STATUTORY INSTRUMENTS

1984 No. 673

MEDICINES

The Medicines (Exemption from Licences) (Importation) Order 1984

Made - - - -	*14th May* 1984
Laid before Parliament	*16th May* 1984
Coming into Operation	*6th June* 1984

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 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 pursuant to section 129(6) of that Act, hereby make the following Order:—

Citation and commencement

1. This Order may be cited as the Medicines (Exemption from Licences) (Importation) Order 1984 and shall come into operation on 6th June 1984.

Interpretation

2.— (1) In this Order—

(*a*) "the Act" means the Medicines Act 1968;

"British approved name" means the name which appears in the current edition of the list prepared by the appropriate body in accordance with section 100 of the Act and published by the Ministers on the recommendation of the Medicines Commission;

"international non-proprietary name" means a name which has been selected by the World Health Organisation as a recommended

(**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).

international non-proprietary name and in respect of which the Director-General of the World Health Organisation has given notice to that effect in the World Health Organisation Chronicle;

"medicinal product" includes any article or substance specified in an order made under section 104 or section 105 of the Act which is for the time being in force and which directs that section 13(2) and (3) and section 15(1) and (2) of the Act shall have effect in relation to that article or substance (**a**), but does not include—

(i) a medicinal product which is a veterinary drug as defined in section 132(1) of the Act, or

(ii) an article or substance in respect of which section 13(2) and (3) and section 15(1) and (2) of the Act have such effect only where that article or substance is for administration to animals;

"monograph name" means the name or approved synonym which appears at the head of a monograph in the British Pharmacopoeia, the British Pharmaceutical Codex, the European Pharmacopoeia or a foreign or international compendium of standards;

(*b*) a reference to a numbered Article is to the Article of this Order bearing that number and a reference in an Article to a numbered paragraph is to the paragraph of that Article bearing that number.

(2) Section 127 of the Act applies to any notice required or authorised to be given or sent by any provision of this Order as it applies to any notice required or authorised to be given or sent by any provision of the Act.

(3) For the purpose of calculating any period of days referred to in this Order no account shall be taken of Christmas Day, Good Friday or a bank holiday in England under the Banking and Financial Dealings Act 1971(**b**).

Exemption from product licences for imported medicinal products in certain circumstances

3.— (1) Subject to the conditions specified in Article 4 and to the provisions of Article 5, the restrictions imposed by section 7 of the Act (restrictions as to dealing in medicinal products) shall not apply to anything done which consists of—

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

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

(2) The circumstances specified for the purposes of paragraph (1) are that—

(*a*) no product licence has been granted by the licensing authority for the purposes of section 7 of the Act to any person in respect of the

(**a**) *See* the Medicines (Control of Substances for Manufacture) Order 1971 (S.I. 1971/1200), the Medicines (Surgical Materials) Order 1971 (S.I. 1971/1267), the Medicines (Dental Filling Substances) Order 1975 (S.I. 1975/533) and the Medicines (Specified Articles and Substances) Order 1976 (S.I. 1976/968).

(**b**) 1971 c. 80.

medicinal product in question or, if such a licence has been granted, such medicinal product is not effectively on the market in the United Kingdom; and

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

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

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

(iii) by a person lawfully conducting a retail pharmacy business and is 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

(iv) by a wholesale dealer solely for the purpose of sale or supply in accordance with the circumstances specified in any of the preceding heads of this sub-paragraph.

Conditions

4.— (1) The exemption conferred by Article 3 is subject to the conditions that—

(*a*) the person importing a medicinal product which is the subject of that exemption has given or sent to the licensing authority, prior to each such importation, a notice in writing which states his intention to import that medicinal product for sale or supply in the circumstances specified in Article 3(2), or as stock for such sale or supply, and which states the following particulars—

(i) the name of that medicinal product, being the brand name, or the common name together with a trademark or name of the manufacturer, or the scientific name together with a trademark or name of the manufacturer, and any name, if different, under which that medicinal product is to be sold or supplied in the United Kingdom,

(ii) in respect of each active constituent of that medicinal product, the British approved name or the monograph name or the international non-proprietary name or, where that constituent does not have a British approved name or a monograph name or an international non-proprietary name, the accepted scientific name or any other name descriptive of the true nature of that constituent,

(iii) the quantity of that medicinal product which is to be imported, and

(iv) the name and address of the manufacturer or assembler of that medicinal product in the form in which it is to be imported or, if the person who will supply that medicinal product for importation is not the manufacturer or assembler, the name and address of such supplier;

(*b*) the person importing a medicinal product which is the subject of that exemption has given or sent to the licensing authority, together with the notice referred to in paragraph (1)(*a*) an undertaking in writing that—

