



# Medicines Act 1968

## 1968 CHAPTER 67

### PART II

#### LICENCES AND CERTIFICATES RELATING TO MEDICINAL PRODUCTS

##### *Clinical trials and medicinal tests on animals*

#### **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- (2) Any such certificate, if it has not been revoked, may, on the application of the holder of the certificate, be renewed by the licensing authority for a further period of two years from the date on which it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.

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*Status: This is the original version (as it was originally enacted).*

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- (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.