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DRAFT STATUTORY INSTRUMENTS

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**2010 No.**

**The Pharmacy Order 2010**

**PART 3**

**Registered Pharmacies: Standards in retail pharmacies**

**Standards: general**

7.—(1) In the exercise of its functions under article 4(3)(b), the Council must make provision in rules about the standards that are to be met in connection with the carrying on of a retail pharmacy business at a registered pharmacy.

- (2) Those standards may relate to requirements that are to be met—
- (a) by the person carrying on the retail pharmacy business; or
  - (b) by a superintendent pharmacist.
- (3) The standards may, in particular, relate to—
- (a) record keeping;
  - (b) standard operating procedures;
  - (c) the training of staff;
  - (d) incident reporting mechanisms;
  - (e) arrangements for the obtaining, keeping, handling, use and security of medicinal products or medical devices;
  - (f) the conditions in which medicinal products (including controlled drugs) are to be stored;
  - (g) the condition of the premises (including the physical state, safety and security of the premises);
  - (h) the availability or condition of facilities or equipment at the premises used to carry out certain activities (including the conducting of clinical procedures (such as the taking of blood), the undertaking of consultations with patients and the carrying on of activities to which section 10 of the Medicines Act 1968<sup>(1)</sup> (exemptions for pharmacists) applies);
  - (i) the management of waste (including the adequate procedures for the safe destruction and disposal of medicinal products kept on the premises); and
  - (j) the use of the premises as a training establishment.
- (4) The Council must also make provision in rules—
- (a) requiring any person carrying on a retail pharmacy business to provide information to the Council;
  - (b) for such information to be provided—
    - (i) at the request of the Council, or

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(1) 1968 c.67. Section 10 was amended by paragraph 5 of Schedule 3 to the Regulation of Care (Scotland) Act 2001 (asp 8) and by S.I.1971/1445, 1993/384, 1994/2987 and 2006/2407.

- (ii) on such dates or at such intervals as the Council may determine, either generally or in relation to particular persons carrying on a retail pharmacy business or such persons of a particular description; and
- (c) in respect of—
  - (i) the form and manner in which such information is to be provided to the Council, and
  - (ii) the time within which such information is to be provided to the Council pursuant to a request under sub-paragraph (b)(i).
- (5) Rules under paragraph (4) must, in particular, enable the Council to obtain the following information—
  - (a) details of the person carrying on the retail pharmacy business including—
    - (i) where the business is carried on by an individual, details of the home address in the Register of that individual,
    - (ii) where the business is carried on by a partnership, details of the address of the principal office of the partnership and of the names and home addresses of the partners in the partnership,
    - (iii) where the business is carried on by a body corporate, details of the address of the registered or principal office of the body corporate and of the names and home addresses of its directors;
  - (b) a list of all premises at which the retail pharmacy business is carried on;
  - (c) where medicinal products, other than medicinal products on a general sale list, are sold by retail at any premises at which a retail pharmacy business is carried on, or are supplied in circumstances corresponding to retail sale, and the retail pharmacy business is owned by a body corporate, the name of the superintendent pharmacist under whose management the business is carried on;
  - (d) details of the type or types of activities undertaken at the premises at which the retail pharmacy business is carried on; and
  - (e) details of any relevant offence or relevant investigation.
- (6) For the purposes of paragraph (5)(e)—
  - (a) a relevant offence is—
    - (i) where the retail pharmacy business is carried on by an individual, a criminal offence with which that individual has been charged,
    - (ii) where the retail pharmacy business is carried on by a partnership, a criminal offence with which any partner in the partnership has been charged,
    - (iii) where the retail pharmacy business is carried on by a body corporate, a criminal offence with which the body corporate or any of its directors has been charged,and a criminal offence is a relevant offence whether or not the charge has resulted in a caution or conviction;
  - (b) a relevant investigation is an investigation by a licensing, regulatory or other body into the conduct of—
    - (i) where the retail pharmacy business is carried on by an individual, that individual,
    - (ii) where the retail pharmacy business is carried on by a partnership, any partner in the partnership,
    - (iii) where the retail pharmacy business is carried on by a body corporate, that body corporate or any director of it,

and the reference to details of a relevant investigation includes details of the outcome of that investigation.

