Medicines Act 1968

1968 CHAPTER 67

PART II

LICENCES AND CERTIFICATES RELATING TO MEDICINAL PRODUCTS

Applications for, and grant and renewal of, licences

Modifications etc. (not altering text)
C1 Definitions in ss. 18-22 applied (N.I.) (1.4.1992) by S.I. 1991/194 (N.I. 1), art. 7(2), **Sch. 2 para. 5(4)**; S.R. 1991/131, art. 2(e), **Sch. Pt.III**

18 Application for licence.

(1) Any application for the grant of a licence under this Part of this Act 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) Any such application shall indicate the descriptions of medicinal products in respect of which the licence is required, either by specifying the descriptions of medicinal products in question or by way of an appropriate general classification.

[[F1](3) Where documents that constitute a dossier for the purposes of Article 9 of the Second Council Directive [M1]75/319/EEC of 20 May 1975 are forwarded to the licensing authority under and in accordance with the said Article, or documents are forwarded to that authority under and in accordance with Article 17 of Council Directive [M2]81/851/EEC of 28 September 1981, such forwarding shall be deemed to be an application for the grant of a product licence under this Part of this Act.**]**

Textual Amendments
F1 S. 18(3) substituted by S.I. 1983/1724, **art. 4**

Modifications etc. (not altering text)
C2 Pt. II(ss. 6–50) extended with modifications by S.I. 1985/1403, **art. 3(1)**

Marginal Citations
M1 OJ No. L 147. 9.6.1975, p. 13.
M2 OJ No. L 317. 6.11.81, p. 1.

19 Factors relevant to determination of application for licence.

(1) Subject to the following provisions of this Part of this Act, in dealing with an application for a product licence the licensing authority shall in particular take into consideration—

(a) the safety of medicinal products of each description to which the application relates;

(b) the efficacy of medicinal products of each such description for the purposes for which the products are proposed to be administered; and

(c) the quality of medicinal products of each such description, according to the specification and the method or proposed method of manufacture of the products, and the provisions proposed for securing that the products as sold or supplied will be of that quality.

(2) In taking into consideration the efficacy for a particular purpose of medicinal products of a description to which such an application relates, the licensing authority shall leave out of account any question whether medicinal products of another description would or might be equally or more efficacious for that purpose:
Provided that nothing in this subsection shall be construed as requiring the licensing authority, in considering the safety of medicinal products of a particular description, in relation to a purpose for which they are proposed to be administered, to leave out of account any question whether medicinal products of another description, being equally or more efficacious for that purpose, would or might be safer in relation to that purpose.

(3) Where any such application indicates that the purposes for which the licence is required relate (wholly or partly) to medicinal products which have been or are to be imported, then in dealing with the application, in so far as it relates to such products, the licensing authority shall also take into consideration in particular the methods, standards and conditions of manufacture of those products and may, if they think fit, require the production by the applicant of any one or more of the following, that is to say—

(a) an undertaking, given by the manufacturer of any such products, to permit the premises where they are or are to be manufactured, and the operations carried on or to be carried on in the course of manufacturing them, to be inspected by or on behalf of the licensing authority;

(b) an undertaking, given by or on behalf of the manufacturer of any such products, to comply with any prescribed conditions or any conditions attached to the licence by the licensing authority;

(c) a declaration, given by or on behalf of the manufacturer of any such products, that, in relation to the manufacture of those products, any requirements imposed by or under the law of the country in which they are or are to be manufactured have been or will be complied with.

(4) Where any such application indicates that the purposes for which the license is required relate exclusively to the exportation of medicinal products, the licensing authority shall leave out of account considerations of safety and efficacy (as mentioned in paragraphs (a) and (b) of subsection (1) of this section) if satisfied that in the circumstances it is reasonable to do so.

(5) In dealing with an application for a manufacturer's licence the licensing authority shall in particular take into consideration—

(a) the operations proposed to be carried out in pursuance of the licence:

(b) the premises in which those operations are to be carried out;

(c) the equipment which is or will be available on those premises for carrying out those operations;

(d) the qualifications of the persons under whose supervision those operations will be carried out; and

(e) the arrangements made or to be made for securing the safekeeping of, and the maintenance of adequate records in respect of, medicinal products manufactured or assembled in pursuance of the licence.

