STATUTORY INSTRUMENTS

1975 No. 2000

MEDICINES

The Medicines (Child Safety) Regulations 1975

Made - - -	*3rd December* 1975
Laid before Parliament	*11th December* 1975
Coming into Operation	*1st January* 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) Regulations 1975 and shall come into operation on 1st January 1976.

(2) In these regulations, unless the context otherwise requires, "the Act" means the Medicines Act 1968 and other expressions have the same meanings as in the Act.

(3) Except in so far as the context otherwise requires, any reference in these regulations to any provision of any enactment shall be construed as a reference to that provision as amended or extended by any enactment or instrument and as including a reference to any provision which may re-enact or replace it.

(4) The rules for the construction of Acts of Parliament contained in the Interpretation Act 1889(**c**) shall apply for the purposes of the interpretation of these regulations as they apply for the purposes of an Act of Parliament.

(**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**) 1889 c. 63.

Child resistant containers for children's 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 exclusively to children, not being effervescent tablets containing not more than 25 per cent of aspirin by weight and not being such products assembled in containers not intended for use in the retail sale, or supply in circumstances corresponding to retail sale, of such products.

(2) Subject to the exceptions specified in paragraphs (5) and (6) of this regulation, the sale or supply of the 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) below, 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 as aforesaid 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 and in respect of which the licensing authority have been furnished with a report of the test required by the said standard, signed by the person supervising the test, enabling the licensing authority to publish a notice in the Gazette to the effect that the containers in question comply with the said standard, or

(*c*) until 31st December 1976, 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*) any containers possessing child resistant qualities which, by virtue of the relevant product licence, are required to be used for the sale or supply of the medicinal products in question, such product licence being a licence granted, or varied in that respect, subsequent to the coming into operation of these regulations.

(4) The condition referred to in the preceding paragraph is that, in the case of reclosable containers referred to in paragraphs (3)(*b*) and (*c*) of this regulation and, in the case of packages in which containers referred to in paragraph (3)(*a*) are enclosed, the total number of dosage units as aforesaid contained in such containers or packages, as the case may be, shall not exceed 25.

(5) The prohibition imposed by paragraph (2) of this regulation shall be subject to the exception that the retail sale, or supply in circumstances corresponding to retail sale, of medicinal products to which this regulation applies

shall not, by virtue of that paragraph, be prohibited where such sale or supply is by or under the supervision of a pharmacist on premises which are a registered pharmacy and is either—

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

(*b*) in accordance with the pharmacist's own judgment as to the treatment required and such judgment has been exercised at the request of a parent or guardian of the child to whom the product is to be administered, where such parent or guardian 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 as aforesaid.

(6) The prohibition imposed by paragraph (2) of this regulation shall be subject to the further exceptions that the sale or supply of medicinal products to which this regulation applies shall not, by virtue of that paragraph, be prohibited—

(*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*) where the sale or supply involves or is for the purpose of exporting the products, or

(*e*) during the period until 31st December 1976, if the sale or supply is of such medicinal products as have been assembled in containers before 1st January 1976 and the number of dosage units as aforesaid in each such container does not exceed 25, or

(*f*) during the period until 30th June 1976, if the sale is a retail sale or the supply is in circumstances corresponding to retail sale and if the medicinal products in question were in the possession of the person so selling or so supplying those products before 1st November 1975.

Colouring of children's aspirin and paracetamol

3.—(1) Except in the circumstances specified in the following paragraph medicinal products consisting of or containing aspirin or paracetamol in dosage unit form of tablets, capsules, pills, lozenges, pastilles, cachets or suppositories for administration exclusively to children, not being effervescent tablets containing not more than 25 per cent of aspirin by weight and not being such products that are for exportation only, shall not be of any colour other than white.

(2) The circumstances referred to in the preceding paragraph are where the sale or supply, or the possession for such sale or supply, is of a product in respect of which all processes of manufacture had been completed before 1st January 1976 and where such sale or supply or such possession is during the period until and not later than 31st December 1976.

Offences

4. Any person who contravenes section 87(2) of the Act or these regulations shall be guilty of an offence and—

(*a*) shall be liable on summary conviction to a fine not exceeding £400, and

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

Barbara Castle,
Secretary of State for Social Services.

24th November 1975.

John Morris,
Secretary of State for Wales.

25th November 1975.

William Ross,
Secretary of State for Scotland.

2nd December 1975.

Sealed with the official seal of the Department of Health and Social Services for Northern Ireland this 3rd day of December 1975.

(L.S.)

N. Dugdale,
Permanent Secretary.

EXPLANATORY NOTE

(*This Note is not part of the Regulations.*)

These Regulations prohibit the sale or supply of certain children's aspirin or paracetamol other than in child resistant containers, which include opaque reclosable containers complying with British Standard 5321 and specially selected opaque unit packages in the form of bubbles, blisters or other sealed units. The regulations require children's aspirin or paracetamol to be white and limit the contents of each container or pack of unit packages to 25 dosage units. The requirements as to packaging do not apply to children's aspirin or paracetamol assembled in containers or packs not intended for retail sale and there are certain exceptions for sale or supply by doctors or dentists and for dispensing in hospitals, health centres or registered pharmacies. The export of children's aspirin or paracetamol is excepted from the requirements of these regulations and there are temporary provisions relating to certain existing stocks and to containers that comply with child safety requirements of other countries. Regulation 4 provides for offences and penalties.

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