



Medicines Act 1968

1968 CHAPTER 67

PART III

FURTHER PROVISIONS RELATING TO DEALINGS WITH MEDICINAL PRODUCTS

Additional provisions

58 Medicinal products on prescription only

- (1) The appropriate Ministers may by order specify descriptions or classes of medicinal products for the purposes of this section; and, in relation to any description or class so specified, the order shall state which of the following, that is to say—
 - (a) doctors,
 - (b) dentists, and
 - (c) veterinary surgeons and veterinary practitioners,are to be appropriate practitioners for the purposes of this section.
- (2) Subject to the following provisions of this section—
 - (a) no person shall sell by retail, or supply in circumstances corresponding to retail sale, a medicinal product of a description, or falling within a class, specified in an order under this section except in accordance with a prescription given by an appropriate practitioner; and
 - (b) no person shall administer (otherwise than to himself) any such medicinal product unless he is an appropriate practitioner or a person acting in accordance with the directions of an appropriate practitioner.
- (3) Subsection (2)(a) of this section shall not apply—
 - (a) to the sale or supply of a medicinal product to a patient of his by a doctor or dentist who is an appropriate practitioner, or
 - (b) to the sale or supply of a medicinal product, for administration to an animal or herd under his care, by a veterinary surgeon or veterinary practitioner who is an appropriate practitioner.

Status: This is the original version (as it was originally enacted).

- (4) Without prejudice to the last preceding subsection, any order made by the appropriate Ministers for the purposes of this section may provide—
- (a) that paragraph (a) or paragraph (b) of subsection (2) of this section, or both those paragraphs, shall have effect subject to such exemptions as may be specified in the order;
 - (b) that, for the purpose of paragraph (a) of that subsection, a medicinal product shall not be taken to be sold or supplied in accordance with a prescription given by an appropriate practitioner unless such conditions as are prescribed by the order are fulfilled.
- (5) Any exemption conferred by an order in accordance with subsection (4)(a) of this section may be conferred subject to such conditions or limitations as may be specified in the order.
- (6) Before making an order under this section the appropriate Ministers shall consult the appropriate committee, or, if for the time being there is no such committee, shall consult the Commission.

59 Special provisions in relation to new medicinal products

- (1) The following provisions of this section shall have effect where an order under section 58 of this Act is made so as to apply to all medicinal products which fall within a class specified in the order and are of a description in respect of which the following conditions are fulfilled, that is to say, that—
- (a) medicinal products of that description were not effectively on the market in the United Kingdom immediately before the first appointed day ;
 - (b) a product licence granted under Part II of this Act (whether before, on or after the date on which the order comes into operation) applies to medicinal products of that description (whether it also applies to medicinal products of any other description or not); and
 - (c) before the grant of that licence, no product licence had been granted which was applicable to medicinal products of that description.
- (2) Where such an order is made in accordance with the preceding subsection—
- (a) the restrictions imposed by section 58(2) of this Act shall not apply by virtue of the order to medicinal products of any description except during a period beginning with the date which, in relation to medicinal products of that description, is the relevant date and of such duration from that date as may be specified in the order;
 - (b) in section 58(4)(a) of this Act the reference to exemptions specified in the order shall, in relation to that order, be construed as including a reference to any exemption specified in a direction given by the appropriate Ministers and relating to medicinal products of a particular description specified in that direction.
- (3) In subsection (2)(a) of this section " the relevant date ", in relation to medicinal products of any description to which an order made in accordance with subsection (1) of this section applies, means the date on which the order comes into operation, or the date on which the product licence applicable to medicinal products of that description (as mentioned in subsection (1)(b) of this section) comes into operation, whichever is the later.

