Medicines Act 1968

1968 CHAPTER 67

PART II

LICENCES AND CERTIFICATES RELATING TO MEDICINAL PRODUCTS

Clinical trials and medicinal tests on animals

31 Clinical trials.

(1) In this Act "clinical trial" means an investigation or series of investigations consisting of the administration of one or more medicinal products of a particular description—

(a) by, or under the direction of, a doctor or dentist to one or more patients of his, or

(b) by, or under the direction of, two or more doctors or dentists, each product being administered by, or under the direction of, one or other of those doctors or dentists to one or more patients of his,

where (in any such case) there is evidence that medicinal products of that description have effects which may be beneficial to the patient or patients in question and the administration of the product or products is for the purpose of ascertaining whether, or to what extent, the product has, or the products have, those or any other effects, whether beneficial or harmful.

(2) Subject to the following provisions of this Act, no person shall, in the course of a business carried on by him,—

(a) sell or supply any medicinal product for the purposes of a clinical trial, or

(b) procure the sale or supply of any medicinal product for the purposes of a clinical trial, or

(c) procure the manufacture or assembly of any medicinal product for sale or supply for the purposes of a clinical trial,

unless one or other of the conditions specified in the next following subsection is fulfilled.

(3) Those conditions, in relation to a person doing any of the things specified in the preceding subsection, are—

(a) that he is the holder of a product licence which authorises the clinical trial in question, or does it to the order of the holder of such a licence, and (in either case) he does it in accordance with that licence;

(b) that a certificate for the purposes of this section (in this Act referred to as a "clinical trial certificate") has been issued certifying that, subject to the provisions of the certificate, the licensing authority have consented to the clinical trial in question and that certificate is for the time being in force and the trial is to be carried out in accordance with that certificate.

(4) Subject to the following provisions of this Act, no person shall import any medicinal product for the purposes of a clinical trial unless either—

(a) he is the holder of a product licence which authorises that clinical trial or imports the product to the order of the holder of such a licence, and (in either case) he imports it in accordance with that licence, or

(b) a clinical trial certificate has been issued certifying as mentioned in subsection (3)(b) of this section and that certificate is for the time being in force and the trial is to be carried out in accordance with that certificate.

(5) Subject to the next following subsection, the restrictions imposed by the preceding provisions of this section do not apply to a doctor or dentist in respect of his selling or supplying, or procuring the sale or supply of, a medicinal product, or procuring the manufacture or assembly of a medicinal product specially prepared to his order, or specially importing a medicinal product, where (in any such case) he is, or acts at the request of, the doctor or dentist by whom, or under whose direction, the product is to be administered.

(6) The exemptions conferred by the last preceding subsection do not apply in a case where the clinical trial in question is to be carried out under arrangements made by, or at the request of, a third party (that is to say, a person who is not the doctor or dentist, or one of the doctors or dentists, by whom, or under whose direction, one or more medicinal products are to be administered in that trial).

(7) The restrictions imposed by subsection (2) of this section do not apply to anything which is done in a registered pharmacy, a hospital or a health centre and is done there by or under the supervision of a pharmacist in accordance with a prescription given by a doctor or dentist; and those restrictions do not apply to anything done by or under the supervision of a pharmacist which consists of procuring the preparation or dispensing of a medicinal product in accordance with a prescription given by a doctor or dentist, or of procuring the assembly of a medicinal product.

(8) The restrictions imposed by subsection (2) of this section also do not apply to anything done in relation to a medicinal product where—

(a) it is done by the person who, in the course of a business carried on by him, has manufactured or assembled the product, where he has manufactured or assembled it to the order of a doctor or dentist who has stated that it is required for administration to a patient of his or is required, at the request of another doctor or dentist, for administration to a patient of that other doctor or dentist, or

(b) it is done by the person who, in the course of a business carried on by him, has manufactured or assembled the product to the order of a pharmacist in accordance with a prescription given by a practitioner, or

(c) consists of selling the product by way of wholesale dealing where it has been manufactured or assembled in the circumstances specified in paragraph (a) or paragraph (b) of this subsection.

(9) For the purposes of this section a product licence shall be taken to be a licence which authorises a particular clinical trial if—

(a) the trial is to be a trial of medicinal products of a description to which the licence relates, and

(b) the uses of medicinal products of that description which are referred to in the licence are such as to include their use for the purposes of that trial.

(10) A clinical trial certificate may certify as mentioned in subsection (3)(b) of this section without specifying the doctor or dentist (or, if there is to be more than one, any of the doctors or dentists) by whom, or under whose direction, any medicinal product is to be administered, or the patient or patients to whom any medicinal product is to be administered.

