Health Act 2006

2006 CHAPTER 28

PART 3 U.K.

DRUGS, MEDICINES AND PHARMACIES

CHAPTER 1 U.K.

SUPERVISION OF MANAGEMENT AND USE OF CONTROLLED DRUGS

17 Accountable officers and their responsibilities as to controlled drugs U.K.

(1) The relevant authority may by regulations make provision for or in connection with requiring designated bodies to nominate or appoint persons who are to have prescribed responsibilities in relation to the safe, appropriate and effective management and use of controlled drugs in connection with—

(a) activities carried on by or on behalf of the designated bodies, and

(b) activities carried on by or on behalf of bodies or persons providing services under arrangements made with the designated bodies.

(2) The person who is to be so nominated or appointed by a designated body is to be known as its accountable officer.

This is subject to any regulations made by virtue of subsection (5)(e).

(3) In this Chapter "designated body" means—

(a) a body falling within any description of bodies prescribed as designated bodies for the purposes of this section, or

(b) a body prescribed as a designated body for those purposes.

(4) The descriptions of bodies, or bodies, that may be so prescribed are descriptions of bodies, or bodies, appearing to the relevant authority—

(a) to be directly or indirectly concerned with the provision of health care (whether or not for the purposes of the health service), or

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Changes to legislation: *There are currently no known outstanding effects for the Health Act 2006, Part 3. (See end of Document for details)*

(b) to be otherwise carrying on activities that involve, or may involve, the supply or administration of controlled drugs.

(5) Regulations under this section may make provision—

(a) for conditions that must be satisfied in relation to a person if he is to be nominated or appointed by a designated body as the body's accountable officer;

(b) for a single person to be nominated or appointed as the accountable officer for each of two or more designated bodies where those bodies are satisfied as to the prescribed matters;

(c) requiring a designated body that has an accountable officer to provide the officer with funds and other resources necessary for enabling the officer to discharge his responsibilities as accountable officer for the body;

(d) for ensuring that an accountable officer, in discharging his responsibilities, has regard to best practice in relation to the use of controlled drugs;

(e) for the persons required to be nominated or appointed as mentioned in subsection (1) to be known by such name as is prescribed;

(f) for making such amendments of any enactment as appear to the relevant authority to be required in connection with any provision made in pursuance of paragraph (e);

(g) for creating offences punishable on summary conviction by a fine not exceeding level 5 on the standard scale or for creating other procedures for enforcing any provisions of the regulations.

(6) The responsibilities that may be imposed on a designated body's accountable officer by regulations under this section include responsibilities as to the establishment and operation of arrangements for—

(a) securing the safe management and use of controlled drugs;

(b) monitoring and auditing the management and use of such drugs;

(c) ensuring that relevant individuals receive appropriate training and that their training needs are regularly reviewed;

(d) monitoring and assessing the performance of such individuals in connection with the management or use of such drugs;

(e) making periodic inspections of premises used in connection with the management or use of such drugs;

(f) recording, assessing and investigating concerns expressed about incidents that may have involved improper management or use of such drugs;

(g) ensuring that appropriate action is taken for the purpose of protecting patients or members of the public in cases where such concerns appear to be well-founded;

(h) where required by regulations under section 18, the sharing of information.

(7) The arrangements mentioned in subsection (6) may be arrangements established (according to the circumstances)—

(a) by the accountable officer,

(b) by the designated body (or any of the designated bodies) for which he is the accountable officer, or

(c) by a body or person acting on behalf of, or providing services under arrangements made with, the designated body (or any of the designated bodies).

(8) In subsection (6)—

(a) references to the management or use of controlled drugs are to the management or use of drugs in connection with activities carried on by a body or person within subsection (7)(b) or (c), and

(b) "relevant individual" means an individual who, whether as—

(i) a health care professional, or

(ii) an employee who is not a health care professional, or

(iii) otherwise,

is engaged in any activity carried on by a body or person within subsection (7)(b) or (c) that involves, or may involve, the management or use of controlled drugs.

(9) A designated body may confer on its accountable officer such powers as it thinks appropriate to enable him to discharge any of the responsibilities imposed on him as accountable officer for the body by regulations under this section.

(10) Nothing in subsections (5) to (7) is to be read as prejudicing the generality of subsection (1).

(11) In this section "prescribed" means prescribed by regulations under this section.

