



# Medicines Act 1968

## 1968 CHAPTER 67

### PART II

#### LICENCES AND CERTIFICATES RELATING TO MEDICINAL PRODUCTS

##### *Supplementary provisions*

#### **43      Extension of s.7 to certain special circumstances**

- (1) Where in the course of a business carried on by him a person sells, supplies or exports a substance or article for use wholly or mainly in either or both of the ways specified in section 130(1) of this Act, and the substance or article, not having been—
  - (a) manufactured or imported for such use, or
  - (b) previously sold or supplied for such use,does not constitute a medicinal product before that person so sells, supplies or exports it, then (subject to subsection (2) of this section) subsection (2) of section 7 of this Act, if apart from this subsection it would not so have effect, shall have effect in relation to the sale, supply or exportation of the substance or article as if he were selling, supplying or exporting it in circumstances to which that subsection applies.
- (2) Subsection (1) of this section shall not have effect in relation to a transaction whereby a person, in the course of a business carried on by him, sells a substance or article by retail or supplies a substance or article in circumstances corresponding to retail sale unless in the course of that business the substance or article has been assembled for the purpose of being sold or supplied by him.
- (3) In any reference in this Part of this Act to the provisions of, or the restrictions imposed by, section 7 of this Act, the reference to that section shall be construed as including a reference to subsection (2) of that section as extended by the preceding subsections.
- (4) Where in the course of a business carried on by him a person proposes to sell, supply or export a substance or article for use as mentioned in subsection (1) of this section, where the substance or article will not constitute a medicinal product before he so sells, supplies or exports it and he will not be selling, supplying or exporting it in

circumstances to which section 7(2) of this Act applies, he may, if he so desires, apply for a product licence in respect of that substance or article, and the licensing authority (subject to the provisions of sections 19 to 22 of this Act) may grant to him a product licence in respect of it, as if he were proposing to sell, supply or export it in circumstances to which section 7(2) of this Act applies ; and a product licence so granted may be renewed, suspended, revoked or varied accordingly.

- (5) In subsection (2) of this section the reference to assembling a substance or article in the course of a business carried on by a person is a reference to doing in the course of that business anything which (in accordance with section 132(1) of this Act) would constitute assembling if it had been a medicinal product when sold or supplied to him.

#### **44 Provision of information to licensing authority**

- (1) Where an application has been made to the licensing authority for a licence under this Part of this Act (including a licence of right) or for a clinical trial certificate or animal test certificate (including a certificate to which a person is entitled by virtue of section 37(4) of this Act) the licensing authority, before determining the application, may request the applicant to furnish to the licensing authority such information relating to the application as the licensing authority may consider requisite; and, where any such request has been made, the licensing authority shall not be required to determine the application until either—
- (a) the information requested has been furnished to them, or
  - (b) it has been shown to their reasonable satisfaction that the applicant is unable to furnish the information.
- (2) The licensing authority may serve on the holder of a licence under this Part of this Act, or of a clinical trial certificate or animal test certificate, a notice requiring him, within such time as may be specified in the notice, to furnish to the licensing authority information of any description specified in the notice in accordance with the following provisions of this section.
- (3) Except as provided by subsection (4) of this section, a notice under subsection (2) of this section shall not be served unless it appears to the licensing authority, or it is represented to them by the Commission or by the appropriate committee, that circumstances exist by reason of which it is necessary to consider whether the licence or certificate should be varied, suspended or revoked; and the information required by such a notice shall be such as appears to the licensing authority, or is represented to them by the Commission or by the committee, to be requisite for considering that question.
- (4) Subsection (3) of this section shall not have effect in the case of a licence of right, or of a certificate issued in pursuance of section 37 (4) of this Act, whether the licence or certificate has been renewed or not; and, in the case of such a licence or certificate, a notice under this section may be served at any time and may require any information which, in the opinion of the licensing authority, would be relevant if—
- (a) sections 25 and 37(4) of this Act had not been enacted, and
  - (b) the licensing authority were then dealing with an application, by the person who is the holder of the licence or certificate, for the grant or issue of a licence or certificate containing the same provisions as those contained in the licence or certificate in question.
- (5) Before the end of the period of two years from the date on which a product licence, other than a licence of right, is granted, the holder of the licence shall, in respect of each

description of medicinal products to which the licence relates which is effectively on the market in the United Kingdom within that period, notify to the licensing authority a date on which medicinal products of that description were effectively on that market.