Modifications etc. (not altering text)

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

C2 S. 31(2) restricted (8.12.1995) by S.I. 1995/2809, **art. 2**
S. 31 amended (E.W.S.) (*prosp.*) by 1954 c. 61, **s. 13I(1)(b)**, (as inserted (*prosp.*) by 1997 c. 19, ss. 1, 2, **Sch. para.2**)

32 Medicinal tests on animals.

(1) Subject to the following provisions of this Act, no person shall, in the course of a business carried on by him,—

(a) sell or supply any medicinal product for the purposes of a medicinal test on animals, or

(b) procure the sale or supply of any medicinal product for the purposes of such a test, or

(c) procure the manufacture or assembly of any medicinal product for sale or supply for the purposes of such a test,

unless one or other of the conditions specified in the next following subsection is fulfilled.

(2) Those conditions, in relation to a person doing any of the things specified in the preceding subsection, are—

(a) that he is the holder of a product licence which authorises the test in question, or he does it to the order of the holder of such a licence, and (in either case) he does it in accordance with that licence;

(b) that a certificate for the purposes of this section (in this Act referred to as an “animal test certificate") has been issued certifying that, subject to the provisions of the certificate, the licensing authority have consented to the test in question and that certificate is for the time being in force and the test is to be carried out in accordance with that certificate.

(3) Subject to the following provisions of this Act, no person shall import any medicinal product for the purposes of a medicinal test on animals unless either—

(a) he is the holder of a product licence which authorises that test, or imports the product to the order of the holder of such a licence, and (in either case) he imports it in accordance with that licence, or

(b) an animal test certificate has been issued certifying as mentioned in subsection (2)(b) of this section and that certificate is for the time being in force and the test is to be carried out in accordance with that certificate.

(4) Subject to the following provisions of this Act, no person shall, in the course of a business carried on by him, administer any substance or article to an animal by way of a medicinal test on animals, or procure any substance or article to be so administered, unless either—

(a) in the case of a medicinal product, there is in force a product licence (whether held by him or by another person) which authorises that test and the product is administered in accordance with that licence or in accordance with any instructions required by the licence to be communicated to the person carrying out the test, or

(b) whether the substance or article is a medicinal product or not, an animal test certificate has been issued certifying as mentioned in subsection (2)(b) of this section and that certificate is for the time being in force and the substance or article is administered in accordance with that certificate.

(5) For the purposes of this section a product licence shall be taken to be a licence which authorises a particular medicinal test on animals if—

(a) the substance or article to be administered in the test is a medicinal product of a description to which the licence relates, and

(b) the uses of medicinal products of that description which are referred to in the licence are such as to include their use for the purposes of that test.

(6) In this Act "medicinal test on animals" means an investigation or series of investigations consisting of any of the following, that is to say—

(a) the administration of a medicinal product of a particular description to one or more animals, where there is evidence that medicinal products of that description have effects which may be beneficial to, or otherwise advantageous in relation to, that animal or those animals, and the product is administered for the purpose of ascertaining whether, or to what extent, it has those or any other effects, whether advantageous or otherwise;

(b) the administration of a medicinal product to one or more animals in circumstances where there is no such evidence as is mentioned in the preceding paragraph, and the product is administered for the purpose of ascertaining whether, or to what extent, it has any effects relevant to a medicinal purpose;

(c) the administration of any substance or article, other than a medicinal product, to one or more animals for the purpose of ascertaining whether it has any effects relevant to a medicinal purpose, whether there is evidence that it has effects which may be beneficial to, or otherwise advantageous in relation to, that animal or those animals or not.

Modifications etc. (not altering text)

C3 Pt. II(ss. 6–50) extended with modifications by S.I. 1985/1403, **art. 3(1)**

C4 Ss. 32-39 modified (1.1.1995) by S.I. 1994/3142, **reg. 18(4)**

C5 S. 32 applied (with modifications) (2.8.1999) by S.I. 1999/1871, **reg. 92(3)**

33 Exemptions in respect of medicinal tests on animals.

(1) The restrictions imposed by subsections (1) and (4) of section 32 of this Act do not apply to anything done in relation to a substance or article for the purposes or by way of a medicinal test on animals if—

(a) the test is, or is to be, carried out in circumstances where there is no evidence that the substance or article has effects which may be beneficial to, or otherwise advantageous in relation to, the animal or animals to which it is, or is to be, administered, and

(b) the arrangements for the test are such as to secure that no animal to which the substance or article is administered in the course of the test, and no carcase or part of the carcase or produce of any such animal, will be sold or supplied for human consumption.

