STATUTORY INSTRUMENTS

1973 No. 1120

MEDICINES

The Medicines (Hexachlorophane Prohibition) Order 1973

Made - - -	*25th June* 1973
Laid before Parliament	*4th July* 1973
Coming into Operation	*30th July* 1973

The Secretaries of State respectively concerned with health in England and in Wales, the Secretary of State concerned with health and with agriculture in Scotland, the Secretary of State for Northern Ireland and the Minister of Agriculture, Fisheries and Food, acting jointly, in exercise of the powers conferred by section 62(1) 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 taking into account the advice of the Committee on Safety of Medicines **(c)** and the advice of the Veterinary Products Committee **(d)**, hereby make the following order:—

Citation, commencement and interpretation

1.—(1) This order may be cited as the Medicines (Hexachlorophane Prohibition) Order 1973 and shall come into operation on 30th July 1973.

(2) In this order unless the context otherwise requires—

"the Act" means the Medicines Act 1968;

"hexachlorophane" means the substance for which such name is shown in the list of names prepared and published under section 100 of the Act, otherwise known as hexachlorophene or 2,2′-Methylenebis(3,4,6-trichlorophenol);

"soap" means any compound of a fatty acid with an alkali or amine;

and other expressions have the same meaning as in the Act.

(3) Except in so far as the context otherwise requires, any reference in this order to any enactment, regulation or order shall be construed as a reference to that enactment, regulation or order, as the case may be, amended or extended by any other enactment, regulation or order.

(a) 1968 c. 67.

(b) In the case of the Secretary of State concerned with health in Wales by virtue of the provisions 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 Secretary of State for Northern Ireland by virtue of the provisions of section 1(1)(*a*) of the Northern Ireland (Temporary Provisions) Act 1972 (c. 22).

(c) S.I. 1970/1257 (1970 I, p. 4098). **(d)** S.I. 1970/1304 (1970 I, p. 4335).

(4) The rules for the construction of Acts of Parliament contained in the Interpretation Act 1889(a) shall apply for the purposes of the interpretation of this order as they apply for the purposes of the interpretation of an Act of Parliament.

Provisions prohibiting sale, supply and importation

2.—(1) Subject to the following provisions of this order, the sale, supply and importation of any medicinal product containing hexachlorophane is hereby prohibited.

(2) The prohibition imposed by paragraph (1) of this Article shall be subject to the exceptions that—

(i) the sale, supply or importation shall not be prohibited in the case of a medicinal product, not being an aerosol, which contains—

(*a*) where the medicinal product is for use by being administered to human beings, 0·1% or less of hexachlorophane provided that the conditions specified in Article 3(i) of this order are satisfied, or

(*b*) where the medicinal product is for use by being administered to animals, 0·75% or less of hexachlorophane provided that the conditions specified in Article 3(ii) of this order are satisfied;

(ii) the sale, supply or importation shall not be prohibited in the case of a medicinal product, being an aerosol, the contents of the container of which shall be 0·1% or less of hexachlorophane provided that the conditions specified in Article 3(i) or Article 3(ii) of this order, as the case may be, are satisfied;

(iii) the sale, supply or importation shall not be prohibited in the case of a medicinal product for use by being administered to human beings, not being an aerosol, which contains 0·75% or less of hexachlorophane provided that the conditions specified in Article 3(i) of this order are satisfied and—

(*a*) the sale or supply is by a person lawfully conducting a retail pharmacy business at a registered pharmacy, or

(*b*) the sale or supply is by the manufacturer of such medicinal product—

(1) to a person lawfully conducting a retail pharmacy business, or

(2) to a person carrying on the business of wholesale dealing for sale to a person lawfully conducting a retail pharmacy business, or

(3) to a doctor or dentist, or

(4) to a hospital or health centre, or

(*c*) the sale is by way of wholesale dealing and is for sale or supply in the circumstances specified in (1) (2) (3) or (4) of (*b*) of this sub-paragraph, or

(*d*) in the case of importation, where the importation is for the purposes of sale or supply in the circumstances specified in (1) (2) (3) or (4) of (*b*) of this sub-paragraph;

(iv) the sale, supply or importation shall not be prohibited—

(*a*) in the case of the sale or supply of a medicinal product that is a soap in the form of a cake, tablet or bar which is for use by being administered to human beings, and which contains 2% or less of hexachlorophane provided that the conditions specified in Article

(a) 1889 c. 63.

