STATUTORY INSTRUMENTS

1978 No. 1461

MEDICINES

The Medicines (Exemption from Licences) (Importation) Order 1978

Made - - - -	*4th October* 1978
Laid before Parliament	*13th October* 1978
Coming into Operation	*3rd November* 1978

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 sections 13(2) and (3) and 15(1) and (2) of the Medicines Act 1968**(a)** and now vested in them**(b)** and of all other powers enabling them in that behalf, after consulting such organisations as appear to them to be representative of interests likely to be substantially affected by the following Order, hereby make the following Order:—

Citation, commencement and interpretation

1.—(1) This Order may be cited as the Medicines (Exemption from Licences) (Importation) Order 1978 and shall come into operation on 3rd November 1978.

(2) In this Order, 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 this Order to any enactment, order or regulations shall be construed as a reference to that enactment or order or to those regulations, as the case may be, as amended, extended or re-enacted by any other enactment, order or regulations.

(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 this Order as they apply for the purposes of the interpretation 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) 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).

(c) 1889 c. 63.

Exemption for certain medicinal products

2.—(1) The restrictions imposed by section 7 of the Act shall not apply to anything done by any person which relates to a medicinal product that is for human use and consists of—

(*a*) specially importing such medicinal product for sale or supply in the circumstances specified in paragraph (2) below or as stock for such sale or supply, or

(*b*) selling or supplying such imported medicinal product in the said specified circumstances,

subject however to the conditions specified in Article 3 of this Order.

(2) The circumstances specified for the purpose of paragraph (1) above are where the sale or supply is—

(*a*) to a doctor or dentist for administration to a particular patient of his, or

(*b*) by a hospital for use in accordance with a prescription given by a doctor or dentist for a particular patient of his, or

(*c*) by a person lawfully conducting a retail pharmacy business solely for sale or supply from a registered pharmacy to a particular person in accordance with a prescription given by a doctor or dentist naming that person, or

(*d*) by a wholesale dealer solely for the purpose of sale or supply in accordance with the circumstances specified in sub-paragraphs (*a*), (*b*) or (*c*) of this Article.

Conditions to be fulfilled

3. The conditions referred to in Article 2 above are that—

(*a*) the person who imports the medicinal product for human use notifies the licensing authority within 21 days of the first occasion upon which each particular description of such product is received for the purpose of sale or supply;

(*b*) the licensing authority has not directed that, upon the ground of safety, the exemption granted by this Order should not apply, or should cease to apply, in relation to a medicinal product for human use of a particular description;

(*c*) no advertisement or representation (in each case within the meaning of section 92 of the Act) relating to any medicinal product for human use is issued or made and that any sale or supply of such product in accordance with the exemption granted by this Order is in response to a bona fide unsolicited order;

(*d*) written records of the importation and sale and supply of the medicinal products for human use to which the exemption granted by this Order applies are kept and maintained, and are made available to the licensing authority or the enforcement authority on request by either authority;

(*e*) any person who holds stock of any medicinal product for human use to which the exemption granted by this Order applies shall store them

in such a way as to reduce to a minimum the risks of deterioration or contamination.

David Ennals,
Secretary of State for Social Services.

21st September 1978.

John Morris,
Secretary of State for Wales.

21st September 1978.

Bruce Millan,
Secretary of State for Scotland.

22nd September 1978.

Sealed with the official seal of the Department of Health and Social Services for Northern Ireland this 4th day of October 1978.

(L.S.)

J. H. Copeland,
Deputy Secretary.

EXPLANATORY NOTE

(This Note is not part of the Order.)

This Order exempts from the restrictions imposed by section 7 of the Medicines Act 1968 the importation and sale or supply of certain medicinal products for human use. The exemption is granted in accordance with the circumstances specified in the Order and is subject to the conditions specified in Article 3.

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