(i) the quantity of that medicinal product which is imported in accordance with the notice referred to in paragraph (1)(*a*) does not exceed such quantity as will be sufficient for 25 single administrations or for 25 courses of treatment not exceeding 3 months;

(ii) he will inform the licensing authority forthwith of any matter coming to his attention which might reasonably cause the licensing authority to believe that that medicinal product can no longer be regarded either as a product which can safely be administered to human beings or as a product which is of satisfactory quality for such administration;

(iii) he will not at any time issue or cause another person to issue any advertisement or make any representation in respect of that medicinal product and that he will sell or supply that medicinal product only in response to a bona fide unsolicited order;

(iv) he will make and maintain written records
—in respect of the importation of that medicinal product, specifying the name and quantity of that medicinal product, the name and address of the manufacturer or assembler, or if different, the supplier and the date of such importation, and

—in respect of the sale or supply of that medicinal product, specifying the name and address of the person to whom that medicinal product is sold or supplied, the quantity and the date of such sale or supply,

and that he will make all such records available for inspection by the licensing authority on request during a period of five years from the date of the sale or supply of that medicinal product; and

(v) he will provide and maintain such premises, equipment and facilities for the storage of that medicinal product as are necessary to avoid its deterioration and will permit the licensing authority to inspect such premises on request;

(*c*) the licensing authority have not, before the end of the specified period, given or sent to the person proposing to import that medicinal product a notice in writing stating that the provisions of this Order shall not apply to anything which the said person proposes to do which consists of importing or selling or supplying that medicinal product because—

(i) any of the conditions specified in the preceding sub-paragraphs of this paragraph is not satisfied, or

(ii) the licensing authority have reasonable cause to believe that that medicinal product cannot be regarded as a product which can safely be administered to human beings or is not a product which is of satisfactory quality for such administration.

(2) In paragraph (1)(*c*) and Article 5(1), "the specified period" means the period of 28 days from the date on which the person proposing to import the medicinal product is given or sent an acknowledgment in writing by the licensing authority that they have received the notice referred to in paragraph (1)(*a*).

Coming into effect and termination of exemption

5.— (1) The exemption conferred by Article 3 shall take effect on the expiry of the specified period.

(2) The licensing authority may at any time, by notice in writing given or sent to the person importing the medicinal product which is the subject of the exemption conferred by Article 3, terminate that exemption on one or more of the following grounds, that is to say—

(*a*) that any of the matters stated in the notice referred to in Article 4(1)(*a*) was false or incomplete in a material particular;

(*b*) that the person importing that medicinal product is in breach of any part of the undertaking referred to in Article 4(1)(*b*);

(*c*) that the medicinal product which is the subject of that exemption can no longer be regarded either as a product which can safely be administered to human beings or as a product which is of satisfactory quality for such administration; or

(*d*) that a product licence has been granted for the purposes of section 7 of the Act to any person in respect of a medicinal product which is effectively on the market in the United Kingdom and which is the same as the medicinal product which is the subject of that exemption.

(3) The date on which the termination referred to in paragraph (2) shall take effect shall be such date as may be specified by the licensing authority in the notice referred to in that paragraph.

Revocation

6. The Medicines (Exemption from Licences) (Importation) Order 1978(**a**) is revoked.

Signed by authority of the Secretary of State for Social Services.

K. Clarke,
Minister of State,
Department of Health and Social Security.

9th May 1984.

Nicholas Edwards,
Secretary of State
for Wales.

10th May 1984.

(**a**) S.I. 1978/1461.

George Younger,
Secretary of State
for Scotland.

14th May 1984.

In witness whereof the official seal of the Minister of Agriculture, Fisheries and Food is hereunto affixed on 10th May 1984.

L.S.

Michael Jopling,
Minister of Agriculture,
Fisheries and Food.

Sealed with the official seal of the Department of Health and Social Services for Northern Ireland this 10th day of May 1984.

L.S.

Maurice N. Hayes,
Permanent Secretary.

Sealed with the official seal of the Department of Agriculture for Northern Ireland this 10th day of May 1984.

L.S.

J. C. Chalmers,
Under Secretary.

EXPLANATORY NOTE

(This Note is not part of the Order.)

This Order revokes and replaces the Medicines (Exemption from Licences) (Importation) Order 1978 (Article 6).

The Order grants exemption from restrictions imposed by section 7 of the Medicines Act 1968 on the importation, sale or supply of a medicinal product without a product licence. The Order applies only to medicinal products for human use. Article 3(1) provides for the exemption, which applies only in the circumstances specified in Article 3(2) and is subject to the conditions specified in Article 4. Article 5 provides for the coming into effect of the exemption and its termination.

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