60 Restricted sale, supply and administration of certain medicinal products

- (1) Subject to the following provisions of this section, regulations made by the appropriate Ministers may provide that no person shall sell by retail, or supply in circumstances corresponding to retail sale, a medicinal product of a description specified in the regulations, or falling within a class so specified, unless—
 - (a) he is a practitioner holding a certificate issued for the purposes of this section by the appropriate Ministers in respect of medicinal products of that description or falling within that class, or a person acting in accordance with the directions of such a practitioner, and the product is so sold or supplied for the purpose of being administered in accordance with the directions of that practitioner, or
 - (b) he is a person lawfully conducting a retail pharmacy business and the product is so sold or supplied in accordance with a prescription given by such a practitioner.
- (2) Any regulations made under this section may provide that no person shall administer (otherwise than to himself) a medicinal product of a description specified in the regulations, or falling within a class so specified, unless he is such a practitioner as is mentioned in subsection (1)(a) of this section or a person acting in accordance with the directions of such a practitioner.
- (3) The powers conferred by the preceding subsections shall not be exercisable in respect of medicinal products of a particular description, or falling within a particular class, except where it appears to the appropriate Ministers that the sale by retail, or supply in circumstances corresponding to retail sale, or the administration, of such products requires specialised knowledge on the part of the practitioner by whom or under whose directions they are sold, supplied or administered.
- (4) Any regulations made under this section in respect of a particular description or class of medicinal products may specify the qualifications and experience which an applicant for a certificate in respect of that description or class of medicinal products must have, and may provide for the appointment of a committee to advise the appropriate Ministers, in such cases as may be prescribed by or determined in accordance with the regulations, with respect to the grant, renewal, suspension and revocation of such certificates.
- (5) Any such regulations shall include provision as to the grant, duration, renewal, suspension and revocation of certificates for the purposes of this section, including provision for affording—
 - (a) to an applicant for the grant or renewal of such a certificate, where the appropriate Ministers propose to refuse to grant or renew it, and
 - (b) to the holder of such a certificate, where the appropriate Ministers propose to suspend or revoke it,an opportunity of appearing before, and being heard by, a person appointed for the purpose by the appropriate Ministers or of making representations in writing to those Ministers with respect to that proposal.
- (6) Regulations made under this section may provide that, for the purposes of paragraph (b) of subsection (1) of this section, a medicinal product shall not be taken to be sold or supplied in accordance with a prescription as mentioned in that paragraph unless such conditions as are prescribed by the regulations are fulfilled.

- (7) Before making any regulations under this section the appropriate Ministers shall consult the appropriate committee, or, if for the time being there is no such committee, shall consult the Commission.

61 Special restrictions on persons to be supplied with medicinal products

The appropriate Ministers may by regulations provide, either in respect of medicinal products generally or in respect of medicinal products of a description or falling within a class specified in the regulations, that, subject to such exceptions as may be so specified, no person—

- (a) being the holder of a product licence, or
- (b) in the course of business carried on by him and consisting (wholly or partly) of manufacturing medicinal products or of selling medicinal products by way of wholesale dealing,

shall sell or supply any medicinal product to which the regulations apply to any person who does not fall within a class specified in the regulations.

62 Prohibition of sale or supply, or importation, of medicinal products of specified description, or of animal feeding stuffs incorporating such products

- (1) Subject to the following provisions of this section, the appropriate Ministers, where it appears to them to be necessary to do so in the interests of safety, may by order—
- (a) prohibit the sale or supply, or the importation, of medicinal products of any description, or falling within any class, specified in the order, or (in such manner as may appear to them to be sufficient to identify the products in question) designate particular medicinal products and prohibit the sale or supply, or the importation, of those particular products;
 - (b) prohibit the sale or supply, or the importation, of animal feeding stuffs in which medicinal products of any description, or falling within any class, specified in the order have been incorporated, or (in such manner as may appear to them to be sufficient to identify the feeding stuffs in question) designate particular animal feeding stuffs in which medicinal products have been incorporated and prohibit the sale or supply, or the importation, of those particular feeding stuffs.
- (2) A prohibition imposed by order under this section may be a total prohibition or may be imposed subject to such exceptions as may be specified in the order.
- (3) Before making an order under this section the appropriate Ministers, unless in their opinion it is essential to make the order with immediate effect to avoid serious danger to health, whether of human beings or of animals, shall consult the appropriate committee, or if for the time being there is no such committee, shall consult the Commission.
- (4) Where an order is made under this section without prior consultation with the appropriate committee or the Commission in accordance with subsection (3) of this section, the prohibition imposed by the order shall not have effect after the end of such period, not exceeding three months from the date on which it comes into operation, as may be specified in the order, but without prejudice to the making of any further order in accordance with the provisions of this section (including this subsection).

- (5) If any organisation consulted in pursuance of section 129(6) of this Act with respect to a proposal to make an order under this section have given notice to the appropriate Ministers of their desire to be heard under this subsection, or have made representations in writing to those Ministers with respect to that proposal, then before making the order—
- (a) if the organisation have given notice of their desire to be heard, the appropriate Ministers shall arrange for them to have an opportunity of appearing before, and being heard by, the Commission, or
 - (b) if they have made representations in writing, the appropriate Ministers shall refer those representations to the Commission,
- and, where the organisation have availed themselves of the opportunity of being heard, or after considering the representations, as the case may be, the Commission shall report their findings and conclusions to the appropriate Ministers and those Ministers shall take that report into account in determining whether to make the order.
- (6) Subsection (5) of this section shall not have effect where in the opinion of the appropriate Ministers it is essential to make the order with immediate effect as mentioned in subsection (3) of this section.
- (7) If an order is made under this section in circumstances where either—
- (a) neither the appropriate committee (if any) nor the Commission have considered the proposal to make the order (whether on being consulted under subsection (3) of this section or, in the case of the Commission, in pursuance of subsection (5) of this section), or
 - (b) the order is made contrary to the advice of the Commission or, in a case where the Commission have not, but the appropriate committee have, considered the proposal to make the order, is made contrary to the advice of that committee,
- the order shall include a statement of the fact that it has been so made.

