Public Safety

D. C. Gowdy
Permanent Secretary,
5th September 2003 Department of Health, Social Services and Public Safety

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(**a**) S.I. 1975/2000.
(**b**) S.I. 1976/1643.
(**c**) S.I. 1987/877.
(**d**) S.I. 1994/1402.
(**e**) There are no relevant amending instruments.

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations contain measures relating to the packaging of medicinal products consisting of or containing aspirin, paracetamol or more than 24mg of elemental iron, and a measure relating to the colouring of solid dosage forms of aspirin and paracetamol.

Medicinal products that come within the scope of these Regulations have to be packaged in containers that are child resistant, which is defined with reference to two British Standards Institution standards (regulation 2). However, there are exemptions from regulation 2 for certain products dispensed by pharmacists or supplied by doctors or dentists (regulation 3).

Solid dosage forms of aspirin or paracetamol have to be coloured white (regulation 4), and breaches of the requirements of these Regulations are made an offence (regulation 5). There are transitional provisions in respect of products the sale or supply of which is prohibited by these Regulations but was not prohibited by the Medicines (Child Safety) Regulations 1975 (regulation 6), and those Regulations are revoked along with the spent provisions containing the various amendments to them (regulation 7).

These Regulations have been notified to the European Commission and other Member States of the European Community in accordance with Directive 98/34/EC of the European Parliament and of the Council laying down a procedure for the provision of information in the field of technical standards and regulations and rules on Information Society services(**a**), as amended(**b**).

A Regulatory Impact Assessment in relation to these Regulations has been placed in the libraries of both Houses of Parliament, and copies can be obtained from the Medicines and Healthcare products Regulatory Agency, Market Towers, 1 Nine Elms Lane, London SW8 5NQ. The British Standards referred to in these Regulations may be obtained from any of the sales outlets operated by the British Standards Institution or by post from the British Standards Institution at Linford Wood, Milton Keynes MK14 6LE.

(**a**) OJ No. L 204, 21.7.1998, p. 37.
(**b**) *See* Directive 98/48/EC (OJ No. L 217, 5.8.1998, p. 18).

STATUTORY INSTRUMENTS

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