STATUTORY INSTRUMENTS

1979 No. 1114

MEDICINES

The Medicines (Exemption From Licences) (Assembly) Order 1979

Made - - - -	*24th August 1979*
Laid before Parliament	*12th September 1979*
Coming into Operation	*2nd October 1979*

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 section 15(1) and (2) 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, commencement and interpretation

1.—(1) This Order may be cited as the Medicines (Exemption from Licences) (Assembly) Order 1979 and shall come into operation on 2nd October 1979.

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

"the Act" means the Medicines Act 1968;

"assemble" means to label the container in which a medicinal product is already enclosed and in which it is to be sold or supplied before the product is sold or supplied in it, and "assembly" has a corresponding meaning;

"exemption" means exemption from the restrictions imposed by section 8(2) of the Act;

"registering body" means any professional body whose members customarily administer medicinal products to human beings in the course of their profession and which is required by law to maintain a register of its members.

(3) In this Order, unless the context otherwise requires, any reference to a numbered Article is a reference to the Article of this Order bearing that number and any reference in an Article to a numbered paragraph is a reference to the paragraph of that Article bearing that number.

(**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) 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).

Exemption from manufacturer's licences for assembly

2.—(1) The restrictions imposed by section 8(2) of the Act (licences for manufacture or assembly) shall not apply to the assembly of any medicinal product where the conditions specified in paragraph (2) are satisfied.

(2) The conditions referred to in paragraph (1) are that—

(a) the medicinal product is for human use and may be lawfully sold by retail or supplied in circumstances corresponding to retail sale otherwise than by or under the supervision of a pharmacist, except where the product may be so sold or supplied by virtue only of the provisions of Article 2 of the Medicines (Pharmacy and General Sale—Exemption) Order 1977(**2**) (transitional exemptions on certain conditions for products not on a general sale list);

(b) the medicinal product is to be sold or supplied—

(i) by a person who is either a member of a registering body or customarily administers medicinal products to human beings in the course of a business in the field of osteopathy, chiropody, naturopathy or other similar field, and

(ii) in circumstances where the person selling or supplying it sells or supplies it for administration to a particular person after being requested by or on behalf of that person and in that person's presence to use his own judgement as to the treatment required; and

(c) a notification in writing has been received by the licensing authority from the person seeking exemption under this Order or from a registering body of which he is a member, containing the name of that person and the address at which he proposes to carry out the assembly of any medicinal product in relation to which the provisions of sub-paragraphs (a) and (b) of this paragraph are satisfied.

Coming into effect and duration of exemption

3.—(1) Any exemption under the provisions of this Order shall have effect from the date of a direction in writing that it shall do so from the licensing authority to the person seeking exemption or a registering body of which he is a member.

(2) Subject to the provisions of Article 2(1) and 4, any such exemption applying to a person not being a member of a registering body shall continue in force for a period of five years from the date on which it has effect. If before the end of such a period the licensing authority receive from that person a further notification in the form described in Article 2(2)(c), that exemption shall continue in force for a further period of five years and the licensing authority shall notify him accordingly.

Termination of exemption by the licensing authority

4.—(1) The licensing authority may direct that any exemption under the provisions of this Order shall cease to have effect, either wholly or to such extent as they consider appropriate, by giving notice in accordance with the provisions of paragraph (3) specifying the date from which and the extent to which that exemption shall cease to have effect, in any of the circumstances specified in paragraph (2).

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

(a) where it appears to the licensing authority at any time that on grounds of safety an exemption should cease to apply to a particular person either wholly or in respect of certain medicinal products; or

(**2**) , to which there are amendments not relevant to this Order.

(b) where any person not being a member of a registering body has been requested in writing by the licensing authority to furnish particulars in writing of any medicinal products being assembled by him to which an exemption applies and has failed to furnish those particulars within 21 days of the date of such request or within such further time as the licensing authority may in a particular case allow; or

(c) where any person not being a member of a registering body has failed to notify the licensing authority in writing within 21 days of any change in the address at which he is assembling any medicinal product to which an exemption applies.

(3) Notice under paragraph (1) shall be given in writing to the person to whom exemption relates, save that where paragraph (2)(a) applies and that person is a member of a registering body notice in writing may be given instead to that body.

Patrick Jenkin
27th July 1979 — Secretary of State for Social Services

Nicholas Edwards
31st July 1979 — Secretary of State for Wales

George Younger
10th August 1979 — Secretary of State for Scotland

Sealed with the official seal of the Department of Health and Social Services for Northern Ireland this 24th day of August 1979.

L.S.

N. Dugdale
Permanent Secretary

EXPLANATORY NOTE

This Order exempts certain medicinal products for human use from the restrictions imposed by section 8(2) of the Medicines Act 1968 on the labelling without a manufacturer's licence of any medicinal product. The Order specifies the persons to whom and the conditions upon which exemption is granted, its duration in certain cases and the circumstances in which it may be terminated by the licensing authority.