



Medicines Act 1968

1968 CHAPTER 67

PART II

LICENCES AND CERTIFICATES RELATING TO MEDICINAL PRODUCTS

Licences of right

25 Entitlement to licence of right

- (1) Where any of the provisions of subsections (2) to (5) of section 16 of this Act has effect in relation to a person, he may, before such date as may be appointed for the purposes of this section by an order made by the Ministers, make an application in accordance with section 18 of this Act, stating that it is an application for a licence of right.
- (2) On any such application made as mentioned in the preceding subsection the applicant, on proving that any of the provisions of subsections (2) to (5) of section 16 of this Act has effect in relation to him, shall be entitled to the grant of a licence under this Part of this Act in accordance with the next following section.
- (3) In this section and in sections 26 and 27 of this Act any reference to proof is a reference to proof to the reasonable satisfaction of the licensing authority
- (4) In this Act " licence of right" means a licence to which a person is entitled by virtue of this section, including such a licence which has been renewed (with or without modifications) but not a licence granted instead of the renewal of such a licence.

26 Scope of licence of right in different cases

- (1) Where a person is entitled to the grant of a licence of right by reason that subsection (2) or subsection (3) of section 16 of this Act has effect in relation to him, he shall be entitled to the grant of a product licence ; but, subject to the following provisions of this section.—

Status: This is the original version (as it was originally enacted).

- (a) the licence shall be granted so as not to extend to medicinal products of any description other than those in respect of which the conditions specified in the subsection in question are proved to have been fulfilled, and
 - (b) where the conditions specified in subsection (3) (but not those specified in subsection (2)) of that section are proved to have been fulfilled, then, without prejudice to the preceding paragraph, the licence granted shall be limited to the importation of medicinal products.
- (2) Where a person is entitled to the grant of a licence of right by reason that subsection (4) of section 16 of this Act has effect in relation to him, he shall be entitled to the grant of a manufacturer's licence; but, subject to the following provisions of this section, the licence shall be granted so as not to extend—
 - (a) to medicinal products of any description, unless it is proved that medicinal products of that description were being manufactured or assembled in the course of the business in question during the period mentioned in that subsection, or
 - (b) to operations of any kind other than those in relation to which that subsection has been proved to have effect.
- (3) Where a person is entitled to the grant of a licence of right by reason that subsection (5) of section 16 of this Act has effect in relation to him, he shall be entitled to the grant of a wholesale dealer's licence.
- (4) A licence of right granted in accordance with subsection (1) or subsection (2) of this section shall (without prejudice to either of those subsections) be granted subject to such provisions as appear to the licensing authority to be requisite for securing that the specification of medicinal products of any description to which the licence relates, and the purposes for which any such products are authorised by the licence to be sold, supplied, exported, imported, manufactured or assembled, will be in accordance with those stated in the application for the licence.
- (5) Where a licence of right—
 - (a) is granted in accordance with subsection (1) or subsection (2) of this section in circumstances where, immediately before the first appointed day, the manufacture of medicinal products of any description to which the licence relates was authorised by a licence issued under Part I of the Therapeutic Substances Act 1956 or under Part II of the Diseases of Animals Act 1950 or of the Diseases of Animals Act (Northern Ireland) 1958, or
 - (b) is granted in accordance with subsection (1) of this section in circumstances where, immediately before the first appointed day, the importation of medicinal products of any such description was authorised by a licence so issued,

the provisions of the licence so issued, and the provisions of any regulations made under Part I of the Therapeutic Substances Act 1956 or (as the case may be) of any order made under Part II of the said Act of 1950 or of the said Act of 1958, in so far as immediately before that day they were applicable to medicinal products of that description, shall be deemed to be incorporated in the licence of right granted under this Act, in its application to medicinal products of that description, and shall have effect accordingly as provisions of the licence of right until it expires or is renewed.
- (6) A breach of any requirement imposed by this section in respect of the grant of a licence shall not invalidate the licence ; and, except as provided by section 107 of this Act,

the duty of the licensing authority to comply with any such requirement shall not be enforceable by any legal proceedings.

27 Proceedings on application for licence of right

- (1) Sections 19 to 22 of this Act shall not have effect in relation to any application for a licence of right.
- (2) If on any such application the licensing authority—
 - (a) propose to refuse to grant a licence on that application, on the grounds that none of the provisions of subsections (2) to (5) of section 16 of this Act has been proved to have effect in relation to the applicant, or
 - (b) propose to grant a licence which will not extend to some of the matters specified in the application,the licensing authority shall, before the end of the period of three months from the date on which the application is received by them, serve on the applicant a notice stating their proposals and the reasons for them and, in a case falling within paragraph (b) of this subsection, the matters specified in the application to which it is proposed that the licence should not extend.
- (3) If, within the time allowed after the service of a notice under subsection (2) of this section, the applicant gives notice to the licensing authority of his desire to be heard under this subsection or makes representations in writing to the licensing authority with respect to their proposals, then, before determining the application, the licensing authority shall afford to him an opportunity of appearing before, and being heard by, a person appointed for the purpose by the licensing authority, or shall take those representations into account, as the case may be.
- (4) Where the applicant avails himself of the opportunity afforded to him in pursuance of subsection (3) of this section or makes representations in writing as mentioned in that subsection, then if—
 - (a) the licensing authority refuse to grant a licence on the application, or
 - (b) grant a licence otherwise than in accordance with the application, and the applicant requests the licensing authority to state their reasons,the licensing authority shall serve on the applicant a notice stating the reasons for their decision.
- (5) If, in a case where the licensing authority have served a notice under subsection (2) of this section, the application is not finally disposed of before the date which, in relation to any matters specified in the application, is the relevant date, then on and after that date, and until the application has been finally disposed of, the provisions of this Act shall have effect in relation to those matters as if the licensing authority had granted a licence of right in accordance with the application.
- (6) Where, on an application for a licence of right, the licensing authority do not serve a notice under subsection (2) of this section before the end of the period mentioned in that subsection, the licensing authority shall be required to grant a licence in accordance with sections 25 and 26 of this Act as if all the matters specified in the application had been proved; and if such a licence has not been granted before the date which, in relation to any of those matters, is the relevant date, the provisions of this Act shall have effect on and after that date in relation to those matters as if the licensing authority had granted a licence of right in accordance with the application.

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- (7) For the purposes of this section the relevant date, in relation to any matters specified in an application, is the date on which, in accordance with one or more orders made under section 17 of this Act, that subsection of section 16 of this Act which has effect in relation to those matters ceases to have effect in relation to them ; and an application shall for the purposes of this section be taken to be finally disposed of on (but not before) the occurrence of whichever of the following events last occurs, that is to say—
- (a) the licensing authority make a decision determining the application;
 - (b) the time within which an application under section 107 of this Act with respect to that decision can be made expires without its having been made ;
 - (c) if such an application under section 107 of this Act is made, the proceedings on the application under that section are finally determined or abandoned or otherwise disposed of;
 - (d) if there is an appeal against the decision in any such proceedings as are mentioned in paragraph (c) of this subsection, or an appeal against the decision on such an appeal, the proceedings on that appeal are finally determined or abandoned or otherwise disposed of;
 - (e) the time for bringing any such appeal as is mentioned in paragraph (d) of this subsection expires without its having been brought.
- (8) Subsection (7) of section 21 of this Act shall have effect in relation to a person appointed under subsection (3) of this section as it has effect in relation to a person appointed under subsection (5) of that section.