3(i) of this order are satisfied and the label therein referred to contains the further words "Not to be used for whole-body bathing except on medical advice" and—

(1) the sale or supply is by a person lawfully conducting a retail pharmacy business at a registered pharmacy, or

(2) the sale or supply is by the manufacturer of such medicinal product—

(*aa*) to a person lawfully conducting a retail pharmacy business, or

(*bb*) to a person carrying on the business of wholesale dealing for sale to a person lawfully conducting a retail pharmacy business, or

(*cc*) to a doctor or dentist, or

(*dd*) to a hospital or health centre, or

(3) the sale is by way of wholesale dealing and is for sale or supply in the circumstances specified in (*aa*) (*bb*) (*cc*) or (*dd*) of (2) of this sub-paragraph;

(*b*) in the case of the sale or supply of a medicinal product that is a soap or shampoo, and is for use by being administered to animals, and which contains 2% or less of hexachlorophane provided that the conditions specified in Article 3(ii) of this order are satisfied;

(*c*) in the case of importation, where the importation is for the purposes of sale or supply of medicinal products to which (*a*) or (*b*) of this sub-paragraph refers.

(3) the prohibition imposed by paragraph (1) of this Article shall be subject to the further exceptions that the sale, supply or importation of a medicinal product containing hexachlorophane shall not be prohibited, provided that the conditions specified in Article 3(i) or Article 3(ii) of this order, as the case may be, are satisfied—

(*a*) where the 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 by a veterinary surgeon or veterinary practitioner for administration by him or under his direction to an animal or herd which is under his care, or

(*b*) where the 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 the sale or supply is by a veterinary surgeon or veterinary practitioner at the request of, and to, another veterinary surgeon or veterinary practitioner for administration to a particular animal or herd which is under the care of that other veterinary surgeon or veterinary practitioner, or

(*d*) where the sale or supply is by a person lawfully conducting a retail pharmacy business at a registered pharmacy and is in accordance with a prescription given by a practitioner, or

(*e*) where the 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

(*f*) where the sale is by way of wholesale dealing provided that the sale is—

(i) to another person carrying on the business of wholesale dealing, or

(ii) to a person lawfully conducting a retail pharmacy business, or

(iii) to a practitioner, or

(iv) to a hospital or health centre,

and the medicinal product is for sale or supply in any of the circumstances specified in (*a*) to (*e*) of this paragraph, or

(*g*) where the sale or supply is by the manufacturer of such medicinal product and the sale or supply is for the purpose of sale or supply in any of the circumstances specified in (*a*) to (*f*) of this paragraph, or

(*h*) where the sale or supply of a medicinal product is for use by being administered orally to sheep or cattle for the prevention or treatment of liver fluke disease, or

(*i*) in the case of importation, where the importation is for the purpose of sale or supply in the circumstances specified in any of the sub-paragraphs (*a*) to (*h*) of this paragraph, or

(*j*) where the sale or supply is to or by any of the following persons:—

(i) a public analyst appointed under section 89 of the Food and Drugs Act 1955**(a)**, section 27 of the Food and Drugs (Scotland) Act 1956**(b)** or section 31 of the Food and Drugs Act (Northern Ireland), 1958**(c)**;

(ii) a sampling officer within the meaning of the Food and Drugs Act 1955, the Food and Drugs (Scotland) Act 1956 or the Food and Drugs Act (Northern Ireland), 1958;

(iii) a sampling officer within the meaning of Schedule 3 of the Act;

(iv) an inspector appointed by the Pharmaceutical Society of Great Britain under section 25 of the Pharmacy and Poisons Act 1933**(d)**.