## **45 Offences under Part II**

- (1) Subject to the next following section, any person who contravenes any of the provisions of section 7, section 8, section 31, section 32, section 34 or section 40 of this Act, or who is in possession of any medicinal product or animal feeding stuff for the purpose of selling, supplying or exporting it in contravention of any of those sections, shall be guilty of an offence.
- (2) Where any medicinal product or animal feeding stuff is imported in contravention of section 7, section 31, section 32 or section 40 of this Act, any person who, otherwise than for the purpose of performing or exercising a duty or power imposed or conferred by or under this Act or any other enactment, is in possession of the product or feeding stuff knowing or having reasonable cause to suspect that it was so imported shall be guilty of an offence.
- (3) Any person who, being the holder of a product licence or of a clinical trial certificate or animal test certificate, procures another person to carry out a process in the manufacture or assembly of medicinal products of a description to which the licence or certificate relates, and—
  - (a) does not communicate to that person the provisions of the licence or certificate which are applicable to medicinal products of that description, or
  - (b) in a case where any of those provisions has been varied by a decision of the licensing authority, does not communicate the variation to that person within fourteen days after notice of the decision has been served on him,shall be guilty of an offence.
- (4) Any person who, being the holder of a product licence or of an animal test certificate, sells or supplies a substance or article to which the licence or certificate relates to another person for the purpose of its being incorporated in any animal feeding stuff, and does not communicate to that person any provisions of the licence or certificate which relate to the incorporation of that substance or article in animal feeding stuffs, or any instructions required by the licence to be communicated by him to persons to whom the substance or article is sold or supplied for that purpose, shall be guilty of an offence.
- (5) Where any such provisions of a product licence or animal test certificate as are mentioned in subsection (4) of this section are varied by the licensing authority, and on varying those provisions the licensing authority serve on the holder of the licence or certificate a notice requiring him, within such time (not being less than fourteen days from the date of service of the notice) as may be specified in the notice, to take such steps as may be so specified for making the variation known, either generally or to persons or classes of persons specified in the notice, then if the holder of the licence or certificate does not comply with the requirements of that notice he shall be guilty of an offence.
- (6) Any person who, in giving any information which he is required to give under section 44 of this Act, makes a statement which he knows to be false in a material particular shall be guilty of an offence.

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- (7) Any person who without reasonable excuse fails to comply with a requirement imposed on him by a notice under section 44(2) of this Act shall be guilty of an offence.
- (8) Any person guilty of an offence under any of subsections (1) to (6) of this section shall be liable—
  - (a) on summary conviction, to a fine not exceeding £400 ;
  - (b) on conviction on indictment, to a fine or to imprisonment for a term not exceeding two years or to both.
- (9) Any person guilty of an offence under subsection (7) of this section shall be liable on summary conviction to a fine not exceeding £50.

#### **46 Special defences under s. 45**

- (1) Where the holder of a product licence or of a clinical trial certificate or animal test certificate is charged with an offence under the last preceding section in respect of any substance or article which has been manufactured (or, in the case of a medicinal product, manufactured or assembled) to his order by another person and has been so manufactured or assembled as not to comply with the provisions of that licence or certificate which are applicable to it, it shall be a defence for him to prove—
  - (a) that he had communicated those provisions to that other person, and
  - (b) that he did not know, and could not by the exercise of reasonable care have discovered, that those provisions had not been complied with.
- (2) Where the holder of a manufacturer's licence is charged with an offence under the last preceding section in respect of any medicinal products which have been manufactured or assembled by him, in circumstances where he is not the holder of a product licence or of a clinical trial certificate or animal test certificate which is applicable to those products, but the products were manufactured or assembled to the order of another person, it shall be a defence for him to prove that he believed, and had reasonable grounds for believing.—
  - (a) that the other person in question was the holder of a product licence applicable to those products, or of a clinical trial certificate or animal test certificate applicable to them, and
  - (b) that the products were manufactured or assembled in accordance with that product licence or certificate.
- (3) Where a person is charged with an offence under the last preceding section in respect of a contravention of any provision of section 40 of this Act, in a case where he is not the holder of such a product licence or animal test certificate as is mentioned in subsection (1)(a) or subsection (3)(a) of the said section 40, it shall be a defence for him to prove that he believed, and had reasonable grounds for believing.—
  - (a) that another person was the holder of such a licence or certificate, and
  - (b) that the substance or article to which the contravention relates was incorporated in the animal feeding stuff in accordance with that licence or certificate.
- (4) In the last preceding subsection any reference to section 40 of this Act shall be construed as including a reference to that section as extended by section 42 of this Act.

