



# Health Act 2006

## 2006 CHAPTER 28

### PART 3

#### DRUGS, MEDICINES AND PHARMACIES

### CHAPTER 2

#### MEDICINES AND PHARMACIES

#### **26 Requirements about supervision**

- (1) In section 10 of the Medicines Act 1968 (c. 67) (which provides for exemptions for pharmacists in relation to certain dealings with medicinal products), after subsection (7) insert—

“(7A) The Health Ministers may make regulations prescribing conditions which must be complied with if a thing is to be considered for the purposes of this section as done under the supervision of a pharmacist.

(7B) Conditions prescribed under subsection (7A) may relate to supervision in the case where the pharmacist is not at the place where the thing is being done, and in that case the thing is not to be so considered if no such conditions are prescribed.

(7C) In any case, compliance with any applicable conditions is sufficient for the thing to be so considered.”

- (2) In section 52 of that Act (sale or supply of medicines not on general sale list)—

- (a) the existing text is to be subsection (1),  
(b) after that subsection insert—

“(2) The Health Ministers may make regulations prescribing conditions which must be complied with if a transaction mentioned in

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subsection (1)(c) is to be considered for the purposes of this section as done under the supervision of a pharmacist.

- (3) Conditions prescribed under subsection (2) may relate to supervision in the case where the pharmacist is not on the premises, and in that case the transaction is not to be so considered if no such conditions are prescribed.
- (4) In any case, compliance with any applicable conditions is sufficient for the transaction to be so considered.”

## 27 **Control of pharmacy premises: individuals and partnerships**

- (1) For section 70 of the Medicines Act 1968 (pharmacy business carried on by individual pharmacist or by partners) substitute—

### **“70 Business carried on by individual pharmacist or by partners**

- (1) The conditions referred to in section 69(1)(a) of this Act are that subsections (2) and (3) of this section are both satisfied as respects each of the premises where the retail pharmacy business is carried on and medicinal products, other than medicinal products on a general sale list, are sold by retail.
- (2) This subsection is satisfied if a responsible pharmacist who satisfies the requirements of subsections (4) and (5) of this section is in charge of the business at those premises, so far as concerns—
  - (a) the retail sale at those premises of medicinal products (whether they are on a general sale list or not), and
  - (b) the supply at those premises of such products in circumstances corresponding to retail sale.
- (3) This subsection is satisfied if a notice is conspicuously displayed at those premises stating—
  - (a) the name of the responsible pharmacist for the time being,
  - (b) the number of his registration under the Pharmacy Act 1954 or (in relation to Northern Ireland) the Pharmacy (Northern Ireland) Order 1976, and
  - (c) the fact that he is for the time being in charge of the business at those premises.
- (4) The responsible pharmacist must be—
  - (a) the person carrying on the business, or
  - (b) if the business is carried on by a partnership, one of the partners or, in Scotland, one of the partners who is a pharmacist, or
  - (c) another pharmacist.
- (5) In relation to premises in Great Britain that have been registered pharmacies for less than three years, the responsible pharmacist may not be a person who is a pharmacist by virtue of section 4A of the Pharmacy Act 1954 (qualification by European diploma) or any corresponding provision applying to Northern Ireland.”

- (2) In section 78 of the Medicines Act 1968 (c. 67) (restrictions on use of titles, descriptions and emblems), in subsection (7), for the words from “under whose” to the end substitute “who is in charge of the business at those premises (so far as concerns the retail sale of medicinal products or the supply of such products in circumstances corresponding to retail sale) is also a pharmacist”.

## **28 Control of pharmacy premises: bodies corporate**

- (1) For section 71 of the Medicines Act 1968 (pharmacy business carried on by body corporate) substitute—

### **“71 Business carried on by body corporate**

- (1) The conditions referred to in section 69(1)(b) of this Act are—
- (a) that the retail pharmacy business, so far as concerns the keeping, preparing and dispensing of medicinal products other than medicinal products on a general sale list, is under the management of a superintendent in respect of whom the requirements specified in subsection (6) of this section are fulfilled, and
  - (b) that subsections (2) and (3) of this section are both satisfied as respects each of the premises where the business is carried on and medicinal products, other than medicinal products on a general sale list, are sold by retail.
- (2) This subsection is satisfied if a responsible pharmacist who satisfies the requirements of subsections (4) and (5) of this section is in charge of the business at the premises mentioned in subsection (1)(b) of this section, so far as concerns—
- (a) the retail sale at those premises of medicinal products (whether they are on a general sale list or not), and
  - (b) the supply at those premises of such products in circumstances corresponding to retail sale.
- (3) This subsection is satisfied if a notice is conspicuously displayed at those premises stating—
- (a) the name of the responsible pharmacist for the time being,
  - (b) the number of his registration under the Pharmacy Act 1954 or (in relation to Northern Ireland) the Pharmacy (Northern Ireland) Order 1976, and
  - (c) the fact that he is for the time being in charge of the business at those premises.
- (4) The responsible pharmacist must be—
- (a) the superintendent mentioned in subsection (1)(a) of this section, or
  - (b) a manager or assistant subject to the directions of the superintendent and who is a pharmacist.
- (5) In relation to premises in Great Britain that have been registered pharmacies for less than three years, the responsible pharmacist may not be a person who is a pharmacist by virtue of section 4A of the Pharmacy Act 1954 (qualification by European diploma) or any corresponding provision applying to Northern Ireland.