(2) Subject to the next following subsection, the restrictions imposed by subsections (1) and (4) of that section do not apply to a veterinary surgeon or veterinary practitioner in respect of his—

(a) selling or supplying, or procuring the sale or supply of, a medicinal product for the purpose of its being administered to one or more animals which are under his care, or

(b) procuring the manufacture or assembly of a medicinal product where the product is specially prepared to his order for the purpose of its being administered to one or more such animals, or

(c) administering a substance or article to an animal which is under his care, or procuring a substance or article to be so administered.

(3) Subsection (2) of this section shall not have effect in relation to a veterinary surgeon or veterinary practitioner where the medicinal test in question is to be carried out under arrangements made by, or at the request of, another person, and (where the arrangements are made by the veterinary surgeon or veterinary practitioner and not at the request of any other person) shall not have effect so as to exempt from the restrictions in question anything done—

(a) in relation to a vaccine specially prepared for administration to poultry, or

(b) in relation to any other vaccine, unless the vaccine is specially prepared for administration to the animal from which it is derived, or

(c) in relation to plasma or a serum, unless the plasma or serum is specially prepared for administration to one or more animals in the herd from which it is derived.

(4) Subject to subsection (6) of this section, the restrictions imposed by subsection (1) of that section do not apply to anything which is done in a registered pharmacy and is done there by or under the supervision of a pharmacist and consists of dispensing a medicinal product in accordance with a prescription given by a veterinary surgeon or veterinary practitioner; and those restrictions do not apply to anything done by or under the supervision of a pharmacist which consists of procuring the preparation or dispensing of a medicinal product in accordance with a prescription given by a veterinary surgeon or veterinary practitioner or of procuring the assembly of a medicinal product.

(5) Subject to subsection (6) of this section, the restrictions imposed by subsection (1) of that section also do not apply to anything done in relation to a medicinal product where—

(a) it is done by the person who, in the course of a business carried on by him, has manufactured or assembled the product to the order of a veterinary surgeon or veterinary practitioner who has stated that it is required for administration to an animal or herd which is under his care, or is required, at the request of another veterinary surgeon or veterinary practitioner, for administration to an animal or herd which is under the care of that other veterinary surgeon or veterinary practitioner, or

(b) it is done by the person who, in the course of a business carried on by him, has manufactured or assembled the product to the order of a pharmacist in accordance with a prescription given by a practitioner, or

(c) it consists of selling the product by way of wholesale dealing where it has been manufactured or assembled in the circumstances specified in paragraph (a) or paragraph (b) of this subsection.

(6) The exemptions conferred by subsections (4) and (5) of this section do not apply to a vaccine specially prepared for administration to poultry, and do not apply to any other vaccine or any plasma or serum prepared or dispensed for administration to an animal or herd unless—

(a) in the case of a vaccine, it is specially prepared for administration to the animal from which it is derived, or

(b) in the case of plasma or a serum, it has been specially prepared for administration to one or more animals in the herd from which it is derived.

Modifications etc. (not altering text)

C6 Pt. II(ss. 6–50) extended with modifications by S.I. 1985/1403, **art. 3(1)**

C7 Ss. 32-39 modified (1.1.1995) by S.I. 1994/3142, **reg. 18(4)**

C8 S. 33 amended (E.W.S.) (*prosp.*) by 1954 c. 61, **s. 13I(1)(b)** (as inserted (*prosp.*) by 1997 c. 19, ss. 1, 2, **Sch. para.2**)

C9 S. 33 applied (with modifications) (2.8.1999) by S.I. 1999/1871, **reg. 92(3)**

34 Restrictions as to animals on which medicinal tests have been carried out.

(1) Subject to the following provisions of this Act, no person shall in the course of a business carried on by him sell or supply for human consumption an animal to which in the course of that business a substance or article has been administered by way of a test to which this section applies, or the carcase or any part of the carcase or any produce of such an animal, unless—

(a) at the time when the substance or article was so administered there was in force an animal test certificate issued in respect of that test, and

(b) all the provisions of that certificate relating to the carrying out of the test and the disposal of the animal or its carcase or produce are, and have at all material times been, complied with.

(2) This section applies to any medicinal test on animals which is carried out in the course of the business of the person who has manufactured the substance or article administered in the test, or is carried out on his behalf in the course of the business of a laboratory or research establishment carried on by another person, and (in either

case) is so carried out on one or more animals kept in the course of the business of the person carrying out the test.