63 Adulteration of medicinal products

No person shall—

- (a) add any substance to, or abstract any substance from, a medicinal product so as to affect injuriously the composition of the product, with intent that the product shall be sold or supplied in that state, or
- (b) sell or supply, or offer or expose for sale or supply, or have in his possession for the purpose of sale or supply, any medicinal product whose composition has been injuriously affected by the addition or abstraction of any substance.

64 Protection of purchasers of medicinal products

- (1) No person shall, to the prejudice to the purchaser, sell any medicinal product which is not of the nature or quality demanded by the purchaser.
- (2) For the purposes of this section the sale of a medicinal product shall not be taken to be otherwise than to the prejudice of the purchaser by reason only that the purchaser buys the product for the purpose of analysis or examination.
- (3) Subsection (1) of this section shall not be taken to be contravened by reason only that a medicinal product contains some extraneous matter, if it is proved that the presence of that matter was an inevitable consequence of the process of manufacture of the product.

- (4) Subsection (1) of this section shall not be taken to be contravened by reason only that a substance has been added to, or abstracted from, the medicinal product, if it is proved that—
- (a) the addition or abstraction was not carried out fraudulently, and did not injuriously affect the composition of the product, and
 - (b) the product was sold having attached to it, or to a container or package in which it was sold, a conspicuous notice of adequate size and legibly printed, specifying the substance added or abstracted.
- (5) Where a medicinal product is sold or supplied in pursuance of a prescription given by a practitioner, the preceding provisions of this section shall have effect as if—
- (a) in those provisions any reference to sale included a reference to supply and (except as provided by the following paragraph) any reference to the purchaser included a reference to the person (if any) for whom the product was prescribed by the practitioner, and
 - (b) in subsection (1) of this section, for the words "demanded by the purchaser", there were substituted the words "specified in the prescription".

65 Compliance with standards specified in monographs in certain publications

- (1) No person shall, in the course of a business carried on by him.—
- (a) sell a medicinal product which has been demanded by the purchaser by, or by express reference to, a particular name, or
 - (b) sell or supply a medicinal product in pursuance of a prescription given by a practitioner in which the product required is described by, or by express reference, to a particular name,
- if that name is a name at the head of the relevant monograph and the product does not comply with the standard specified in that monograph.
- (2) No person shall, in the course of a business carried on by him, sell or supply a medicinal product which, in the course of that business, has been offered or exposed for sale and has been so offered or exposed for sale by, or by express reference to, a particular name, if that name is a name at the head of the relevant monograph and the product does not comply with the standard specified in that monograph.
- (3) Where a medicinal product is sold or supplied in the circumstances specified in subsection (1) or subsection (2) of this section, and the name in question is the name, not of the product itself, but of an active ingredient of the product, then for the purposes of the subsection in question the product shall be taken not to comply with the standard specified in the relevant monograph if, in so far as it consists of that ingredient, it does not comply with the standard so specified.
- (4) Subject to subsection (7) of this section, in this section "publication" means one of the following, that is to say, the British Pharmacopoeia, the British Pharmaceutical Codex, the British Veterinary Codex and any compendium published under Part VII of this Act; "the relevant monograph", in relation to the sale or supply of a medicinal product which has been demanded, described in a prescription, or offered or exposed for sale, by or by express reference to a particular name.—
- (a) if, together with that name, there was specified a particular edition of a particular publication, means the monograph (if any) headed by that name in that edition of that publication, or, if there is no such monograph in that

edition, means the appropriate current monograph (if any) headed by that name ;

- (b) if, together with that name, there was specified a particular publication, but not a particular edition of that publication, means the monograph (if any) headed by that name in the current edition of that publication, or, if there is no such monograph in that edition, means the appropriate current monograph (if any) headed by that name, or, in default of such a monograph, means the monograph headed by that name in the latest edition of the specified publication which contained a monograph so headed;
- (c) if no publication was specified together with that name, means the appropriate current monograph (if any);

and " current" means current at the time when the medicinal product in question is demanded, described in a prescription, or offered or exposed for sale, as mentioned in subsection (1) or subsection (2) of this section.

- (5) In this section " the appropriate current monograph ", in relation to a particular name, means—

- (a) the monograph (if any) headed by that name in the current edition of the British Pharmacopoeia, or
- (b) if there is no such monograph, then the monograph (if any) headed by that name in the current edition of a compendium published under Part VII of this Act, or
- (c) if there is no such monograph, then the monograph (if any) headed by that name in the current edition of the British Pharmaceutical Codex or the British Veterinary Codex.