(6) In dealing with an application for a wholesale dealer's licence the licensing authority shall in particular take into consideration—

(a) the premises on which medicinal products of the descriptions to which the application relates will be stored;

(b) the equipment which is or will be available for storing medicinal products on those premises;

(c) the equipment and facilities which are or will be available for distributing medicinal products from those premises; and

(d) the arrangements made or to be made for securing the safekeeping of, and the maintenance of adequate records in respect of, medicinal products stored on or distributed from those premises.

(7) The preceding provisions of this section shall have effect subject to the provisions of this Part of this Act relating to licences of right.

Modifications etc. (not altering text)
C3 Pt. II(ss. 6–50) extended with modifications by S.I. 1985/1403, **art. 3(1)**

20 Grant or refusal of licence.

(1) Subject to the last preceding section, and to the following provisions of this Act, on any application to the licensing authority for a licence under this Part of this Act the licensing authority—

(a) may grant a licence containing such provisions as they consider appropriate, or

(b) if, having regard to the provisions of this Act **[**F2and any Community obligation**]**, they consider it necessary or expedient to do so, may refuse to grant a licence.

(2) The licensing authority shall not refuse to grant such a licence on any grounds relating to the price of any product, and shall not insert in any such licence any provisions as to the price at which any product may be sold, supplied, imported or exported.

(3) The licensing authority shall not refuse to grant such a licence on any grounds relating to the safety, quality or efficacy of medicinal products of any description, except after consultation with the appropriate committee or, if for the time being there is no such committee, with the Commission.

(4) Where the licensing authority grant a licence under this Part of this Act, they shall send a copy of the licence to every committee established under section 4 of this Act whose functions consist of or include the giving, in relation to medicinal products of any description to which the licence relates, of advice with respect to safety, quality or efficacy, or, if for the time being there is no such committee, the licensing authority shall send a copy of the licence to the Commission.

(5) Where on an application for a licence under this Part of this Act—

(a) the licensing authority refuse to grant a licence, or

(b) the licensing authority 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.

Textual Amendments

F2 Words inserted by (E.W.) S.I. 1977/1050, **art. 4(3)** and (N.I.) S.R. 1977 No. 170, **reg. 5(3)**

Modifications etc. (not altering text)

C4 Pt. II(ss. 6–50) extended with modifications by S.I. 1985/1403, **art. 3(1)**

21 Procedure on reference to appropriate committee or Commission.

(1) Where the appropriate committee or the Commission are consulted under subsection (3) of section 20 of this Act with respect to an application for the grant of a licence, and on any such grounds as are specified in that subsection they have reason to think that they may be unable to advise the licensing authority to grant the licence, or may be unable to advise the licensing authority to grant it unless it contains provisions otherwise than in accordance with the application, the committee or Commission shall notify the applicant accordingly, and, before giving their advice to the licensing authority, shall afford to him an opportunity of appearing before and being heard by them, or of making representations in writing to them with respect to those grounds.

(2) Where the applicant has availed himself of the opportunity of being heard under the preceding subsection, or after considering any representations made by him under that subsection, the appropriate committee or the Commission, as the case may be, shall report to the licensing authority their findings and advice and the reasons for their advice and the licensing authority shall take that report into account in determining the application.

(3) Whether the applicant has been heard or has made representations under subsection (1) of this section or not, if the appropriate committee or the Commission advise the licensing authority that the licence ought on any such grounds as are referred to in that subsection to be refused, or ought, if granted. to contain provisions specified in their advice, the licensing authority shall serve notice on the applicant stating the advice

so given to the authority and the reasons stated by the appropriate committee or the Commission for giving that advice.

