Medicines Act 1968

1968 CHAPTER 67

PART II

LICENCES AND CERTIFICATES RELATING TO MEDICINAL PRODUCTS

Clinical trials and medicinal tests on animals

35 Supplementary provisions as to clinical trials and medicinal tests on animals.

(1) The restrictions imposed by section 7 of this Act do not apply to anything done in accordance with a clinical trial certificate or an animal test certificate.

(2) The restrictions imposed by section 8(2) of this Act—

(a) do not apply to the manufacture or assembly of any medicinal product for the sole purpose of its being administered by way of a clinical trial, or of its being sold, supplied or exported for the sole purpose of being so administered, and

(b) do not apply to the manufacture or assembly of any medicinal product for the sole purpose of its being administered by way of a medicinal test on animals, or of its being sold, supplied or exported for the sole purpose of its being so administered, unless the product falls within a class of medicinal products specified in an order made for the purposes of this paragraph by the Agriculture Ministers.

(3) No class of medicinal products shall be specified in an order for the purposes of paragraph (b) of subsection (2) of this section unless it appears to the Agriculture Ministers to be requisite to do so for securing that the exemption conferred by that paragraph does not apply to medicinal products consisting wholly or partly of substances the purity or potency of which cannot, in their opinion, be adequately tested by chemical means.

(4) Neither the restrictions imposed by section 7 of this Act nor those imposed by section 31(2) of this Act apply to anything done exclusively for the purpose of a clinical trial which is to be carried out wholly outside the United Kingdom; and neither the restrictions imposed by section 7 of this Act nor those imposed by section 32(1)

of this Act apply to anything done in relation to a medicinal product for the purposes of a medicinal test on animals which is to be carried out wholly outside the United Kingdom, unless the product falls within a class specified in an order made for the purposes of subsection (2)(b) of this section.

(5) Where the holder of a manufacturer's licence manufactures or assembles any medicinal product for sale or supply for the purposes of a clinical trial or a medicinal test on animals, and—

(a) a clinical trial certificate or animal test certificate has been issued and is for the time being in force in respect of that trial or test, and the trial or test is to be carried out in accordance with that certificate, and

(b) the product is so manufactured or assembled as to comply with any requirements of the certificate relating to the products to be administered in the trial or test,

then, if the conditions specified in subsection (1) of section 23 of this Act are not fulfilled in relation to the product, that section shall have effect in relation to it as if those conditions were fulfilled.

(6) Without prejudice to subsection (5) of this section, section 23(1) of this Act shall not have effect in relation to the manufacture or assembly of any medicinal product for sale or supply for the purposes of a medicinal test on animals, where the product falls within a class specified in an order made for the purposes of subsection (2)(b) of this section.

(7) For the purposes of sections 31 and 32 of this Act a person shall not be treated as doing anything, or procuring anything to be done, for the purposes of a clinical trial or of a medicinal test on animals if—

(a) the trial or test is, or is to be, carried out under arrangements to which he is not a party, and

(b) he has not been informed of those arrangements.

(8) The appropriate Ministers may by order provide—

(a) that subsection (2) or subsection (4) of section 31 of this Act shall have effect subject to such exemptions (other than those for the time being having effect by virtue of subsections (5) to (8) of that section and subsection (4) of this section) as may be specified in the order;

(b) that section 32 of this Act shall have effect subject to such exemptions (other than those for the time being having effect by virtue of section 33 of this Act and subsection (4) of this section) as may be so specified.

(9) Any exemption conferred by an order under subsection (8) of this section may be conferred subject to such conditions or limitations as may be specified in the order.

(10) The appropriate Ministers may by order provide that any of the provisions of subsections (5) to (8) of section 31 of this Act, or any of the provisions of section 33 of this Act, or subsection (4) of this section, shall cease to have effect, or shall have effect subject to such exceptions or modifications as may be specified in the order.

(11) No order shall be made under subsection (10) of this section unless a draft of the order has been laid before Parliament and approved by a resolution of each House of Parliament.

Modifications etc. (not altering text)

C1 Pt. II(ss. 6–50) extended with modifications by S.I. 1985/1403, **art. 3(1)**

Status:
Point in time view as at 01/02/1991. This version of this provision has been superseded.

Changes to legislation:
Medicines Act 1968, Section 35 is up to date with all changes known to be in force on or before 09 September 2024. There are changes that may be brought into force at a future date. Changes that have been made appear in the content and are referenced with annotations.