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- (6) The requirements referred to in subsection (1)(a) of this section in relation to a superintendent are that—
- (a) he is a pharmacist,
  - (b) a statement in writing signed by him, and signed on behalf of the body corporate, specifying his name and stating whether he is a member of the board of that body or not, has been sent to the registrar, and
  - (c) he does not act in a similar capacity for any other body corporate.”
- (2) In section 124 of the Medicines Act 1968 (c. 67) (offences by bodies corporate), in subsection (2)(b), for “subsection (1)(a)” substitute “subsection (4)(b)”.

## 29 **Control of pharmacy premises: representative of pharmacist in case of death or disability**

In section 72 of the Medicines Act 1968 (representative of pharmacist in case of death or disability), for subsection (2) substitute—

- “(2) The conditions referred to in section 69(1)(c) of this Act are—
- (a) that the name and address of the representative, and the name of the pharmacist whose representative he is, have been notified to the registrar, and
  - (b) that subsections (2A) and (2B) of this section are both satisfied as respects each of the premises at which the business is carried on and medicinal products, other than medicinal products on a general sale list, are sold by retail.
- (2A) This subsection is satisfied if a responsible pharmacist is in charge of the business at the premises mentioned in subsection (2)(b) of this section, so far as concerns—
- (a) the retail sale at those premises of medicinal products (whether they are on a general sale list or not), and
  - (b) the supply at those premises of such products in circumstances corresponding to retail sale.
- (2B) This subsection is satisfied if a notice is conspicuously displayed at those premises stating—
- (a) the name of the responsible pharmacist for the time being,
  - (b) the number of his registration under the Pharmacy Act 1954 or (in relation to Northern Ireland) the Pharmacy (Northern Ireland) Order 1976, and
  - (c) the fact that he is for the time being in charge of the business at those premises.”

## 30 **The responsible pharmacist**

- (1) After section 72 of the Medicines Act 1968 (c. 67) insert—

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### **“72A The responsible pharmacist**

- (1) It is the duty of the responsible pharmacist mentioned in sections 70, 71 and 72 of this Act to secure the safe and effective running of the pharmacy business at the premises in question so far as concerns—
  - (a) the retail sale at those premises of medicinal products (whether they are on a general sale list or not), and
  - (b) the supply at those premises of such products in circumstances corresponding to retail sale.
- (2) A person may not be the responsible pharmacist in respect of more than one set of premises at the same time, except in circumstances specified by the Health Ministers in regulations, and then only if such conditions as may be so specified are complied with.
- (3) The responsible pharmacist must establish (if they are not already established), maintain and keep under review procedures designed to secure the safe and effective running of the business as mentioned in subsection (1) of this section.
- (4) The responsible pharmacist must make a record (which must be available at the premises) of—
  - (a) who the responsible pharmacist is in relation to the premises on any day and at any time, and
  - (b) such other matters as the Health Ministers specify in regulations.
- (5) It is the duty of the person carrying on the business to secure that—
  - (a) the record is properly maintained, and
  - (b) it is preserved for at least as long as is specified in regulations made by the Health Ministers.
- (6) The Health Ministers may make further provision in regulations in relation to the responsible pharmacist.
- (7) The regulations may, in particular, make further provision about the matters mentioned in subsections (1) to (4) of this section, and make provision about—
  - (a) the qualifications and experience which a person must have if he is to be a responsible pharmacist,
  - (b) the responsible pharmacist’s absence from the premises,
  - (c) the supervision by the responsible pharmacist, when he is not present on the premises, of relevant activities there,
  - (d) circumstances in which the responsible pharmacist may supervise relevant activities at a pharmacy of which he is not the responsible pharmacist,
  - (e) the form in which the procedures referred to in subsection (3) of this section are to be recorded and matters which must be covered by them,
  - (f) the form in which the record referred to in subsection (4) of this section is to be kept and particulars which must be included in it.
- (8) In subsection (7)(c) and (d), “relevant activities” means things mentioned in section 10 and transactions mentioned in section 52(1)(c) of this Act.