Modifications etc. (not altering text)

C10 Pt. II(ss. 6–50) extended with modifications by S.I. 1985/1403, **art. 3(1)**

C11 Ss. 32-39 modified (1.1.1995) by S.I. 1994/3142, **reg. 18(4)**

C12 S. 34 applied (with modifications) (2.8.1999) by S.I. 1999/1871, **reg. 92(3)**

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)
C13 Pt. II(ss. 6–50) extended with modifications by S.I. 1985/1403, **art. 3(1)**

36 Application for, and issue of, certificate.

(1) Any application for a clinical trial certificate or an animal test certificate shall be made to the licensing authority and shall be made in such form and manner, and shall contain, or be accompanied by, such information, documents, samples and other material, as may be prescribed.

(2) In dealing with any such application, the licensing authority shall have regard in particular to any evidence available to them as to any risks involved in the proposed clinical trial or medicinal test on animals.

(3) Subject to the next following section, the provisions of sections 20 to 22 of this Act shall have effect in relation to applications for clinical trial certificates or animal test certificates, as if in those sections any reference to a licence under this Part of this Act were a reference to such a certificate.

Modifications etc. (not altering text)

C14 Pt. II(ss. 6–50) extended with modifications by S.I. 1985/1403, **art. 3(1)**

C15 Ss. 32-39 modified (1.1.1995) by S.I. 1994/3142, **reg. 18(4)**

C16 S. 36 applied (with modifications) (2.8.1999) by S.I. 1999/1871, **reg. 92(3)**

37 Transitional provisions as to clinical trials and medicinal tests on animals.

(1) The provisions of sections 31, 32, 34 and 36 of this Act shall have effect subject to the following provisions of this section.

(2) The restrictions imposed by sections 31 and 32 of this Act do not apply to anything done before the first appointed day, and the restrictions imposed by section 34 of this Act do not apply where the substance or article in question was administered before that day.

(3) Where, in the course of a series of investigations carried out during a period ending on the first appointed day,—

(a) medicinal products of a particular description have been administered by way of a clinical trial, or

(b) substances or articles have been administered by way of a medicinal test on animals,

the restrictions imposed by section 31 or section 32 of this Act do not apply to anything done in relation to medicinal products of that description or (as the case may be) in relation to similar substances or articles for the purpose of continuing that series of investigations, if it is done on or after the first appointed day but before such date as may be appointed for the purposes of this section by an order made by the Ministers.

(4) If, on an application for a clinical trial certificate or an animal test certificate which is made before the date appointed for the purposes of this section, it is proved to the reasonable satisfaction of the licensing authority that—

(a) medicinal products of a description specified in the application were administered by way of a clinical trial or (as the case may be) substances or articles so specified were administered by way of a medicinal test on animals in the course of a series of investigations as mentioned in subsection (3) of this section, and

(b) that series of investigations was in progress immediately before the first appointed day, and

(c) the certificate is required for the purpose of continuing the series,

the applicant shall be entitled to the issue of a certificate such as will enable the series to be continued and completed within a reasonable time after the date appointed for the purposes of this section.

(5) Section 36(3) of this Act shall not have effect in relation to any application for a certificate as being a certificate to which the applicant is entitled by virtue of

subsection (4) of this section; but the provisions of section 27 of this Act shall have effect in relation to any such application, as if—

(a) any reference in that section to a licence of right were a reference to such a certificate;

(b) for the reference in subsection (2)(a) of that section to the grounds of refusal therein mentioned there were substituted a reference to the grounds that the conditions specified in subsection (4) of this section have not been fulfilled in relation to the application; and

(c) in subsection (6) of that section the reference to sections 25 and 26 of this Act were a reference to subsection (4) of this section;

and for the purposes of the application of those provisions in accordance with this subsection the relevant date, in relation to any matters specified in the application, shall be the date appointed for the purposes of this section.

Modifications etc. (not altering text)

C17 Pt. II(ss. 6–50) extended with modifications by S.I. 1985/1403, **art. 3(1)**

C18 Ss. 32-39 modified (1.1.1995) by S.I. 1994/3142, **reg. 18(4)**

38 Duration and renewal of certificate.

(1) Subject to the following provisions of this section, every clinical trial certificate or animal test certificate, unless previously renewed or revoked, shall expire at the end of the period of two years from the date on which it was issued or the date as from which it was last renewed, as the case may be, or at the end of such shorter period from that date as may be specified in the certificate as issued or last renewed.

(2) Any such certificate, if it has not been revoked, may, on the application of the holder of the certificate, be renewed by the licensing authority for a further period of two years from the date on which it would otherwise expire or such shorter period from that date as the licensing authority may determine.