## **47 Standard provisions for licences or certificates**

- (1) The Ministers may by regulations prescribe standard provisions for the purposes of this Part of this Act, either generally or in relation to any class of medicinal products specified in the regulations.
- (2) Any standard provisions so prescribed may be incorporated by the licensing authority in any licence under this Part of this Act or any clinical trial certificate or animal test certificate granted or issued on or after the date on which the regulations come into operation, and may be so incorporated with or without modifications and either generally or in relation to medicinal products of any particular class.
- (3) The following provisions of this section shall have effect where—
  - (a) standard provisions are prescribed by regulations made under this section, or
  - (b) after any such provisions have been so prescribed, they are amended by, or superseded by new standard provisions prescribed by, subsequent regulations so made ;and in the following provisions of this section, in a case falling within paragraph (a) but not within paragraph (b) of this subsection, " the operative standard provisions " means the standard provisions prescribed by the regulations and " the relevant regulations " means those regulations, and, in any other case, " the operative standard provisions " means the standard provisions as amended by the subsequent regulations or the new standard provisions prescribed by those regulations, as the case may be, and " the relevant regulations " means the subsequent regulations.
- (4) Subject to the following provisions of this section, as from the end of the period of three months from the date on which the relevant regulations come into operation, the operative standard provisions shall be deemed to be incorporated in any licence under this Part of this Act, or any clinical trial certificate or animal test certificate, which is in force at the end of that period or, in the case of a suspended licence or certificate, would then be in force if it were not suspended, in so far as, in accordance with the relevant regulations, the operative standard provisions are applicable to medicinal products of any description to which that licence or certificate relates.
- (5) Notwithstanding anything in subsection (4) of this section, the operative standard provisions shall not by virtue of that subsection be deemed to be incorporated in any licence of right, or in any certificate issued in pursuance of section 37(4) of this Act, including any such licence or certificate which has been renewed, except in circumstances where, immediately before the first appointed day, the manufacture or importation of substances or articles to which the licence or certificate 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, and, where those circumstances exist, shall be deemed to be so incorporated only in relation to substances or articles to which the licence so issued was applicable.
- (6) At any time after the relevant regulations are made and before the end of the period of three months from the date on which they come into operation, the holder of any licence or certificate may apply to the licensing authority to direct—
  - (a) that the operative standard provisions shall not be deemed to be incorporated in that licence or certificate, or
  - (b) that the operative standard provisions shall be deemed to be so incorporated subject to such exceptions or modifications as may be specified in the application ;

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and if, on any such application, the licensing authority direct that the operative standard provisions shall not be deemed to be so incorporated, or shall be deemed to be so incorporated subject to exceptions and modifications specified in the direction, with or without provision postponing the date as from which they are to be deemed to be so incorporated, that direction shall have effect notwithstanding anything in subsection (4) of this section.

(7) Where an application is made to the licensing authority under subsection (6) of this section, then, if the licensing authority propose to refuse to give a direction in accordance with the application, the licensing authority, 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; and, if the licensing authority then determine to refuse to give a direction in accordance with the application, they shall serve on the applicant a notice stating the reasons for their decision.

