

1989 No. 2322

MEDICINES

The Medicines (Exemption from Licences) (Wholesale Dealing) Order 1989

<i>Made</i> - - - -	<i>8th December 1989</i>
<i>Laid before Parliament</i>	<i>11th December 1989</i>
<i>Coming into force</i>	<i>1st January 1990</i>

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 by section 15(1) and 129(4) 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 in accordance with section 129(6) of that Act, hereby make the following Order:—

Title, commencement and interpretation

1.—(1) This Order may be cited as the Medicines (Exemption from Licences) (Wholesale Dealing) Order 1989 and shall come into force on 1st January 1990.

(2) In this Order, unless the context otherwise requires —

“the Act” means the Medicines Act 1968;

“intermediate feed” means a medicated feeding stuff sold, supplied or imported for use wholly or mainly as an ingredient in the preparation of a substance which is to be fed to one or more animals for a medicinal purpose or for purposes that include that purpose, with or without further processing;

“medicinal product” includes:

- (a) substances or articles specified in Orders made under section 104 or section 105 of the Act which are for the time being in force and which direct that Part II of the Act shall have effect in relation to such substances or articles as that Part has effect in relation to medicinal products within the meaning of the Act;

(a) 1968 c.67; “the appropriate Ministers” referred to in section 15(1) is defined in section 1 (*see also following footnote*).

(b) In the case of the Secretaries of State concerned with health in England and in Wales by virtue of S.I. 1969/388, in the case of the Secretary of State concerned with agriculture in Wales by virtue of S.I. 1978/272 and in the case of the Northern Ireland Departments by virtue of the Northern Ireland Constitution Act 1973 (c.36), section 40 and Schedule 5, and the Northern Ireland Act 1974 (c.28), section 1(3) and Schedule 1, paragraph 2(1)(b).

- (b) articles or substances described in paragraphs 2 and 3 of Schedule 1 to the Medicines (Specified Articles and Substances) Order 1976(a); and
- (c) intermediate feed;

“proprietary medicinal product” and “ready-made veterinary drug” have the same meanings as in sections 7(7) and 8(4) of the Act(b)

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 or Order shall be construed as a reference to that enactment or Order as the case may be amended or extended by any other enactment or Order.

Exemption from wholesale dealer's licences

2.—(1) The restrictions imposed by section 8(3) of the Act (restrictions as to wholesale dealing) shall not apply to the sale or offer for sale of a medicinal product by way of wholesale dealing where such sale or offer for sale is either –

- (a) by the holder of a product licence which relates to that medicinal product, including such holder of such product licence who is the person who assembled that medicinal product, or
- (b) by a person who, not being the holder of such a product licence, assembled that medicinal product, where such assembly was to the order of a person who is the holder of such a product licence,

provided that throughout the period until such sale that medicinal product has not left the premises of any person who either manufactured or assembled that medicinal product being premises which by virtue of the relevant manufacturer's licence the person who so manufactures or, as the case may be, assembles that medicinal product is enabled or authorised to use for the purposes of that licence (hereinafter in this article referred to as “the authorised premises”).

(2) For the purposes of this article a medicinal product shall not be regarded as having left the authorised premises whilst that medicinal product is being moved from any of the authorised premises to another, or from one part of the authorised premises to another part, or whilst it is being moved from any of the authorised premises by way of delivery to the purchaser.

(3) The restriction imposed by section 8(3)(b) of the Act (wholesale dealer's licences) shall not apply in relation to anything done in relation to a proprietary medicinal product or a ready-made veterinary drug which has been imported when it is done by a person who handles the medicinal product –

- (a) in the course of the provision of facilities solely for the transport of the medicinal product, or
- (b) in the course of a business carried on by him as an import agent where he imports the medicinal product solely to the order of another person who intends, in the course of a business carried on by him, to sell, or offer for sale the medicinal product by way of wholesale dealing or in any other way intends to distribute the medicinal product.

Revocation

3. The Medicines (Exemption from Licences) (Wholesale Dealing) Order 1972(c), the Medicines (Exemption from Licences) (Wholesale Dealing) Order 1977(d) and the Medicines (Exemption from Licences) (Wholesale Dealing) Amendment Order 1983(e) are hereby revoked.

(a) S.I. 1976/968. The articles and substances described in paragraph 2 of Schedule 1 to that Order are contact lenses and intra-uterine contraceptive devices.

(b) Sections 7(7) and 8(4) were inserted by S.I. 1977/1050 and S.R. (N.I.) 1977 No. 170 and amended by S.I. 1983/1724.

(c) S.I. 1972/640

(d) S.I. 1977/1054

(e) S.I. 1983/1728

8th December 1989

Kenneth Clarke
Secretary of State for Health

7th December 1989

Sanderson of Bowden
Minister of State, Scottish Office

8th December 1989

Peter Walker
Secretary of State for Wales

In Witness whereof the Official Seal of the Minister of Agriculture, Fisheries and Food is hereunto affixed on 7th December 1989



John Gummer
Minister of Agriculture, Fisheries and Food

Sealed with the Official Seal of the Department of Health and Social Services for Northern Ireland this 8th day of December 1989



Under Secretary
on behalf of the Permanent Secretary

Sealed with the Official Seal of the Department of Agriculture for Northern Ireland this 8th day of December 1989



W. J. Hodges
Permanent Secretary

EXPLANATORY NOTE

(This note is not part of the Order)

This Order revokes and re-enacts the provisions of the Medicines (Exemption from Licences) (Wholesale Dealing) Orders 1972, 1977 and 1983. The Order continues to exempt from restrictions imposed by section 8(3) of the Medicines Act 1968 as to wholesale dealing in medicinal products (except in accordance with a licence granted under that Act) the sale or offer for sale by way of wholesale dealing of a medicinal product by the product licence holder or by the person who assembled that medicinal product to the order of the licence holder, where the product has not left the premises of a licensed manufacturer or assembler throughout the period until the sale of that medicinal product.

The Order continues to exempt from the restrictions imposed by section 8(3)(b) of that Act as to the sale or offer for sale of medicinal products by way of wholesale dealing and the distribution (otherwise than by way of sale) of any proprietary medicinal product or ready-made veterinary drug imported from outside the European Economic Community, except in accordance with a licence under the Act, anything done by a person solely in the provision of transport facilities or in the course of his business as an import agent.

In addition, this Order further extends the meaning of "medicinal product" to include "intermediate feed" (as defined in article 1(2)).

90p net

ISBN 0 11 098322 X