(4) If, within the time allowed after the service of a notice under subsection (3) of this section, in a case where the applicant has not been heard by, or made representations to, the Commission under subsection (1) of this section, he gives notice to the licensing authority of his desire to be heard with respect to the advice given to the authority or makes representations in writing to the licensing authority with respect to that advice, then, before determining the application,—

(a) if the applicant has given notice of his desire to be heard, the licensing authority shall arrange for him to have an opportunity of appearing before, and being heard by, the Commission, or

(b) if he has made representations in writing, the licensing authority shall refer those representations to the Commission,

and, where the applicant has availed himself of the opportunity of being heard, or after considering the representations, as the case may be, the Commission shall report to the licensing authority their findings and advice and the reasons for their advice, and the licensing authority shall take that report into account in determining the application.

(5) If the licensing authority—

(a) propose to determine the application in a way which differs from the advice of the Commission under subsection (2) or subsection (4) of this section, or

(b) where there has been no hearing before, and no representations have been made or referred to, the Commission, propose to determine the application in a way which differs from the advice of the appropriate committee under subsection (2) of this section, or

(c) in the absence of any such advice as is mentioned in either of the preceding paragraphs, propose to determine the application in a way which differs from the advice given by the appropriate committee or the Commission, or

(d) propose, on grounds not relating to safety, quality or efficacy, to refuse to grant the licence, or to grant a licence otherwise than in accordance with the application,

the licensing authority shall notify the applicant accordingly, and, before determining the application, shall afford to the applicant an opportunity of appearing before, and being heard by, a person appointed for the purpose by the licensing authority, or of making representations in writing to the licensing authority with respect to that proposal.

(6) Any notification given to the applicant under subsection (5) of this section—

(a) in a case falling within paragraph (a) or paragraph (b) of that subsection, shall state the advice of the Commission or of the appropriate committee and the reasons stated by the Commission or the committee for giving that advice, or

(b) in a case falling within paragraph (c) of that subsection, shall state the advice given by the appropriate committee or the Commission and the reasons stated by the committee or the Commission for giving that advice,

and in a case falling within paragraph (d) of that subsection (whether it also falls within any of the other paragraphs of that subsection or not) the notification shall include a statement of the proposals of the licensing authority and of the reasons for them.

(7) Where under subsection (5) of this section the applicant avails himself of the opportunity of appearing before, and being heard by, a person appointed for the purpose by the licensing authority—

(a) the person so appointed shall not, except with the consent of the applicant, be an officer or servant of any of the Ministers specified in paragraphs (a) and (b) of section 1(1) of this Act;

(b) if the applicant so requests, the hearing shall be in public; and

(c) if the applicant so requests, the licensing authority shall furnish to him a copy of the report of the person so appointed.

(8) In this Part of this Act "the time allowed" means the period of twenty-eight days or such extended period as the licensing authority may in any particular case allow.

Modifications etc. (not altering text)
C5 Pt. II(ss. 6–50) extended with modifications by S.I. 1985/1403, **art. 3(1)**

22 Procedure in other cases.

(1) The provisions of this section shall have effect where an application is made for the grant of a licence under this Part of this Act and the provisions of section 21 of this Act do not apply.

(2) If the licensing authority propose to refuse to grant the licence, or propose to grant a licence otherwise than in accordance with the application, they shall serve notice on the applicant stating their proposals and the reasons for them.

(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) 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.

Modifications etc. (not altering text)
C6 Pt. II(ss. 6–50) extended with modifications by S.I. 1985/1403, **art. 3(1)**

23 Special provisions as to effect of manufacturer's licence.

(1) Subject to the provisions of this Part of this Act relating to clinical trials and medicinal tests on animals and to the following provisions of this section, a manufacturer's licence shall not have effect so as to authorise the manufacture or assembly of medicinal products of any description for sale or supply to any other person, or for exportation, unless either—

(a) the holder of the licence is also the holder of a product licence which is applicable to medicinal products of that description, or

(b) the products are manufactured or assembled to the order of a person who is the holder of such a product licence,

and (in either case) the products are manufactured or assembled in accordance with that product licence.

(2) Subject to the next following subsection, the preceding subsection shall not have effect in relation to the manufacture or assembly of any medicinal product to the order of a practitioner, where the practitioner—

(a) being a doctor or dentist, states that the product 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) being a veterinary surgeon or veterinary practitioner, states that the product 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,

and shall not have effect in relation to the manufacture or assembly of any medicinal product to the order of a pharmacist in accordance with a prescription given by a practitioner.