(3) Subsections (1) and (2) of section 36 of this Act shall have effect in relation to applications for the renewal of such certificates as they have effect in relation to applications for the issue of such certificates.

(4) On an application for the renewal of such a certificate the licensing authority—

(a) may renew the certificate, with or without modifications, for such a further period as is mentioned in subsection (2) of this section, or

(b) may issue to the applicant a new clinical trial certificate or animal test certificate containing such provisions as the licensing authority consider appropriate, or

(c) if, having regard to the provisions of this Act, they consider it necessary or expedient to do so, may refuse to renew the certificate or to issue a new certificate.

(5) In relation to any such application the provisions of subsections (2) to (5) of section 20, and of sections 21 and 22, of this Act shall have effect as if in those provisions any reference to refusing a licence under this Part of this Act included a reference to refusing to renew a clinical trial certificate or animal test certificate and any reference to granting such a licence included a reference to renewing such a certificate.

(6) Every application for the grant or renewal of a clinical trial certificate or animal test certificate shall, unless it otherwise expressly provides, be taken to be an application for the grant or renewal of the certificate for the full period of two years mentioned in subsection (1) or subsection (2) of this section, as the case may be; and in any provisions of section 21 or section 22 of this Act as applied by the last preceding subsection any reference to the grant or renewal of a certificate otherwise than in accordance with the application shall be construed accordingly.

(7) Where an application for the renewal of such a certificate has been duly made—

(a) the certificate shall not cease to be in force by virtue of the preceding provisions of this section before the licensing authority have determined the application, and

(b) if by an interim order made under section 107(3)(a) of this Act the operation of the decision of the licensing authority on the application is suspended, the certificate shall not cease to be in force by virtue of those provisions so long as the operation of the decision continues to be suspended by the order.

Modifications etc. (not altering text)

C19 Pt. II(ss. 6–50) extended with modifications by S.I. 1985/1403, **art. 3(1)**

C20 Ss. 32-39 modified (1.1.1995) by S.I. 1994, reg. 18(4)

C21 S. 38 applied (with modifications) (2.8.1999) by S.I. 1999/1871, **art. 92(3)**

39 Suspension, revocation or variation of certificate.

(1) Subject to the following provisions of this section, the licensing authority may suspend, for such period as the authority may determine, a clinical trial certificate or animal test certificate, or may revoke, or vary the provisions of, any such certificate.

(2) The powers conferred by this section shall not be exercisable by the licensing authority except on one or more of the following grounds, that is to say—

(a) that the matters stated in the application on which the certificate was issued were false or incomplete in a material particular;

(b) that any of the provisions of the certificate has to a material extent been contravened;

(c) that medicinal products of any description to which the certificate relates, as sold, supplied, exported, imported, manufactured or assembled for the purposes of the clinical trial or medicinal test on animals to which it relates, fail to a material extent to correspond to the characteristics by reference to which the certificate was issued;

(d) that the holder of the certificate has without reasonable excuse failed to comply with a requirement imposed on him under section 44(2) of this Act to furnish information to the licensing authority with respect to any substances or articles to which the certificate relates;

(e) that any such substances or articles can no longer be regarded as substances or articles which can safely be administered for the purposes of the clinical trial or medicinal test on animals to which the certificate relates;

(f) that the specification and standards to which any such substances or articles are manufactured can no longer be regarded as satisfactory.

(3) The provisions of section 29 of, and Schedule 2 to, this Act shall have effect in relation to a clinical trial certificate or animal test certificate as they have effect in relation to a product licence, as if in paragraph 1 of that Schedule the reference to paragraph (g) or paragraph (h) of section 28(3) of this Act were a reference to paragraph (e) or paragraph (f) of subsection (2) of this section.

(4) Without prejudice to any power exercisable by virtue of the preceding provisions of this section, the licensing authority may, on the application of the holder of a clinical trial certificate or animal test certificate, vary the provisions of the certificate in accordance with any proposals contained in the application, if they are satisfied that the variation will not adversely affect the safety, quality or efficacy of medicinal products of any description to which the certificate relates.

Modifications etc. (not altering text)

C22 Pt. II(ss. 6–50) extended with modifications by S.I. 1985/1403, **art. 3(1)**

C23 Ss. 32-39 modified (1.1.1995) by S.I. 1994/3142, **reg. 18(4)**

C24 S. 39 applied (with modifications) (2.8.1999) by S.I. 1999/1871, **reg. 92(3)**

Status:
Point in time view as at 01/02/1991.

Changes to legislation:
Medicines Act 1968, Cross Heading: Clinical trials and medicinal tests on animals is up to date with all changes known to be in force on or before 12 April 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.