(8) Without prejudice to any direction given under subsection (6) of this section, where such an application is made—

- (a) the operative standard provisions shall not be deemed to be incorporated in the licence or certificate to which the application relates before the licensing authority have made a decision on that application, and
- (b) if an application under section 107 of this Act is made with respect to that decision, those provisions shall not be deemed to have been or to be so incorporated before the application under subsection (6) of this section has been finally disposed of ;

and so much of subsection (7) of section 27 of this Act as relates to the time when an application is to be taken to be finally disposed of shall have effect for the purposes of this subsection as it has effect for the purposes of that section.

(9) The powers conferred on the licensing authority by the preceding provisions of this Part of this Act to vary the provisions of a licence or certificate shall be exercisable with respect to any provisions which, in accordance with this section, are incorporated or deemed to be incorporated in a licence or certificate.

#### **48 Postponement of restrictions in relation to exports**

(1) Notwithstanding anything in sections 7 to 47 of this Act but subject to the next following section, in relation to anything done before such day (subsequent to the first appointed day) as the Ministers may by order appoint for the purposes of this subsection (in this section referred to as " the special appointed day ") those sections shall have effect as if in them—

- (a) every reference to exportation (in whatever form the reference occurs) were omitted ;
- (b) any reference to the sale or supply of a medicinal product did not include sale or supply which involves, or is for the purposes of, exporting the product; and
- (c) any reference to offering a medicinal product for sale did not include an offer for sale where the prospective sale would involve, or would be for the purposes of, exporting the product.

(2) The Ministers shall not make an order under the preceding subsection unless it appears to them to be necessary or expedient to do so for the purpose of giving effect to an

agreement to which the United Kingdom or Her Majesty's Government in the United Kingdom is a party or will be a party on the day appointed by the order.

- (3) The following provisions of this section shall have effect where an order is made under subsection (1) of this section; and for the purposes of those provisions the relevant transitional conditions shall be taken to be fulfilled by a person in relation to medicinal products of any description if, in the course of a business carried on by him.—
- (a) substantial quantities of medicinal products of that description (that is to say, quantities exceeding those required for distribution as samples) were exported or procured to be exported during the period of twenty-four months ending immediately before the special appointed day, and
  - (b) during the whole of that period further substantial quantities of medicinal products of that description were available, or could within a reasonable time have been made available, to be so exported or procured to be exported if required.
- (4) Unless the order expressly excludes the operation of this subsection.—
- (a) subject to any order made by virtue of paragraph (b) of this subsection, section 7(2) of this Act shall not have effect in relation to a person in respect of his exporting on or after the special appointed day, or procuring the exportation on or after that day of, medicinal products of any description in relation to which he fulfils the relevant transitional conditions;
  - (b) section 17 of this Act shall have effect in relation to paragraph (a) of this subsection as it has effect in relation to the subsections of section 16 of this Act mentioned in that section.
- (5) Where a product licence which is in force on the special appointed day authorises the holder of the licence to sell medicinal products of any description, or to procure the sale, or procure the manufacture or assembly for sale, of medicinal products of any description, that licence shall have effect on and after that day as if—
- (a) it also authorised him to export medicinal products of that description, or (as the case may be) to procure the exportation, or procure the manufacture or assembly for exportation, of medicinal products of that description, and
  - (b) it authorised him to do so subject to the like provisions as (apart from subsections (3) to (7) of section 47 of this Act) are specified in the licence in relation to selling or (as the case may be) procuring the sale, or procuring the manufacture or assembly for sale, of such products:

Provided that, if the operation of subsection (4) of this section is not excluded by the order, a product licence shall not have effect as mentioned in this subsection in relation to medicinal products of any description so long as paragraph (a) of that subsection has effect in relation to the holder of the licence in respect of his exporting, or procuring the exportation of, medicinal products of that description.

