STATUTORY INSTRUMENTS

1977 No. 161

MEDICINES

The Medicines (Exemption from Licences) (Medicinal Tests on Animals) Order 1977

Made - - -	31*st January* 1977
Laid before Parliament	11*th February* 1977
Coming into Operation	4*th March* 1977

The Secretaries of State respectively concerned with health in England and in Wales, the Secretary of State concerned with health and with agriculture in Scotland, 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 powers conferred by sections 13(2) and (3), 15(1) and (2), 35(8)(*b*) and (9) 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, hereby make the following order:—

Citation, commencement and interpretation

1.—(1) This order may be cited as the Medicines (Exemption from Licences) (Medicinal Tests on Animals) Order 1977 and shall come into operation on 4th March 1977.

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

"the Act" means the Medicines Act 1968, and other expressions have the same meanings as in the Act;

"medicinal product" shall not include substances or articles specified in orders made under sections 104 or 105(1)(*b*) of the Act which are for the time being in force unless such order specifically directs that this order has effect in relation to such substances or articles as this order has effect in relation to medicinal products within the meaning of 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 amended or extended by any other enactment or order.

(**a**) 1968 c. 67.

(**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 (1969 I, p. 1070)), and 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 of, and paragraph 2(1)(*b*) of Schedule I to, the Northern Ireland Act 1974 (c. 28).

(4) The rules for the construction of Acts of Parliament contained in the Interpretation Act 1889(**a**) shall apply for the purposes of the interpretation of this order as they apply for the purposes of the interpretation of an Act of Parliament.

Exemptions in respect of medicinal tests on animals

2.—(1) The following provisions of this Article may have effect in relation only to medicinal products in respect of which there is in force a product licence and which are manufactured in accordance with that product licence (hereinafter in this Article referred to as "the relevant product licence").

(2) Subject to Article 3 of this order, the restrictions imposed by sections 7 and 32 of the Act shall not apply to anything done in relation to medicinal products of a particular description which consists of—

(*a*) selling or supplying, or procuring the sale, supply, manufacture or assembly of, or importing, medicinal products of that description for the purposes of a medicinal test on animals, or

(*b*) administering medicinal products of that description to an animal by way of a medicinal test on animals or procuring such medicinal products to be so administered,

if the conditions specified in paragraph (3) of this Article are satisfied.

(3) The conditions referred to in the preceding paragraph are that—

(*a*) the provisions of the relevant product licence, in so far as such provisions relate to manufacture, testing, maintenance of records or adverse reactions or effects, are complied with by the person so selling or supplying, so procuring or so importing,

(*b*) the medicinal products are to be administered in accordance with those particulars of the relevant product licence which relate to indications for which the products are to be administered, the dosage, and the method or routes of administration and with regard to any directions, contra-indications or warnings contained in the relevant product licence, and

(*c*) the person who makes arrangements for or requests the carrying out of the test in question notifies the licensing authority of any adverse reactions or effects or of any unexplained or unexpected absence of any effects associated with the administration of the medicinal products in relation to which the exemption conferred by this Article applies.

Further conditions

3. The exemptions conferred by Article 2 of this order shall not apply if, and so long as, the licensing authority are of the opinion that in the interests of safety the said exemptions should not apply and if the licensing authority have so notified any and every person whose activities in relation to the medicinal product in question would have been exempt by virtue of the said exemptions but for the provisions of this paragraph, and so long as such notification has not been withdrawn by the licensing authority.

Variation of Article 4 *of the Medicines (Exemption from Licences) (Special Cases and Miscellaneous Provisions) Order* 1972

4. The exemptions conferred by Article 4(1) of the Medicines (Exemption from Licences) (Special Cases and Miscellaneous Provisions) Order 1972(**b**), in so far as those exemptions apply to medicinal tests on animals shall not

(**a**) 1889 c. 63.
(**b**) S.I. 1972/1200 (1972 II, p. 3553).

apply if, and so long as, the licensing authority are of the opinion that in the interests of safety the said exemptions shall not apply and if the licensing authority have so notified any and every person whose activities in relation to the medicinal products in question would have been exempt by virtue of the said exemptions but for the provisions of this paragraph, and so long as such notification has not been withdrawn by the licensing authority.

25th January 1977.

David Ennals,
Secretary of State for Social Services.

27th January 1977.

John Morris,
Secretary of State for Wales.

26th January 1977.

Bruce Millan,
Secretary of State for Scotland.

In Witness whereof the Official Seal of the Minister of Agriculture, Fisheries and Food is hereunto affixed on 21st January 1977.

(L.S.)

John Silkin,
Minister of Agriculture, Fisheries and Food.

Sealed with the Official Seal of the Department of Health and Social Services for Northern Ireland this 31st day of January 1977.

(L.S.)

N. Dugdale,
Permanent Secretary.

Sealed with the Official Seal of the Department of Agriculture for Northern Ireland this 31st day of January 1977.

(L.S.)

J. A. Young,
Permanent Secretary.

EXPLANATORY NOTE

(*This Note is not part of the Order.*)

This Order exempts from those restrictions imposed by Part II of the Medicines Act 1968 concerning medicinal tests on animals, certain dealings and activities involving medicinal products in respect of which there is in force a product licence. The exemptions apply only if certain specified conditions are satisfied or complied with.

The Order also varies Article 4 of the Medicines (Exemption from Licences) (Special Cases and Miscellaneous Provisions) Order 1972 so as to provide that when, in the interests of safety, the licensing authority have notified the persons concerned, the exemptions conferred by that Article shall not apply in relation to medicinal tests on animals.

SI 1977/161
ISBN 0-11-070161-5

