



# Medicines Act 1968

## 1968 CHAPTER 67

### PART II

#### LICENCES AND CERTIFICATES RELATING TO MEDICINAL PRODUCTS

##### *Supplementary provisions*

#### **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

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- 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
- (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

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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.