
STATUTORY INSTRUMENTS

1977 No. 640

MEDICINES

**The Medicines (Importation of Medicinal Products
for Re-Exportation) Amendment Order 1977**

<i>Made</i>	- - - -	<i>31st March 1977</i>
<i>Laid before Parliament</i>		<i>14th April 1977</i>
<i>Coming into Operation</i>		<i>5th May 1977</i>

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 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 129(4) of the Medicines Act 1968 and now vested in them⁽¹⁾ 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, interpretation and commencement

1. This order, which may be cited as the Medicines (Importation of Medicinal Products for Re-exportation) Amendment Order 1977, shall be read as one with the Medicines (Importation of Medicinal Products for Re-exportation) Order 1971⁽²⁾ (hereinafter referred to as “the principal order”) and shall come into operation on 5th May, 1977.

Amendment of article 3 of the principal order

2.—(1) Article 3 of the principal order (removal of restriction on importation of certain medicinal products) shall be amended in accordance with the following paragraphs of this article.

(2) In paragraph (1) for the words “paragraph (2)” there shall be substituted the words “the following provisions”.

(3) For paragraph (2) there shall be substituted the following paragraph—

(1) 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(1969 I, p. 1070)), 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).

(2) (1971 II, p. 3790).

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“(2) The exemption conferred by paragraph (1) of this article shall take effect only in relation to medicinal products, articles and substances which, having been imported, are to be exported in the form in which they were imported and either—

- (a) they are not assembled in a way different from the way in which they were assembled on being imported, or
- (b) if they are assembled in a way different from the way in which they were assembled on being imported, the conditions specified in the following paragraphs of this article are satisfied.”.

(4) After paragraph (2) there shall be added the following two paragraphs—

“(3) The conditions referred to in sub-paragraph (b) above are—

- (a) that the person so assembling the medicinal products, articles and substances is the holder of a manufacturer's licence;
- (b) that the person to whom, but for the provisions of this order, the restrictions imposed by section 7(3) of the Act would apply, has notified the licensing authority of his intention to import the medicinal products, articles and substances and has supplied that authority with such information as to the medicinal products, articles and substances and their assembly as that authority may from time to time require; and
- (c) that the licensing authority have directed that the provisions of this article may apply to the importation of such products, articles and substances and the person referred to in sub-paragraph (b) of this paragraph has been notified in writing of that direction.

(4) Where after a direction under sub-paragraph (c) above has been notified it appears to the licensing authority that in the interests of safety the said exemption ought not to apply and the licensing authority have so notified the person referred to in sub-paragraph (c) above in writing, the said exemption shall not apply so long as the notification under this paragraph has not been withdrawn by the licensing authority.”.

Amendment of the Schedule to the principal order

3. In Part I of the Schedule to the principal order, for paragraphs 2 and 3 there shall be substituted the following two paragraphs:—

“**2.** Articles and substances to which any of the following orders apply, that is to say:—

- The Medicines (Control of Substances for Manufacture) Order 1971**(3)**;
- The Medicines (Surgical Materials) Order 1971**(4)**;
- The Medicines (Dental Filling Substances) Order 1975**(5)**; and
- The Medicines (Specified Articles and Substances) Order 1976**(6)**.

3. Articles and substances to which any order made under sections 104 or 105 of the Act subsequent to the coming into force of this order applies, being an order by virtue of which the provisions of sections 7(3) and 13(2) and (3) have effect in relation to such articles and substances as those provisions have effect in relation to medicinal products within the meaning of the Act.”.

(3) S.I. 1971/1200 (1971 II, p. 3506).

(4) S.I. 1971/1267 (1971 II, p. 3632).

(5) S.I. 1975/533 (1975 I, p. 1754).

(6) S.I. 1976/968 (1976 II, p. 2544).

23rd March 1977

David Ennals
Secretary of State for Social Services

23rd March 1977

John Morris
Secretary of State for Wales

30th March 1977

Bruce Millan
Secretary of State for Scotland

In witness whereof the official seal of the Minister of Agriculture, Fisheries and Food is hereunto affixed on 30th March 1977.

L.S.

John Silkin
Minister of Agriculture, Fisheries and Food

Sealed with the official seal of the Department of Health and Social Services for Northern Ireland this 31st day of March 1977.

L.S.

N. Dugdale
Permanent Secretary

Sealed with the official seal of the Department of Agriculture for Northern Ireland this 31st day of March 1977.

L.S.

J.A. Young
Permanent Secretary

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EXPLANATORY NOTE

This Order amends the Medicines (Importation of Medicinal Products for Re-exportation) Order 1971 by adding to the cases to which the exemption (conferred by the Order of 1971) from the requirement to hold a product licence applies.

The cases so added are cases where the medicinal products, articles and substances referred to in Part I of the Schedule to the Order of 1971, being imported for re-export in the form in which they were imported, are assembled in a way different from the way in which they were assembled on being imported. The exemption applies only if certain specified conditions are satisfied. Part I of the Schedule is amended so as to include in the exemption articles and substances to which sections 7(3) and 13(2) and (3) of the Medicines Act 1968 have been or will be applied by orders made under sections 104 or 105 of that Act.