Commencement Information

I1 S. 17 in force for certain purposes at Royal Assent, see s. 83

I2 S. 17 in force at 1.1.2007 for E. in so far as not already in force by S.I. 2006/3125, **art. 2(1)**

I3 S. 17 in force at 1.3.2007 for S. in so far as not already in force by S.I. 2006/3125, **art. 2(2)**

I4 S. 17 in force at 13.12.2008 for W. in so far as not already in force by S.I. 2008/3171, **art. 2(a)**

I5 S. 17 in force at 1.8.2012 for N.I. in so far as not already in force by S.R. 2012/307, **art. 2(a)**

18 Co-operation between health bodies and other organisations U.K.

(1) The relevant authority may by regulations make provision for or in connection with requiring responsible bodies to co-operate with each other in connection with—

(a) the identification of cases in which action may need to be taken in respect of matters arising in relation to the management or use of controlled drugs by relevant persons (see section 19);

(b) the consideration of issues relating to the taking of action in respect of such matters;

(c) the taking of action in respect of such matters.

(2) In this Chapter "responsible body" means—

(a) a body falling within any description of bodies prescribed as responsible bodies for the purposes of this section, or

(b) a body prescribed as a responsible body for those purposes.

(3) The descriptions of bodies, or bodies, that may be so prescribed are—

(a) descriptions of bodies, or bodies, which fall within subsection (4); and

(b) police forces.

(4) Descriptions of bodies, or bodies, fall within this subsection if they appear to the relevant authority—

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(a) to be directly or indirectly concerned with the provision of health care (whether or not for the purposes of the health service),

(b) to be otherwise carrying on activities that involve, or may involve, the supply or administration of controlled drugs,

(c) to have powers of inspection in relation to the management or use of controlled drugs,

(d) to be public or local authorities with responsibilities in relation to social care, or

(e) to be public or local authorities (not within paragraphs (a) to (d)) whose responsibilities include responsibilities with respect to matters such as are mentioned in subsection (1).

(5) Regulations under this section may make provision—

(a) for requiring a responsible body to disclose information to any other such body or bodies in prescribed circumstances, or in circumstances where it appears to the responsible body that the prescribed conditions are satisfied, whether or not the disclosure of information has been requested;

(b) in relation to a responsible body which has an accountable officer, for requiring disclosures to be made by or to that officer instead of by or to the body;

(c) in relation to a responsible body which is a police force, for imposing duties on the chief officer;

(d) for requiring a responsible body, in prescribed circumstances, to consult the prescribed accountable officer in connection with any requirement imposed on the body under the regulations;

(e) for imposing duties on accountable officers in relation to the taking of action for the purpose of protecting the safety of patients or the general public.

(6) The duties that may be imposed on an accountable officer in pursuance of subsection (5)(e) include a duty to make recommendations to a responsible body as to any action which the officer considers that the body should take for the purpose mentioned in that provision.

(7) The action that may be so recommended includes action in relation to the institution of disciplinary proceedings.

(8) Nothing in subsections (5) to (7) is to be read as prejudicing the generality of subsection (1).

(9) In this section—

(a) "chief officer" means—

(i) in relation to a police force in England and Wales, the chief officer of police;

(ii) in relation to **[**[F1]the Police Service of Scotland, the chief constable of that Service**]**;

(iii) in relation to the Police Service of Northern Ireland or the Police Service of Northern Ireland Reserve, the Chief Constable of the Police Service of Northern Ireland;

(b) "police force" means—

(i) a police force in England **[**[F2]and Wales,**]**

[[F3](ia) the Police Service of Scotland, or**]**

(ii) the Police Service of Northern Ireland or the Police Service of Northern Ireland Reserve;

(c) "prescribed" means prescribed by regulations under this section.

