



# Medicines Act 1968

## 1968 CHAPTER 67

### PART II

#### LICENCES AND CERTIFICATES RELATING TO MEDICINAL PRODUCTS

##### *Suspension, revocation and variation of licences*

#### **28 General power to suspend, revoke or vary licences**

- (1) Subject to the following provisions of this Part of this Act, the licensing authority may suspend a licence under this Part of this Act for such period as the authority may determine, or may revoke, or vary the provisions of, any such licence.
- (2) The suspension or revocation of a licence under this section may be total or may be limited to medicinal products of one or more descriptions or to medicinal products manufactured, assembled or stored on any particular premises or in a particular part of any premises.
- (3) The powers conferred by this section shall not be exercisable by the licensing authority in relation to a product licence except on one or more of the following grounds, that is to say—
  - (a) that the matters stated in the application on which the licence was granted were false or incomplete in a material particular;
  - (b) that any of the provisions of the licence has to a material extent been contravened by the holder of the licence or by a person procured by him to manufacture or assemble medicinal products of a description to which the licence relates;
  - (c) that medicinal products of any such description, as sold, supplied, exported, imported, manufactured or assembled in pursuance of the licence, fail to a material extent to correspond to the characteristics by reference to which the licence was granted ;
  - (d) that the holder of the licence has without reasonable excuse failed to comply with a requirement imposed on him under section 44(2) of this Act to furnish

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*Status: This is the original version (as it was originally enacted).*

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- information to the licensing authority with respect to medicinal products of any such description ;
- (e) that any premises on which, or in part of which, medicinal products of any such description are manufactured, assembled or stored by or on behalf of the holder of the licence are unsuitable;
  - (f) in the case of a licence other than a licence of right, that the holder of the licence has not, within two years after the grant of the licence, notified to the licensing authority, in relation to each description of medicinal products to which the licence relates, a date on which medicinal products of that description were effectively on the market in the United Kingdom ;
  - (g) that medicinal products of any description to which the licence relates can no longer be regarded as products which can safely be administered for the purposes indicated in the licence, or can no longer be regarded as efficacious for those purposes ;
  - (h) that the specification and standards to which medicinal products of any such description are manufactured can no longer be regarded as satisfactory.
- (4) Subject to the following provisions of this section, the powers conferred by this section shall not be exercisable in relation to a manufacturer's licence or a wholesale dealer's licence except on one or more of the following grounds, that is to say—
- (a) that the matters stated in the application on which the licence was granted were false or incomplete in a material particular;
  - (b) that a material change of circumstances has occurred in relation to any of those matters;
  - (c) that any of the provisions of the licence has to a material extent been contravened by the holder of the licence ;
  - (d) that the holder of the licence 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 medicinal products of a description to which the licence relates.
- (5) In relation to a manufacturer's licence, the powers conferred by this section shall be exercisable on either of the following grounds, in addition to those specified in subsection (4) of this section, that is to say—
- (a) that the holder of the manufacturer's licence has carried out processes of manufacture or assembly to the order of another person who is the holder of a product licence, and has habitually failed to comply with the provisions of that product licence ;
  - (b) that the holder of the manufacturer's licence does not have the requisite facilities for carrying out properly processes of manufacture or assembly authorised by the licence.
- (6) In relation to a wholesale dealer's licence, the powers conferred by this section shall be exercisable on the following grounds, in addition to those specified in subsection (4) of this section, that is to say, that the equipment and facilities for storing or distributing medicinal products which are available to the holder of the licence are inadequate to maintain the quality of medicinal products of one or more descriptions to which the application for the licence related.
- (7) The preceding provisions of this section shall have effect subject to the next following section.