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

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.

[F1(i) that any of the provisions of the licence, insofar as they relate to the incorporation in animal feeding stuffs of any medicinal product . . . F2 are not in accordance with any Community obligation.**]**

[F3(j) that, in relation to medicinal products of any description to which the licence relates any of the provisions contained in regulations which—

(i) are made under section 85 of this Act (labelling and marking of containers and packages), and

(ii) impose requirements which give effect to Community obligations,

has to a material extent been contravened by the holder of the licence or by a person procured by him to manufacture or assemble such medicinal products.**]**

(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.

Textual Amendments

F1 S. 28(3)(i) added by (E.W.)(S.) S.I. 1975/1169 (N.I.), S.R. & O (N.I.) 1975/197

F2 Words repealed by Animal Health and Welfare Act 1984 (c. 40, SIF 2:8), s. 16, Sch. 1 para. 3(2), **Sch. 2**

F3 S. 28(3)(j) inserted by (E.W.)(S.) S.I. 1977/1050, **art. 4(5)** and (N.I.) S.R. 1977 No. 170, **reg. 5(5)**

Modifications etc. (not altering text)

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

C2 S. 28 (1)(2)(3)(7) applied (with modifications)(3.4.1992) by S.I. 1992/605, **reg. 2(1)(2)**,Sch.

29 Procedure where licensing authority propose to suspend, revoke or vary licence under s. 28.

(1) The provisions of Schedule 2 to this Act shall have effect where the licensing authority propose to exercise any power conferred by section 28 of this Act.

(2) Without prejudice to any requirement of that Schedule as to the service of notices, where in the exercise of any such power the licensing authority suspend, revoke or vary a licence, they shall serve on the holder of the licence a notice giving particulars of the suspension, revocation or variation and of the reasons for their decision to suspend, revoke or vary the licence.

Modifications etc. (not altering text)

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

C4 S. 29 applied (with modifications) (3.4.1992) by S.I. 1992/605, **reg. 2(1)(2)**,Sch.
s. 29 extended (with modifications) (14.2.1994) by S.I. 1994/105, reg. 19, **Sch.4**

30 Variation of licence on application of holder.

Without prejudice to any power exercisable by virtue of section 28 of this Act, the licensing authority may, on the application of the holder of a licence under this Part of this Act, vary the provisions of the licence 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 licence relates.

Modifications etc. (not altering text)

C5 Pt. II(ss. 6–50) extended with modifications by S.I. 1985/1403, **art. 3(1)**

C6 S. 30 applied (with modifications) (3.4.1992) by S.I. 1992/605, **reg. 2(1)(2)**,Sch.

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

Changes to legislation:
Medicines Act 1968, Cross Heading: Suspension, revocation and variation of licences is up to date with all changes known to be in force on or before 19 June 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.