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STATUTORY INSTRUMENTS

1971 No. 1450

The Medicines (Exemption from Licences) (Special and Transitional Cases) Order 1971

Exemption from manufacturer's licences for products manufactured in certain circumstances

3.—(1) The restrictions imposed by section 8(2) of the Act (restriction as to manufacture and assembly) shall not apply to the manufacture or assembly of any medicinal product in any of the circumstances specified in paragraph (2) of this Article provided that the person who so manufactures or so assembles—

(a) is the holder of a manufacturer's licence in respect of the manufacture or assembly of medicinal products in circumstances other than those specified in the said paragraph (2), and

(b) has notified the licensing authority of his intention to manufacture or assemble as the case may be, medicinal products in circumstances specified in the said paragraph (2) and has supplied that authority with such information as to the medicinal products and their manufacture or assembly as that authority may from time to time require,

and provided that the licensing authority has directed that the provision of this Article may apply to such manufacture or assembly.

(2) The circumstances referred to in the preceding paragraph in relation to the manufacture or assembly of any medicinal product are circumstances in which—

(a) a medicinal product is assembled in accordance with a product licence in respect of that medicinal product, where that licence has not been granted to the person who so assembles nor to the person to whose order the medicinal product is assembled, but has been granted to some other person, or

(b) the manufacture or assembly of the medicinal product is—

(i) to the order of the Crown, or

(ii) under the supervision of a pharmacist to the order of any person for administration to that person or any person under his care in circumstances where that product may lawfully be supplied otherwise than to a practitioner's prescription,

and in which the person who so manufactures or assembles that medicinal product is not required to be the holder of a product licence in respect of that product under the provisions of the Act.