(4) The prohibition imposed by paragraph (1) of this Article shall be subject to the additional exception that the sale, supply or importation of a medicinal product containing hexachlorophane shall not be prohibited where the sale or supply involves, or the sale, supply or importation is for the purposes of, exporting the medicinal product.

(5) So long as section 12 of the Pharmacy and Poisons Act 1933 remains in force in its application to Great Britain, paragraphs 2 and 3 of this Article, insofar as those paragraphs relate to a registered pharmacy, shall apply to anything done by an authorised seller of poisons within the meaning of that Act at premises that are entered in the register kept under the said section 12.

(6) So long as section 17 of the Pharmacy and Poisons Act (Northern Ireland) 1925**(e)** remains in force paragraphs 2 and 3 of this Article, insofar as those paragraphs relate to a registered pharmacy, shall apply to anything that is done at premises for which an annual licence is in force under the said section 17.

Conditions

3. The conditions referred to in Article 2 of this order are that—

(i) in the case of a medicinal product for use by being administered to human beings, the container of the medicinal product shall bear a label

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(a) 1955 (4 & 5 Eliz. 2) c.16.
(b) 1956 c. 30.
(c) 1958 c. 27 (N.I.).
(d) 1933 c. 25.
(e) 1925 c. 8 (N.I.).

which shall contain the words "Not to be used for babies" or a warning that the medicinal product is not to be administered, except on medical advice, to a child under two years of age;

(ii) in the case of a medicinal product for use by being administered to animals, the container of the medicinal product shall bear a label which shall contain the words "For animal treatment only" and, where the medicinal product is for oral administration for the prevention or treatment of liver fluke disease in cattle, shall contain a warning that the medicinal product is not for use in lactating cattle and, where the medicinal product is for oral administration for the prevention or treatment of liver fluke disease in sheep or cattle, a statement that protective clothing must be worn by the operator when the medicinal product is being administered.

Temporary Provisions

4.—(1) The prohibition imposed by Article 2(1) of this order shall not operate during a period of six months from the date of the coming into operation of this order in the case of medicinal products containing hexachlorophane which have before that date been sold or supplied for retail sale or for supply in circumstances corresponding to retail sale, and which, under this order may be sold or supplied otherwise than in accordance with a prescription given by a practitioner.

(2) The conditions imposed by Article 3 of this order shall not operate for a period of six months from the date of the coming into operation of this order in the case of medicinal products containing hexachlorophane, when sold or supplied in accordance with a prescription given by a practitioner, provided that, before that date, such medicinal products have been sold or supplied to a person lawfully conducting a retail pharmacy business or to a hospital or health centre.

Keith Joseph,
Secretary of State for Social Services.

20th June 1973.

Peter Thomas,
Secretary of State for Wales.

20th June 1973.

Gordon Campbell,
Secretary of State for Scotland.

21st June 1973.

W. S. I. Whitelaw,
Secretary of State for Northern Ireland.

23rd June 1973.

In witness whereof the official seal of the Minister of Agriculture, Fisheries and Food is hereunto affixed on 25th June 1973.

(L.S.)

Joseph Godber,
Minister of Agriculture, Fisheries and Food.

EXPLANATORY NOTE.

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

This Order prohibits, subject to certain exceptions, the sale, supply and importation of medicinal products containing hexachlorophane. Exceptions are provided for various forms of medicinal product according to the amount of hexachlorophane in the medicinal product or in the container of the medicinal product and according to the channel of distribution, provided that there is compliance with labelling requirements. Further exceptions, not related to the amount of hexachlorophane are made by Article 2(3) provided that the sale, supply or importation takes place in the circumstances prescribed and provided that there is compliance with labelling requirements. Article 2(4) makes an exception for exports and Article 4 permits in certain circumstances and for a limited period, the retail sale of existing stock or its supply in circumstances corresponding to retail sale.

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