Textual Amendments

F1 Words in s. 18(9)(a)(ii) substituted (1.4.2013) by The Police and Fire Reform (Scotland) Act 2012 (Consequential Provisions and Modifications) Order 2013 (S.I. 2013/602), art. 1(2), **Sch. 2 para. 51(2)(a)**

F2 Words in s. 18(9)(b)(i) substituted (1.4.2013) by The Police and Fire Reform (Scotland) Act 2012 (Consequential Provisions and Modifications) Order 2013 (S.I. 2013/602), art. 1(2), **Sch. 2 para. 51(2)(b)**

F3 S. 18(9)(b)(ia) inserted (1.4.2013) by The Police and Fire Reform (Scotland) Act 2012 (Consequential Provisions and Modifications) Order 2013 (S.I. 2013/602), art. 1(2), **Sch. 2 para. 51(2)(c)(ii)**

Commencement Information

I6 S. 18 in force for certain purposes at Royal Assent, see s. 83

I7 S. 18 in force at 1.1.2007 for E. in so far as not already in force by S.I. 2006/3125, **art. 2(1)**

I8 S. 18 in force at 1.3.2007 for S. in so far as not already in force by S.I. 2006/3125, **art. 2(2)**

I9 S. 18 in force at 13.12.2008 for W. in so far as not already in force by S.I. 2008/3171, **art. 2(a)**

I10 S. 18 in force at 1.8.2012 for N.I. in so far as not already in force by S.R. 2012/307, **art. 2(a)**

19 Meaning of "relevant person" in section 18 U.K.

(1) In section 18 "relevant person" means—

(a) a person falling within any description of persons prescribed as relevant persons for the purposes of that section, or

(b) an individual to whom subsection (3) applies.

(2) The descriptions of persons that may be prescribed for the purposes of section 18 are descriptions of persons appearing to the relevant authority to be carrying on, or engaged in, activities that involve, or may involve, the supply or administration of controlled drugs.

(3) This subsection applies to an individual who, whether as—

(a) a health care professional, or

(b) an employee who is not a health care professional, or

(c) otherwise,

is engaged in any activity carried on by a designated body, or by a body or person acting on behalf of, or providing services under arrangements made with, a designated body that involves, or may involve, the management or use of controlled drugs.

(4) In this section "prescribed" means prescribed by regulations under section 18.

Commencement Information

I11 S. 19 in force for certain purposes at Royal Assent, see s. 83

I12 S. 19 in force at 1.1.2007 for E. in so far as not already in force by S.I. 2006/3125, **art. 2(1)**

I13 S. 19 in force at 1.3.2007 for S. in so far as not already in force by S.I. 2006/3125, **art. 2(2)**

I14 S. 19 in force at 13.12.2008 for W. in so far as not already in force by S.I. 2008/3171, **art. 2(a)**

I15 S. 19 in force at 1.8.2012 for N.I. in so far as not already in force by S.R. 2012/307, **art. 2(a)**

20 Controlled drugs: power to enter and inspect U.K.

(1) A constable or an authorised person may, for the purpose of securing the safe, appropriate and effective management and use of controlled drugs—

(a) enter any relevant premises;

(b) inspect any precautions taken on the premises for the safe custody of controlled drugs;

(c) inspect any stocks of controlled drugs kept on the premises;

(d) require any relevant records kept on the premises to be produced for his inspection.

(2) The powers conferred by subsection (1) may be exercised only—

(a) at a reasonable hour, and

(b) on production (if required) of the written authority of the person exercising them.

(3) The power conferred by subsection (1)(a) may be exercised by an authorised person to enter relevant premises which are or form part of a private dwelling only if he is accompanied by a constable.

But this subsection does not apply in such circumstances as may be prescribed by regulations made by the relevant authority.

(4) The power conferred by subsection (1)(d) includes power—

(a) to take copies of or extracts from relevant records, and

(b) to take possession of any relevant records kept on the premises and retain them for so long as the person exercising the power considers necessary.

(5) In this section "authorised person" means (subject to subsection (6))—

(a) a person authorised by the relevant authority,

(b) an accountable officer, or

(c) where a designated body is required by regulations under section 17 to nominate or appoint an accountable officer, a member of the staff of the designated body authorised by it.

Authorisations given under this subsection may be general or specific.

(6) The accountable officer of a designated body specified, or of a description specified, in directions given by the relevant authority is not an authorised person for the purposes of this section; and such a designated body may not authorise members of its staff under subsection (5)(c).

(7) The relevant authority may by regulations prescribe descriptions of premises which are to be "relevant premises" for the purposes of this section in relation to constables and authorised persons of descriptions prescribed in the regulations.

(8) The descriptions of premises that may be so prescribed are descriptions of premises (or parts thereof) appearing to the relevant authority to be used in connection with—

(a) the provision of health care (whether or not for the purposes of the health service), or

(b) the supply or administration of controlled drugs.

