STATUTORY INSTRUMENTS

1979 No. 1114

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

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(1) (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.

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