1989 No. 1184

MEDICINES

The Medicines (Exemption from Licences) (Special and Transitional Cases) Amendment Order 1989

Made	-	-	7th July 1989
Laid before Parliament	-	-	11th July 1989
Coming into force for all purposes except article 4 for the purposes of article 4 -	-	-	1st August 1989 1st February 1990

The Secretary of State concerned with health in England, the Secretaries of State respectively concerned with health and with agriculture in Scotland and in Wales, 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 the powers conferred on them by sections 15(1) and (2) and 129(4) of the Medicines Act 1968(a), and the Secretaries of State concerned with health in England, Scotland and Wales and the Department of Health and Social Services for Northern Ireland, acting jointly, in exercise of the powers conferred on them by sections 25(1) and (2) and 129(4) of the Medicines Act 1968(a), and the Secretaries of State concerned with health in England, Scotland and Wales and the Department of Health and Social Services for Northern Ireland, acting jointly, in exercise of the powers conferred on them by sections 62 and 129(4) of that Act, and now vested in them(b) and of all other powers enabling them in that behalf and 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 and after consulting and taking into account the advice of the Medicines Commission pursuant to sections 62(3) and 129(7) of that Act, hereby make the following Order:

Citation and commencement

1.—(1) This Order may be cited as the Medicines (Exemption from Licences) (Special and Transitional Cases) Amendment Order 1989.

(2) Except as provided in article 4, this Order shall come into force on 1st August 1989.

Amendment of the Medicines (Exemption from Licences) (Special and Transitional Cases) Order 1971

2.—(1) The Medicines (Exemption from Licences) (Special and Transitional Cases) Order 1971(c) shall be amended in accordance with the following provisions of this article.

(2) In article 2 of that Order (exemption from product licences for certain special manufactured products):—

- (a) in paragraph (1) for the words "and manufacture" there shall be substituted the words ", manufacture or assembly";
- (b) in paragraph (2)(ii) the words "or assembles" shall be added after the word "manufactures";

⁽a) 1968 c.67; by virtue of section 132(1) of the Act the expression "the appropriate Ministers" is to be construed in accordance with section 1(2) of that Act.

⁽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); 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) S.I. 1971/1450, the relevant amending instrument is S.I. 1972/1200.

- (c) In paragraph (2)(iii) and (iv) the words "or assembly" shall be added after the word "manufacture";
- (d) in paragraph 2(v)-
 - (i) the words "or assembled" shall be added after the word "manufactured"; and
 - (ii) the words "or assembly" shall be added after the word "manufacture".

(3) Article 3 of that Order (exemption from manufacturer's licences for products manufactured in certain circumstances) shall be revoked.

Consequential amendments

3. The Medicines (Chloroform Prohibition) Order 1979(a) shall be amended by omitting---

- (a) the final ", or " in article 3(1)(c)(iii);
- (b) article 3(1)(c)(iv) (exceptions to Prohibition Order).

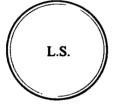
Deferred commencement where directions currently in force

4. For the purposes of any case where a direction issued pursuant to article 3 of the Medicines (Exemption from Licences) (Special and Transitional Cases) Order 1971 is in force on 31st July 1989, the revocation made by article 2 and the amendments made by article 3 shall come into force on 1st February 1990.

Signed by authority of the Secretary of State for Health

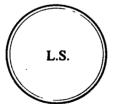
6th July 1989	D. Mellor Minister of State, Department of Health
6th July 1989	P. Walker Secretary of State for Wales
5th July 1989	M. B. Forsyth Parliamentary Under Secretary of State, Scottish Office

In witness whereof the Official Seal of the Minister of Agriculture, Fisheries and Food is hereunto affixed on 7th July 1989.



John MacGregor Minister of Agriculture, Fisheries and Food

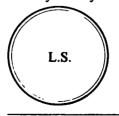
Sealed with the Official Seal of the Department of Health and Social Services for Northern Ireland this 7th day of July 1989.



F. A. Elliot Permanent Secretary

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Sealed with the Official Seal of the Department of Agriculture for Northern Ireland this 7th day of July 1989.



W. J. Hodges Permanent Secretary

(a) S.I. 1979/382, to which there are no relevant amending instruments.

EXPLANATORY NOTE

(This note is not part of the Order)

This Order amends the Medicines (Exemption from Licences) (Special and Transitional Cases) Order 1971 ("the 1971 Order") by—

- (a) extending the product licence exemption in article 2 to the holder of a manufacturer's licence which relates only to the assembly of special manufactured products (article 2(1) and (2)); and
- (b) revoking article 3 which exempted manufacturers in certain circumstances from the requirement imposed by section 8(2) of the Medicines Act 1968, to hold a manufacturer's licence (article 2(1) and (3)).

Article 3 of this Order provides for the consequential deletion of references to article 3 of the 1971 Order in article 3(1)(c)(iv) of the Medicines (Chloroform Prohibition) Order 1979 (prohibition except in prescribed circumstances of the sale or supply of any medicinal product consisting of or containing chloroform, not being a veterinary drug).

Articles 1(2) and 4 of this Order provide, in the case of a direction issued pursuant to article 3 of the 1971 Order which is in force on 31st July 1989, that the revocation made by article 2 and the amendments made by article 3 shall not have effect until the 1st February 1990.

Reference should also be made to the Medicines (Data Sheet and Labelling) Amendment Regulations 1989 (S.I. 1989/1183) for further amendments consequential upon the revocation of article 3 of the 1971 Order.