## STATUTORY INSTRUMENTS

# 1979 No. 382

## **MEDICINES**

## The Medicines (Chloroform Prohibition) Order 1979

Made	28th March 1979
Laid before Parliament	28th March 1979
Coming into Operation	28th March 1980

The Secretaries of State respectively 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 section 62 of the Medicines Act 1968 and now vested in them(1) and of all other powers enabling them in that behalf, it appearing to them to be necessary in the interests of safety to make the following Order, after consulting such organisations as appear to them to be representative of interests likely to be substantially affected by the Order, and after consulting and taking into account the advice of the Committee on Safety of Medicines(2), and after taking into account the report of the Medicines Commission made under section 62(5) of that Act, hereby make the following Order:—

#### Citation, commencement and interpretation

**1.**—(1) This Order, which may be cited as the Medicines (Chloroform Prohibition) Order 1979, shall come into operation on 28th March 1980.

(2) In this Order, "the Act" means the Medicines Act 1968.

(3) In this Order a reference to a numbered Article is a reference to the Article of this Order bearing that number and a reference in a paragraph of an Article of this Order to a lettered sub-paragraph is a reference to the sub-paragraph of that paragraph bearing that letter.

### Prohibition of sale or supply of chloroform

**2.** Subject to the exceptions specified in Article 3 the sale or supply of any medicinal product consisting of or containing chloroform, not being a veterinary drug, is hereby prohibited.

<sup>(1)</sup> 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) 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 section 1(3) of, and paragraph 2(1)(b) of Schedule 1 to, the Northern Ireland Act 1974 (c. 28).

<sup>(2)</sup> S.I. 1970/1257.

### Exceptions

**3.**—(1) The prohibition imposed by Article 2 shall be subject to the exception that the sale or supply of any medicinal product described in that Article shall not by virtue of that Article be prohibited where such sale or supply is—

- (a) by a doctor or dentist to a patient of his and the medicinal product has been specially prepared by that doctor or dentist for administration to that particular patient, or
- (b) by a doctor or dentist who has specially prepared the medicinal product at the request of another doctor or dentist for administration to a particular patient of that other doctor or dentist, or
- (c) from a registered pharmacy or a hospital or by a doctor or dentist and the medicinal product has been specially prepared, in accordance with a prescription given by a doctor or dentist for a particular patient of his—
  - (i) in a registered pharmacy, or
  - (ii) in a hospital, or
  - (iii) by a doctor or dentist, or
  - (iv) by a person to whom there applies an exemption from the restrictions imposed by section 8(2) of the Act (restrictions as to manufacture or assembly) by virtue of Article 3 of the Medicines (Exemption from Licences) (Special and Transitional Cases) Order 1971.

(2) The prohibition imposed by Article 2 shall be subject to the additional exception that the sale or supply of any such medicinal product shall not be prohibited by virtue of that Article where such sale or supply is—

- (a) to a hospital or to a doctor or to a dentist for either or both of the following purposes, namely—
  - (i) solely for use by administration to human beings for the purpose of inducing anaesthesia, or
  - (ii) solely for use as an ingredient in the preparation of a substance or article to be administered to human beings for the purpose of inducing anaesthesia, or
- (b) to a person who buys or obtains it for the purpose of selling or supplying it to a hospital or to a doctor or to a dentist for either or both of the purposes described in sub-paragraph (a).

(3) The prohibition imposed by Article 2 shall be subject to the additional exceptions that the sale or supply or any such medicinal product shall not by virtue of that Article be prohibited in any one or more of the following circumstances, namely—

- (a) where such product contains chloroform in a proportion of not more than 0.5 per cent calculated in terms of weight in weight (w/w) or volume in volume (v/v) as appropriate, or
- (b) where such product is solely for use in dental surgery, or
- (c) without prejudice to sub-paragraph (b) where such product is for sale or supply solely for use by being applied to the external surface of the body.

(4) The prohibition imposed by Article 2 shall be subject to the additional exception that the sale or supply of any such medicinal product shall not by virtue of that Article be prohibited where the said sale or supply involves, or is for the purpose of, exporting the said medicinal product.

(5) The prohibition imposed by Article 2 shall be subject to the additional exception that the sale or supply of any such medicinal product shall not by virtue of that Article be prohibited where the medicinal product is for use as an ingredient in the preparation of any substance or article—

- (a) in a registered pharmacy, or
- (b) in a hospital, or

(c) by a doctor, or

(d) by a dentist.

(6) For the purposes of this Article the external surface of the body shall not include the mouth or any part of the mouth (including teeth) or the mucous membranes.

### **Transitional provisions**

4. The prohibition imposed by Article 2 shall not operate during a period of one year from the date of the coming into operation of this Order in the case of medicinal products consisting of or containing chloroform which have, before that date, been sold or supplied for retail sale or for supply in circumstances corresponding to retail sale.

28th March 1979

David Ennals Secretary of State for Social Services

28th March 1979

*John Morris* Secretary of State for Wales

26th March 1979

*Bruce Millan* Secretary of State for Scotland

Sealed with the official seal of the Department of Health and Social Services for Northern Ireland this 27th day of March 1979.

L.S.

*N. Dugdale* Permanent Secretary

## **EXPLANATORY NOTE**

This Order prohibits the sale or supply of medicinal products which are for human use and which consist of or contain chloroform.

The Order provides exemptions from the prohibition. These include-

(1) certain sales or supplies of medicinal products by medical and dental practitioners and from registered pharmacies and hospitals;

(2) the sale or supply of chloroform as an anaesthetic;

(3) the sale or supply of medicinal products where the chloroform content does not exceed specified limits, or for use in dental surgery, or solely for external use;

(4) the sale or supply or medicinal products for export;

(5) the sale or supply of chloroform for use as an ingredient, in specified circumstances, in the preparation of a substance or article.

Article 4 contains transitional provisions.