(9) In this Chapter "relevant records" means records kept with respect to controlled drugs in pursuance of regulations under section 10 of the Misuse of Drugs Act 1971 (c. 38).

(10) Directions under subsection (6) are to be given by regulations or in writing; but any such directions which relate to more than one designated body are to be given by regulations.

(11) Directions under subsection (6) given in writing may be varied or revoked by subsequent directions under that subsection.

Modifications etc. (not altering text)

C1 S. 20(3) excluded (E.S.) (1.1.2007 for E., 1.3.2007 for S.) by The Controlled Drugs (Supervision of Management and Use) Regulations 2006 (S.I. 2006/3148), regs. 1(1), **21**

C2 S. 20(3) excluded (E.S.) (temp. from 1.4.2013 to 31.3.2020) by The Controlled Drugs (Supervision of Management and Use) Regulations 2013 (S.I. 2013/373), regs. 1(1), **18(3)**

Commencement Information

I16 S. 20 in force for certain purposes at Royal Assent, see s. 83

I17 S. 20 in force at 1.1.2007 for E. in so far as not already in force by S.I. 2006/3125, **art. 2(1)**

I18 S. 20 in force at 1.3.2007 for S. in so far as not already in force by S.I. 2006/3125, **art. 2(2)**

I19 S. 20 in force at 13.12.2008 for W. in so far as not already in force by S.I. 2008/3171, **art. 2(a)**

I20 S. 20 in force at 1.8.2012 for N.I. in so far as not already in force by S.R. 2012/307, **art. 2(a)**

21 Offences in connection with power to enter and inspect U.K.

(1) A person commits an offence if he—

(a) intentionally obstructs a person in the exercise of his powers under section 20(1),

(b) conceals from a person acting under section 20(1) anything which that person is entitled to inspect, or

(c) without reasonable excuse fails to produce any relevant records which a person acting under section 20(1) requires to be produced.

(2) A person guilty of an offence under subsection (1) is liable—

(a) on conviction on indictment, to imprisonment for a term not exceeding two years or to a fine, or to both;

(b) on summary conviction, to imprisonment for a term not exceeding **[**[F4]the general limit in a magistrates' court**]** or to a fine not exceeding the statutory maximum, or to both.

(3) In the application of this section to Scotland and Northern Ireland, the reference to 12 months in subsection (2)(b) is to be read as a reference to 6 months.

Textual Amendments

F4 Words in s. 21(2)(b) (and, by implication, the same words in s. 21(3)) substituted (7.2.2023 at 12.00 p.m.) by virtue of The Judicial Review and Courts Act 2022 (Magistrates' Court Sentencing Powers) Regulations 2023 (S.I. 2023/149), regs. 1(2), 2(1), **Sch. Pt. 1** table

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Commencement Information

I21 S. 21 in force at 1.1.2007 for E. by S.I. 2006/3125, **art. 2(1)**
I22 S. 21 in force at 1.3.2007 for S. by S.I. 2006/3125, **art. 2(2)**
I23 S. 21 in force at 13.12.2008 for W. by S.I. 2008/3171, **art. 2(a)**
I24 S. 21 in force at 1.8.2012 for N.I. by S.R. 2012/307, **art. 2(a)**

22 Guidance U.K.

(1) The relevant authority may issue guidance to designated bodies in connection with—

(a) determining whether conditions specified in regulations under section 17 have been satisfied in relation to the nomination or appointment of a person as a designated body's accountable officer;

(b) the discharge by a designated body's accountable officer of any responsibilities imposed on him by regulations under section 17;

(c) the exercise by designated bodies of their powers under section 17(9);

(d) the exercise by designated bodies of their powers under section 20(5)(c).

(2) The relevant authority may issue guidance to responsible bodies in connection with their discharge of any duties imposed on them by regulations under section 18.

(3) Guidance under this section may make different provision for different cases or circumstances.

(4) Designated bodies and responsible bodies must have regard to any guidance under this section in exercising any functions to which the guidance relates.

