STATUTORY INSTRUMENTS

1976 No. 1643

MEDICINES

The Medicines (Child Safety) Amendment Regulations 1976

Made - - - -	30*th September* 1976
Laid before Parliament	13*th October* 1976
Coming into Operation	3*rd November* 1976

The Secretaries of State concerned with health in England, in Wales and in Scotland and the Department of Health and Social Services for Northern Ireland, acting jointly, in exercise of powers conferred by sections 87(1), 88(1) and (2) and 91(2) of the Medicines Act 1968(**a**) and now vested in them (**b**) and of all other powers enabling them in that behalf, after taking into account the advice of the Medicines Commission and after consulting such organisations as appear to them to be representative of interests likely to be substantially affected by the following regulations, hereby make the following regulations:—

Citation, commencement and interpretation

1.—(1) These regulations may be cited as the Medicines (Child Safety) Amendment Regulations 1976 and shall come into operation on 3rd November 1976.

(2) These regulations shall be read as one with the Medicines (Child Safety) Regulations 1975(**c**) (hereinafter referred to as "the principal regulations").

Amendment of paragraph (3)(b) of regulation 2 of the principal regulations

2. In regulation 2(3)(*b*) of the principal regulations—

(*a*) after "1975" there shall be inserted the words "as amended by AMD 2077 published on 16th August 1976",

(*b*) for the words "of the test required by the said standard, signed by the person supervising the test," there shall be substituted the words "by the British Standards Institution" and

(*c*) in the last line, after the word "standard" there shall be inserted the words "as so amended".

(**a**) 1968 c. 67.

(**b**) In the case of the Secretaries of State concerned with health in England and in Wales by virtue of Article 2(2) of, and Schedule 1 to, the Transfer of Functions (Wales) Order 1969 (S.I. 1969/388; 1969 I, p. 1070), and in the case of the Department of Health and Social Services for Northern Ireland by virtue of section 40 of, and Schedule 5 to, the Northern Ireland Constitution Act 1973 (c. 36), and paragraph 2(1)(*b*) of Schedule 1 to the Northern Ireland Act 1974 (c. 28).

(**c**) S.I. 1975/2000 (1975 III, p. 7401).

Amendment of regulation 2 of the principal regulations

3. As from 1st January 1977 for regulation 2 of the principal regulations there shall be substituted the following regulation:—

"*Child resistant containers for aspirin and paracetamol*

2.—(1) This regulation shall apply to medicinal products consisting of or containing aspirin or paracetamol in dosage unit form of tablets, capsules, pills, lozenges, pastilles, cachets or suppositories for administration to human beings, not being effervescent tablets containing not more than 25 per cent of aspirin or of paracetamol by weight and not being such products assembled in containers not intended for use in the retail sale, or the supply in circumstances corresponding to retail sale, of such products and not being such products that are for exportation only.

(2) Subject to the exceptions specified in paragraphs (5) and (6) of this regulation, the sale or supply of medicinal products to which this regulation applies is hereby prohibited otherwise than in containers which comply with the requirements set out in the following paragraph.

(3) Subject to the condition set out in paragraph (4) of this regulation, the requirements referred to in the preceding paragraph are that the containers shall be child resistant containers, that is to say—

(*a*) containers in the form of bubbles, blisters or other sealed units consisting of paper, film, plastic material, metal foil or other sheet or strip material in which the dosage units are separately enclosed, whether they are part of a continuous series comprising a sheet or strip of like containers or not, being opaque or dark-tinted and selected with a view to their resistance to opening by children, or

(*b*) reclosable containers which are opaque or dark-tinted, identical in all respects to containers which comply with the requirements of British Standard 5321 published on 31st October 1975 as amended by AMD 2077 published on 16th August 1976 and in respect of which the licensing authority have been furnished with a report by the British Standards Institution enabling the licensing authority to publish a notice in the Gazette to the effect that the containers in question comply with the said Standard as so amended, or

(*c*) until 31st December 1977, reclosable containers identical in all respects to containers which meet the requirements imposed in a country other than the United Kingdom with regard to child resistant containers, where such requirements include tests that involve the participation of children, or

(*d*) containers possessing child resistant qualities which, by virtue of the relevant product licence, are required to be used for the sale or supply of any of the medicinal products in question, such product licence being a licence granted, or varied in that respect, subsequent to 1st January 1976.

(4) The condition referred to in the preceding paragraph is that, in respect of medicinal products to which this regulation applies and which are for administration exclusively to children, the total number of dosage units contained in reclosable containers referred to in paragraphs (3)(*b*) and (*c*) of this regulation or in packages in which containers referred to in paragraph 3(*a*) of this regulation are enclosed shall not exceed 25.

(5) The retail sale, or supply in circumstances corresponding to retail sale, of medicinal products to which this regulation applies shall not be prohibited by reason of paragraph (2) of this regulation where such sale or supply is by or under the supervision of a pharmacist on premises which are a registered pharmacy and is—

(*a*) in accordance with a prescription given by a practitioner, or

(*b*) at the request of a person, not being a child, who is present in the pharmacy at the time of the request and specifically requests that the product be not contained in a child resistant container.

(6) The sale or supply of medicinal products to which this regulation applies shall not be prohibited by reason of paragraph (2) of this regulation—

(*a*) where such sale or supply is by a doctor or dentist to a patient of his or to a person under whose care such a patient is, or

(*b*) where such sale or supply is by a doctor or dentist at the request of, and to, another doctor or dentist for administration to a particular patient of that other doctor or dentist, or

(*c*) where such sale or supply is in the course of the business of a hospital or health centre and 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 doctor or dentist, or

(*d*) if such medicinal products are not for administration exclusively to children and a product licence in respect thereof was granted prior to 1st January 1977—

(i) where the sale or supply is by a manufacturer, during the period until 30th June 1977, or

(ii) where the sale or supply is by retail or in circumstances corresponding to retail sale, not being at a registered pharmacy, during the period until 31st December 1977, or

(iii) where the sale or supply is at a registered pharmacy, during the period until 30th June 1978.".

David Ennals,
21st September 1976. Secretary of State for Social Services.

John Morris,
22nd September 1976. Secretary of State for Wales.

Bruce Millan,
27th September 1976. Secretary of State for Scotland.

Sealed with the official seal of the Department of Health and Social Services for Northern Ireland this 30th day of September 1976.

(L.S.)

N. Dugdale,
Permanent Secretary.

EXPLANATORY NOTE

(This Note is not part of the Regulations.)

These Regulations amend the Medicines (Child Safety) Regulations 1975, which prohibit the sale or supply of certain aspirin or paracetamol for administration exclusively to children other than in child resistant containers, by extending that prohibition as from 1st January 1977 to include aspirin or paracetamol for administration to all human beings.

Other amendments provide for exemption from the prohibition for sale or supply at registered pharmacies to persons not wishing to be supplied with such products in child resistant containers and for temporary exemptions for containers that comply with child safety requirements of other countries and for sale or supply in certain circumstances of existing stocks that are not exclusively for administration to children. The reference to British Standard 5321 is amended as from the coming into operation of these regulations so as to refer to that Standard as amended by AMD 2077 published on 16th August 1976.

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