STATUTORY INSTRUMENTS

1979 No. 1181

MEDICINES

The Medicines (Phenacetin Prohibition) Order 1979

Made - - - -	14*th September* 1979
Laid before Parliament	27*th September* 1979
Coming into Operation	27*th March* 1980

The Secretary of State concerned with health in England, the Secretaries of State respectively concerned with health and with agriculture in Wales and in Scotland, the Minister of Agriculture, Fisheries and Food, the Department of Health and Social Services for Northern Ireland and the Department of Agriculture for Northern Ireland, acting jointly, in exercise of powers conferred by section 62 of the Medicines Act 1968(**a**) and now vested in them(**b**) 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 following order, and after consulting and taking into account the advice of the Committee on the Review of Medicines(**c**) 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 may be cited as the Medicines (Phenacetin Prohibition) Order 1979 and shall come into operation on 27th March 1980.

(2) In this Order—

"the Act" means the Medicines Act 1968;

"external use" means—

(*a*) in relation to medicinal products for use by being administered to human beings, application to the skin, hair, teeth, mucosa of the mouth, throat, nose, ear, eye, vagina or anal canal;

(*b*) in relation to veterinary drugs, application to the skin, hair, fur, feathers, scales, hoof, horn, ear, eye, mouth or mucosa of the throat or prepuce;

"phenacetin-only product" means a medicinal product of which phenacetin is the sole active ingredient; and

"the prohibition" means the prohibition imposed by Article 2 of this Order.

(**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), in the case of the Secretary of State concerned with agriculture in Wales by virtue of Article 2(3) of, and Schedule 1 to the Transfer of Functions (Wales) (No. 1) Order 1978 (S.I. 1978/272) and in the case of the Northern Ireland Departments 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).

(**c**) A committee established under section 4 of the Medicines Act 1968 by virtue of the Medicines (Committee on the Review of Medicines) Order 1975 (S.I. 1975/1006).

Prohibition of sale or supply of phenacetin

2. Subject to the exceptions specified in Article 3 of this Order, the sale, supply or importation of any medicinal product consisting of or containing phenacetin is hereby prohibited.

Exceptions to the prohibition

3.—(1) The prohibition is subject to the exceptions specified in the following paragraphs of this Article.

(2) The prohibition does not apply to the sale, supply or importation of a medicinal product for external use which contains phenacetin—

(*a*) only as a stabiliser for a solution of hydrogen peroxide comprising or contained in the medicinal product; and

(*b*) in a proportion calculated on the basis of weight in weight (w/w) in the medicinal product—

(i) where the medicinal product consists of a solution of hydrogen peroxide, of not more than 0·1 per cent;

(ii) where the medicinal product contains a solution of hydrogen peroxide, of not more than the equivalent of 0·1 per cent. in the solution of hydrogen peroxide.

(3) The prohibition does not apply to the sale or supply of a phenacetin-only product where the sale or supply is—

(*a*) by a doctor or dentist to a patient of his or to a person under whose care that patient is, and that product has been specially prepared by that doctor or dentist or by another doctor or dentist for administration to that particular patient; or

(*b*) by a doctor or dentist to and at the request of another doctor or dentist, and that product has been specially prepared for administration to a particular patient of that other doctor or dentist; or

(*c*) from a registered pharmacy by or under the supervision of a pharmacist, from a hospital or health centre, or by a doctor or dentist, and that product has been specially prepared in accordance with a prescription given by a doctor or dentist for administration to a particular patient of his; or

(*d*) to a doctor, a dentist, a hospital, a health centre or a person lawfully conducting a retail pharmacy business, and the sale or supply is one to which the restrictions imposed by section 7 of the Act (restrictions on dealing with medicinal products) do not apply by reason of Article 2(1) and (2) of the Medicines (Exemption from Licences) (Special and Transitional Cases) Order 1971(**a**) (exemption for certain specially manufactured products); or

(*e*) by the manufacturer to the person to whose order the product was manufactured for the purpose only of the subsequent sale or supply of that product in the circumstances specified in sub-paragraph (*d*) of this paragraph.

(4) The prohibition does not apply to the importation of a phenacetin-only product where that product is specially imported by or at the request of a doctor or dentist and has been specially prepared in accordance with a prescription given by that doctor or dentist for a particular patient of his, and the prohibition does not apply to the sale or supply of that imported product to that doctor or dentist.

(**a**) S.I. 1971/1450, amended by S.I. 1972/1200.

(5) The prohibition does not apply to the sale, supply or importation of a medicinal product where the medicinal product is sold, supplied or imported, as the case may be, for use only as an ingredient in the preparation of a substance or article in a registered pharmacy, in a hospital or by a doctor or dentist.

(6) The prohibition does not apply to the sale, supply or importation of a medicinal product where the sale or supply involves, or the sale, supply or importation is for the purpose of, exporting the medicinal product.

Patrick Jenkin,
Secretary of State for Social Services.

30th August 1979.

Nicholas Edwards,
Secretary of State for Wales.

30th August 1979.

George Younger,
Secretary of State for Scotland.

31st August 1979.

In witness whereof the official seal of the Minister of Agriculture, Fisheries and Food is hereunto affixed on 11th September 1979.

(L.S.)

Peter Walker,
Minister of Agriculture, Fisheries and Food.

Sealed with the official seal of the Department of Health and Social Services for Northern Ireland this 13th day of September 1979.

(L.S.)

N. Dugdale,
Permanent Secretary.

Sealed with the official seal of the Department of Agriculture for Northern Ireland this 14th day of September 1979.

(L.S.)

J. A. Young,
Permanent Secretary.

EXPLANATORY NOTE

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

This Order prohibits the sale, supply or importation of medicinal products which consist of or contain phenacetin.

The Order provides exceptions from the prohibition. These relate to—

(1) the sale, supply or importation of hydrogen peroxide solutions which include phenacetin as a stabiliser;

(2) sales or supplies in specified circumstances of certain medicinal products by and to doctors and dentists, and from and to registered pharmacies, hospitals and health centres;

(3) the importation in specified circumstances of certain medicinal products by or at the request of a doctor or dentist;

(4) the sale, supply or importation of phenacetin as an ingredient for use in specified circumstances;

(5) the sale or supply of medicinal products for export.

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