Commencement Information

I25 S. 22 in force at 1.1.2007 for E. by S.I. 2006/3125, **art. 2(1)**
I26 S. 22 in force at 1.3.2007 for S. by S.I. 2006/3125, **art. 2(2)**
I27 S. 22 in force at 13.12.2008 for W. by S.I. 2008/3171, **art. 2(a)**
I28 S. 22 in force at 1.8.2012 for N.I. by S.R. 2012/307, **art. 2(a)**

23 Crown application U.K.

(1) This Chapter binds the Crown.

(2) No contravention by the Crown of any provision of this Chapter shall make the Crown criminally liable; but the High Court (or, in Scotland, the Court of Session) may declare unlawful any act or omission of the Crown which constitutes such a contravention.

(3) The provisions of this Chapter apply to persons in the public service of the Crown as they apply to other persons.

Commencement Information

I29 S. 23 in force at 1.1.2007 for E. by S.I. 2006/3125, **art. 2(1)**
I30 S. 23 in force at 1.3.2007 for S. by S.I. 2006/3125, **art. 2(2)**
I31 S. 23 in force at 13.12.2008 for W. by S.I. 2008/3171, **art. 2(a)**
I32 S. 23 in force at 1.8.2012 for N.I. by S.R. 2012/307, **art. 2(a)**

24 Relevant authorities U.K.

(1) This section applies to functions conferred on the relevant authority by this Chapter.

(2) Subject to subsection (4), any functions to which this section applies are exercisable in relation to England by the Secretary of State.

(3) Subject to subsection (4), any functions to which this section applies are exercisable in relation to Wales by the National Assembly for Wales.

(4) Any power of the relevant authority to make regulations under this Chapter is exercisable in relation to cross-border bodies by the Secretary of State after consultation with the Assembly.

(5) A "cross-border body" is a body which—

(a) performs (and only performs) functions in respect of England and Wales, and

(b) does not perform functions mainly in respect of England or mainly in respect of Wales.

(6) Any functions to which this section applies are exercisable in relation to Scotland by the Secretary of State after consultation with the Scottish Ministers.

(7) Any functions to which this section applies are exercisable in relation to Northern Ireland by the Department of Health, Social Services and Public Safety.

Commencement Information

I33 S. 24 in force for certain purposes at Royal Assent, see s. 83

I34 S. 24 in force at 1.1.2007 for E. in so far as not already in force by S.I. 2006/3125, **art. 2(1)**

I35 S. 24 in force at 1.3.2007 for S. in so far as not already in force by S.I. 2006/3125, **art. 2(2)**

I36 S. 24 in force at 13.12.2008 for W. in so far as not already in force by S.I. 2008/3171, **art. 2(a)**

I37 S. 24 in force at 1.8.2012 for N.I. in so far as not already in force by S.R. 2012/307, **art. 2(a)**

25 Interpretation U.K.

(1) In this Chapter—

"accountable officer" is to be read in accordance with section 17(2);

"body" includes an unincorporated association;

"controlled drug" has the meaning given by section 2 of the Misuse of Drugs Act 1971 (c. 38);

"designated body" has the meaning given by section 17(3);

"health care" means—

(a) services provided to individuals for or in connection with the prevention, diagnosis or treatment of illness, and

(b) the promotion and protection of public health;

"health care professional"—

(a) in relation to England and Wales, has the meaning given by **[**[F5]section 91(2)(a) of the National Health Service Act 2006 (referred to in this Act as "the 2006 Act")**]**,

(b) in relation to Scotland, has the meaning given by section 17D(2) of the National Health Service (Scotland) Act 1978 (c. 29), and

(c) in relation to Northern Ireland, has the meaning given by Article 15C of the Health and Personal Social Services (Northern Ireland) Order 1972 (S.I. 1972/1265 (N.I. 14));

"illness"—

(a) in relation to England and Wales, has the meaning given by **[**[F6]section 275 of the 2006 Act**]**,

(b) in relation to Scotland, has the meaning given by section 108(1) of the National Health Service (Scotland) Act 1978, and

(c) in relation to Northern Ireland, has the meaning given by Article 2(2) of the Health and Personal Social Services (Northern Ireland) Order 1972;

"relevant authority" is to be read in accordance with section 24;

"relevant records" has the meaning given by section 20(9);

"responsible body" has the meaning given by section 18(2).

(2) In this Chapter any reference to the management or use of controlled drugs includes—

(a) the storage, carriage and safe custody of such drugs,

(b) the prescribing and supply of such drugs,

(c) the administration of such drugs,

(d) the recovery of such drugs when no longer needed, and

(e) the disposal of such drugs.