- (6) Where on an application for a product licence made before such date as may be appointed by the order for the purposes of this subsection, which states that it is an application made by virtue of this subsection, it is proved to the reasonable satisfaction of the licensing authority that the applicant fulfilled or will fulfil the relevant transitional conditions in relation to one or more descriptions of medicinal products, then (subject to the next following subsection) he shall be entitled to the grant of a product licence granted so as—
- (a) to be limited to exportation, or procuring exportation, of medicinal products, and

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- (b) not to extend to medicinal products of any description other than those in respect of which it is so proved that the applicant fulfilled or will fulfil those conditions, and
  - (c) not to extend to medicinal products of any description in respect of which, at the time when the licence is granted, a product licence is already held by the applicant.
- (7) If a person would, on making an application under subsection (6) of this section, be entitled to the grant of a product licence under that subsection in respect of medicinal products of a particular description, and he would at the same time, on making an application as mentioned in section 25(1) of this Act, be entitled to the grant of a licence of right in respect of medicinal products of the same description, he may apply to the licensing authority for a single product licence for both purposes, and he shall be entitled to the grant of a product licence having the same effect as the two licences, if granted separately, would together have had.
- (8) Subsection (6) of section 26 of this Act shall have effect for the purposes of subsections (6) and (7) of this section as it has effect for the purposes of that section.
- (9) An order made under subsection (1) of this section may contain such provisions relating to proceedings on an application made under subsection (6) or subsection (7) of this section (whether by way of applying with modifications any of the provisions of section 27 of this Act or otherwise) as the Ministers may consider appropriate.
- (10) No order shall be made under this section unless a draft of the order has been laid before Parliament and approved by a resolution of each House of Parliament.

#### **49 Special provisions in respect of exporting certain products**

- (1) Nothing in subsection (1) of section 48 of this Act shall affect the operation of any of the provisions of sections 7 to 47 of this Act in relation to any medicinal product falling within a class specified in an order made under this section by the Health Ministers or the Agriculture Ministers.
- (2) No class of medicinal products shall be specified in an order made by the Health Ministers or the Agriculture Ministers under this section unless it appears to the Ministers making the order to be requisite to do so for securing that any exemption conferred by section 48(1) of this Act does not apply to medicinal products consisting wholly or partly of substances the purity or potency of which cannot, in their opinion, be adequately tested by chemical means.
- (3) Subsections (3) to (7) of section 48 of this Act shall not have effect in relation to medicinal products of any description falling within a class specified in an order under this section which is in force immediately before the day appointed for the purposes of subsection (1) of that section.
- (4) Subject to the next following subsection, section 7(2) of this Act shall not have effect in relation to a person in respect of his exporting, or procuring the exportation of, medicinal products of any description falling within a class specified in an order under this section which is in force immediately before the first appointed day if, in the course of a business carried on by that person.—
  - (a) substantial quantities of medicinal products of that description (that is to say, quantities exceeding those required for distribution as samples) were exported



- or procured to be exported during the period of twenty-four months ending with the first appointed day, and
- (b) during the whole of that period further substantial quantities of medicinal products of that description were available, or could within a reasonable time have been made available, to be so exported or procured to be exported if required.
- (5) Sections 17 and 25 of this Act shall have effect in relation to subsection (4) of this section as they have effect in relation to subsections (2) to (5) of section 16 of this Act.
- (6) Where a person is entitled to the grant of a licence of right by reason that subsection (4) of this section has effect in relation to him, he shall be entitled to the grant of a product licence ; but, subject to the next following subsection, 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 that subsection are proved to the reasonable satisfaction of the licensing authority to have been fulfilled, and shall be limited to exporting, or procuring the exportation of, medicinal products.
- (7) Subsection (5) of section 26 of this Act (with the omission of paragraph (b) of that subsection) and subsection (6) of that section shall have effect in relation to the grant of a licence of right in accordance with subsection (6) of this section as those subsections have effect in relation to the grant of such a licence in accordance with subsection (1) of that section.
- (8) In relation to any application for a licence of right which is made by virtue of section 25 of this Act as applied by subsection (5) of this section, the provisions of section 27 of this Act shall have effect subject to such modifications as may be specified by order made by the Ministers for the purposes of this subsection.

## **50 Certificates for exporters of medicinal products**

On the application of any person who proposes to export medicinal products of any description, the licensing authority may issue to him a certificate containing any such statement relating to medicinal products of that description as the licensing authority may consider appropriate having regard—

- (a) to any requirements (whether having the force of law or not) which have effect in the country to which the products are to be exported, and
- (b) to the provisions of this Act and to any licence granted or other thing done by virtue of this Act.