(3) The exemption conferred by the last preceding subsection—

(a) in a case falling within paragraph (b) of that subsection, or

(b) in so far as it relates to the manufacture or assembly of a medicinal product to the order of a pharmacist,

does not apply to a vaccine specially prepared for administration to poultry.

(4) If by virtue of an order made under section 15 of this Act an exemption is conferred in respect of the restrictions imposed by section 7 of this Act, but no corresponding exemption is conferred in respect of the restrictions imposed by section 8(2) of this Act, the order may provide that subsection (1) of this section shall have effect subject to such exceptions or modifications as the Ministers consider appropriate in the circumstances.

(5) Where subsection (1) of this section has effect in relation to medicinal products of any description, and the conditions specified in that subsection are not fulfilled, the manufacture or assembly of medicinal products of that description for sale or supply to another person, or for exportation, notwithstanding that it complies with the provisions contained in the manufacturer's licence, shall for the purposes of this Act be deemed to be not in accordance with that licence.

Modifications etc. (not altering text)

C7 Pt. II(ss. 6–50) extended with modifications by S.I. 1985/1403, **art. 3(1)**

C8 S.23 extended (with modifications) (14.2.1994) by S.I. 1994/105, reg. 19, **Sch.4**
S. 23 modified (1.1.1995) by S.I. 1994/3144, **reg.9(3)**
S. 23 applied (1.1.1995) by S. I. 1994/3142, **reg. 18(2)**
S. 23 amended (E.W.S.) (*prosp.*) by 1954 c. 61, **s. 13I para. 1(b)** (as inserted (*prosp.*) by 1997 c. 19, **ss. 1**,2, Sch. para.2)

24 Duration and renewal of licence.

(1) Subject to the following provisions of this section, every licence granted under this Part of this Act, unless previously renewed or revoked, shall expire at the end of the period of five years from the date on which it was granted 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 licence as granted or last renewed.

[F3(1A) Where any licence has been granted under this Part of this Act and the licensing authority subsequently consider that it would no longer be possible to grant that licence without contravening a Community obligation, the licence shall (notwithstanding subsection (1) above) expire on such date as may be specified in a notice served on the holder of the licence by the licence authority.**]**

(2) Any **[**F4licence granted under this Part of this Act**]**, if it has not been revoked, may, on the application of the holder of the licence, be renewed by the licensing authority for a further period of five years from the date on which it would otherwise expire or such shorter period from that date as the licensing authority may determine.

(3) On an application to the licensing authority for the renewal of a licence under this Part of this Act, the licensing authority—

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

(b) may grant to the applicant a new licence 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 licence or to grant a new licence.

(4) In relation to any such application the provisions of sections 18 and 19, subsections (2) to (5) of section 20 and sections 21 and 22 of this Act shall have effect as if in those provisions any reference to refusing a licence included a reference to refusing to renew a licence and any reference to granting a licence included a reference to renewing it.

(5) Every application for the grant or renewal of a licence under this Part of this Act shall, unless it otherwise expressly provides, be taken to be an application for the grant or renewal of the licence for the full period of five years mentioned in subsection (1) or subsection (2) of this section, as the case may be; and in this Part of this Act any reference (including a reference implied by virtue of the last preceding subsection) to the grant or renewal of a licence otherwise than in accordance with the application shall be construed accordingly.

(6) Where an application for the renewal of a licence under this Act has been duly made—

(a) the licence 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 licence 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.

Textual Amendments

F3 S. 24(1A) inserted by (E.W.)(S.) S.I. 1977/1050, **art. 4(4)** and (N.I.) S.R. 1977 No. 170, **reg. 5(4)**

F4 Words substituted by (E.W.)(S.) S.I. 1977/1050, **art. 4(4)** and (N.I.) S.R. 1977 No. 170, **reg. 5(4)**

Modifications etc. (not altering text)

C9 Pt. II(ss. 6–50) extended with modifications by S.I. 1985/1403, **art. 3(1)**

C10 S. 24 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: Applications for, and grant and renewal of, licences is up to date with all changes known to be in force on or before 17 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.