Textual Amendments

F5 Words in s. 25(1) substituted (1.3.2007) by National Health Service (Consequential Provisions) Act 2006 (c. 43), s. 8(2), **Sch. 1 para. 282(a)** (with Sch. 3 Pt. 1)

F6 Words in s. 25(1) substituted (1.3.2007) by National Health Service (Consequential Provisions) Act 2006 (c. 43), s. 8(2), **Sch. 1 para. 282(b)** (with Sch. 3 Pt. 1)

Commencement Information

I38 S. 25 in force for certain purposes at Royal Assent, see s. 83

I39 S. 25 in force at 1.1.2007 for E. in so far as not already in force by S.I. 2006/3125, **art. 2(1)**

I40 S. 25 in force at 1.3.2007 for S. in so far as not already in force by S.I. 2006/3125, **art. 2(2)**

I41 S. 25 in force at 13.12.2008 for W. in so far as not already in force by S.I. 2008/3171, **art. 2(a)**

I42 S. 25 in force at 1.8.2012 for N.I. in so far as not already in force by S.R. 2012/307, **art. 2(a)**

CHAPTER 2 E+W

MEDICINES AND PHARMACIES

PROSPECTIVE

26 Requirements about supervision E+W

(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 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 E+W

(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 **[**[F7]person registered in Part 1 of the Register of Pharmacists maintained under article 10(1) of the Pharmacists and Pharmacy Technicians Order 2007**]**, 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 ".

Textual Amendments

F7 Word in s. 27(1) substituted (3.12.2007) by The European Qualifications (Health and Social Care Professions) Regulations 2007 (S.I. 2007/3101), regs. 1(2), **103(a)**

Commencement Information

I43 S. 27 in force at 1.10.2009 by S.I. 2008/2714, **art. 2(a)**

28 Control of pharmacy premises: bodies corporate E+W

(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.

(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.

[[F8](7) In subsection (6)(a) "pharmacist" does not include a person registered in Part 3 of the Register of Pharmacists maintained under article 10(1) of the Pharmacists and Pharmacy Technicians Order 2007 (visiting pharmacists from relevant European States) **[**[F9]or a person registered in the register of visiting pharmaceutical chemists from a relevant European State maintained under Article 9 of the Pharmacy (Northern Ireland) Order 1976.**]**."**]**

(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) ".

Textual Amendments

F8 Words in s. 28(1) added (3.12.2007) by The European Qualifications (Health and Social Care Professions) Regulations 2007 (S.I. 2007/3101), regs. 1(2), **103(b)**

F9 Words in s. 28(1) inserted (22.5.2008) by The European Qualifications (Pharmacy) Regulations (Northern Ireland) 2008 (S.R. 2008/192), regs. 1(2), **15**

Commencement Information

I44 S. 28 in force at 1.10.2009 by S.I. 2008/2714, **art. 2(a)**

29 Control of pharmacy premises: representative of pharmacist in case of death or disability E+W

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."

Commencement Information

I45 S. 29 in force at 1.10.2009 by S.I. 2008/2714, **art. 2(a)**

30 The responsible pharmacist E+W

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

"**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.

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.

[F10](3) . . . . . .

Textual Amendments

F10 S. 30(3) omitted (1.12.2022) by virtue of The Pharmacy (Responsible Pharmacists, Superintendent Pharmacists etc.) Order 2022 (S.I. 2022/849), art. 1(3), **Sch. 1 para. 10**; S.I. 2022/1023, art. 2

Commencement Information

I46 S. 30 in force for certain purposes at Royal Assent, see s. 83

I47 S. 30 in force at 1.10.2009 in so far as not already in force by S.I. 2008/2714, **art. 2(b)**

31 Enforcement E+W

(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.

(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) ”.

Commencement Information

I48 S. 31 in force at 1.10.2009 by S.I. 2008/2714, **art. 2(a)**

PROSPECTIVE

32 Order-making powers E+W

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 E+W

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).

Commencement Information

I49 S. 33 in force at 1.10.2006 by S.I. 2006/2603, **art. 3**

Status:
This version of this part contains provisions that are prospective.

Changes to legislation:
There are currently no known outstanding effects for the Health Act 2006, Part 3.