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### **72B Section 72A: supplementary**

- (1) The failure by a person to comply with any requirements of section 72A of this Act, or of regulations made under that section, may constitute misconduct for the purposes of section 80 of this Act, section 8 of the Pharmacy Act 1954 and Article 20 of the Pharmacy (Northern Ireland) Order 1976; and the Statutory Committee may deal with such a failure accordingly.
  - (2) A person who does not have the qualifications and experience required by regulations made by virtue of section 72A(7)(a) of this Act is not to be considered as a responsible pharmacist for the purposes of sections 70 to 72 of this Act.
  - (3) Subsection (4) of this section applies if a person—
    - (a) fails to comply with the requirements of subsection (2) of section 72A of this Act, or of regulations made under that subsection,
    - (b) fails to comply with any requirements as to absence from the premises contained in regulations made by virtue of subsection (7)(b) of that section.
  - (4) If this subsection applies, the person in question is not to be considered while the failure continues as being in charge of the business at the premises in question (or in a subsection (3)(a) case at any of them) for the purposes of sections 70 to 72 of this Act.”
- (2) In section 77 of the Medicines Act 1968 (c. 67) (annual return of premises to registrar), omit paragraph (b) and the “and” immediately preceding it.
  - (3) In section 84 of the Medicines Act 1968 (offences), before subsection (1) insert—
 

“(A1) A person who fails to comply with either of the following shall be guilty of an offence and liable on summary conviction to a fine not exceeding level 3 on the standard scale—

    - (a) subsection (4) of section 72A of this Act (which requires the making of entries in a record relating to the responsible pharmacist),
    - (b) subsection (5) of that section (which requires the keeping and preservation of the record).”

## **31 Enforcement**

- (1) In section 108 of the Medicines Act 1968 (c. 67) (enforcement in England and Wales) —
  - (a) in subsection (1), at the beginning insert “Subject to the provisions of subsection (6C) of this section,”,
  - (b) after subsection (6) insert—
 

“(6A) The Pharmaceutical Society shall be under a duty, concurrently with the appropriate Minister, to enforce the provisions of subsections (4) and (5) of section 72A of this Act in their application to England and Wales.

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- (6B) The Pharmaceutical Society shall be under a duty to enforce the other provisions of section 72A of this Act, and any regulations made under them, in their application to England and Wales.
  - (6C) The appropriate Minister shall be under no duty to enforce those other provisions, or any regulations made under them, in their application to England and Wales.
  - (6D) Notwithstanding subsection (6C) of this section the appropriate Minister is to be treated for the purposes of sections 111 to 114 of this Act—
    - (a) as empowered by this section to enforce those other provisions, or any regulations made under them, in their application to England and Wales, and
    - (b) to that extent as an enforcement authority in relation to those other provisions or those regulations in their application to England and Wales.”
  - (c) in subsection (9)(a), after “hospital” insert “(except in relation to so much of the hospital premises as is a registered pharmacy)”,
  - (d) in subsection (10), for “(4) to (8)” substitute “(4) to (6A), (7) and (8)”.
- (2) In section 109 of the Medicines Act 1968 (enforcement in Scotland), in subsection (1), at the beginning insert “Subject to the provisions of section 108(6C) of this Act as applied by subsection (2) of this section,”.
- (3) In section 110 of the Medicines Act 1968 (enforcement in Northern Ireland)—
- (a) in subsection (1), for “subsection (4)” substitute “subsections (3C) and (4)”,
  - (b) after subsection (3) insert—
    - “(3A) The Pharmaceutical Society shall be under a duty, concurrently with the Minister, to enforce the provisions of subsections (4) and (5) of section 72A of this Act in their application to Northern Ireland.
    - (3B) The Pharmaceutical Society shall be under a duty to enforce the other provisions of section 72A of this Act, and any regulations made under them, in their application to Northern Ireland.
    - (3C) The Minister shall be under no duty to enforce those other provisions, or any regulations made under them, in their application to Northern Ireland.
    - (3D) Notwithstanding subsection (3C) of this section the Minister is to be treated for the purposes of sections 111 to 114 of this Act—
      - (a) as empowered by this section to enforce those other provisions, or any regulations made under them, in their application to Northern Ireland, and
      - (b) to that extent as an enforcement authority in relation to those other provisions or those regulations in their application to Northern Ireland.”
  - (c) in subsection (5)(a), for “and (3)” substitute “to (3D)”,
  - (d) in subsection (5)(b), for “(4) to (8)” substitute “(4) to (6A), (7) and (8)”.

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### **32 Order-making powers**

In section 129 of the Medicines Act 1968 (c. 67) (orders and regulations), in subsection (5)—

- (a) after “power to make” insert “an order or”,
- (b) after “making the” insert “order or”.

### **33 Orders under s.60 of the Health Act 1999**

In Schedule 3 to the Health Act 1999 (c. 8) (which makes further provision about orders under section 60 of that Act regulating health care professions), omit paragraph 2(2) (which imposes a limitation on amendment of the Medicines Act 1968).