- (6) Subject to subsection (8) of this section, for the purposes of this section an edition of a publication—

- (a) if it is the current edition of that publication, shall be taken as it is for the time being in force (that is to say, together with any amendments, additions and deletions made to it up to the time referred to in subsection (4) of this section), or
- (b) if it is an edition previous to the current edition of that publication, shall be taken as it was immediately before the time when it was superseded by a subsequent edition of that publication (that is to say, together with any amendments, additions and deletions made to it up to that time),

and any monograph in an edition of a publication shall be construed in accordance with any general monograph or notice or any appendix, note or other explanatory material which is contained in that edition and is applicable to that monograph, and any reference in this section to compliance with the standard specified in a monograph shall be construed accordingly.

- (7) In relation to any time on or after the date on which, by notice published in the Gazette by or on behalf of the Health Ministers, it is declared that the European Pharmacopoeia prepared in pursuance of the Convention in that behalf done at Strasbourg on 22nd July 1964 is to have effect for the purposes of this section, subsections (1) and (2) of this section shall have effect as if, after the words " that name is ", in each place where those words occur, there were inserted the words " or is an approved synonym for, " subsection (4) of this section shall have effect as if, before the words "the British Pharmacopoeia ", there were inserted the words " the European Pharmacopoeia ", and after the words " headed by that name ", in each place where those words occur, there were inserted the words " or by a name for which it is an approved synonym ", and

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

subsection (5) of this section shall have effect as if for paragraph (a) of that subsection there were substituted the following paragraphs:—

- “(a) the monograph (if any) headed by that name, or by a name for which it is an approved synonym, in the current edition of the European Pharmacopoeia, or
- (aa) if there is no such monograph, then the monograph (if any) headed by that name in the current edition of the British Pharmacopoeia, or”.

(8) For the purposes of this section, an edition of the European Pharmacopoeia—

- (a) if it is the current edition of that Pharmacopoeia at the time in question, shall be taken as it is for the time being in force in the United Kingdom (that is to say, together with any amendments, additions and deletions made to it which, by notice published as mentioned in subsection (7) of this section before the time referred to in subsection (4) of this section, have been declared to have effect for the purposes of this section), and
- (b) if it is an edition previous to the current edition of that Pharmacopoeia, shall be taken as it was immediately before the time when it was superseded by a subsequent edition of that Pharmacopoeia in force in the United Kingdom (that is to say, together with any amendments, additions and deletions made to it which, by notice so published before that time, had been declared so to have effect),

and a name shall be taken to be an approved synonym for a name at the head of a monograph in the European Pharmacopoeia if, by a notice so published and not withdrawn by any subsequent notice so published, it has been declared to be approved by the Medicines Commission as a synonym for that name.

66 Further powers to regulate dealings with medicinal products

(1) The appropriate Ministers may by regulations prescribe such requirements as they may consider necessary or expedient with respect to any of the following matters, that is to say—

- (a) the manner in which, or persons under whose supervision, medicinal products may be prepared or may be dispensed;
- (b) the amount of space to be provided in any premises for persons preparing or dispensing medicinal products, the separation of any such space from the remainder of the premises, and the facilities to be provided in any premises for such persons ;
- (c) the amount of space to be provided in any premises for the sale or supply of medicinal products ;
- (d) the accommodation (including the amount of space) to be provided in any premises for members of the public to whom medicinal products are sold or supplied or for whom medicinal products are being prepared or assembled;
- (e) the amount of space to be provided in any premises for the storage of medicinal products ;
- (f) the safekeeping of medicinal products;
- (g) the disposal of medicinal products which have become unusable or otherwise unwanted ;
- (h) precautions to be observed before medicinal products are sold or supplied;
- (i) the keeping of records relating to the sale or supply of medicinal products;
- (j) the supply of medicinal products distributed as samples;

- (k) sanitation, cleanliness, temperature, humidity or other factors relating to the risks of deterioration or contamination in connection with the manufacture, storage, transportation, sale or supply of medicinal products;
 - (l) the construction, location and use of automatic machines for the sale of medicinal products.
- (2) Without prejudice to the generality of the preceding subsection, regulations made under subsection (1) of this section may prescribe requirements in respect of—
- (a) the construction, lay-out, drainage, equipment, maintenance, ventilation, lighting and water supply of premises at or from which medicinal products are manufactured, stored, transported, sold or supplied;
 - (b) the disposal of refuse at or from any such premises; and
 - (c) any apparatus, equipment, furnishings or utensils used at any such premises.