(7) Rules under paragraph (4) must also enable the provision to the Council of a statement which confirms that the standards that are provided for in rules made under paragraph (1) are met in connection with the carrying on of the retail pharmacy business at the registered pharmacies at which it is carried on and which is signed—

- (a) where the retail pharmacy business is carried on by an individual, by that individual;
- (b) where the retail pharmacy business is carried on by a partnership, by a partner in the partnership;
- (c) where the retail pharmacy business is carried on by a body corporate, by a director of that body corporate.

### **The Inspectorate**

8.—(1) The Council must establish an inspectorate which is to consist of inspectors appointed by the Council under this paragraph.

(2) An inspector appointed by the Council under paragraph (1) has the following functions—

- (a) in connection with the Council's functions under article 4(3)(b), to enforce such standards as may be provided for by rules under article 7(1);
- (b) to assist the Council in its investigation of matters to which Part 6 of this Order applies;
- (c) to secure compliance by registrants and by persons carrying on a retail pharmacy business at a registered pharmacy with the provisions of Parts 3 and 4 of the Medicines Act 1968<sup>(2)</sup> (which contain provisions about dealings with medicinal products and about pharmacies) in so far as they relate to the sale and supply of medicinal products;
- (d) to secure compliance by registered pharmacists and persons carrying on a retail pharmacy business with the provisions of the Poisons Act 1972<sup>(3)</sup> and the Poisons Rules;
- (e) to enforce—
  - (i) article 38 of this Order, and
  - (ii) any other provisions of this Order and of rules made under this Order.

(3) An inspector is to hold and vacate office in accordance with the terms of the inspector's appointment.

(4) The Council may pay to an inspector such remuneration, pensions, allowances, expenses or gratuities, or make such contributions or payments towards provision for such pensions, allowances or gratuities, as it may reasonably determine.

### **Inspection and enforcement**

9.—(1) The Council must make provision in rules relating to—

- (a) the intervals at which inspectors may conduct routine inspections of registered pharmacies; and
- (b) the circumstances in which inspectors may conduct special inspections of, and other visits to, registered pharmacies.

(2) Rules under paragraph (1) are not to limit an inspector's power of entry under article 10.

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(2) 1968 c.67.

(3) 1972 c.66.

### **Power of entry**

**10.**—(1) An inspector, on producing (if required)—

- (a) evidence of the inspector's identity; and
- (b) evidence of the inspector's appointment,

may, for the purposes of the exercise of a function conferred on the inspector by article 8(2)(a), (b) or (e) enter any registered pharmacy or other premises at any reasonable hour.

(2) In the case of any premises which are or form part of a private dwelling house, an inspector may enter the premises by virtue of paragraph (1) only if 24 hours notice of the intended entry has been given to the occupier.

(3) If a justice of the peace, on sworn information in writing from an inspector, is satisfied that entry to a registered pharmacy or other premises is required for the purposes of the exercise of a function conferred on the inspector by article 8(2)(a), (b) or (e) and is also satisfied that—

- (a) admission has been refused, or a refusal is expected, and (in either case) that notice to apply for a warrant has been given to the occupier;
- (b) asking for admission, or the giving of such notice, would defeat the object of entry;
- (c) the case is one of urgency; or
- (d) the premises are unoccupied or the occupier is temporarily absent,

the justice may by signed warrant authorise the inspector to enter the premises, if need be by reasonable force.

(4) A warrant issued by a justice of the peace under paragraph (3) is valid for the period of one month beginning with the day on which the warrant is issued.

(5) An inspector who is authorised to enter any premises by a warrant issued by a justice of the peace under paragraph (3) must, on entering the premises, produce the warrant to any person at the premises appearing to the inspector to be in charge of, or responsible for, the premises or, if the premises are unoccupied, leave a copy of the warrant at the premises.

(6) An inspector entering premises by virtue of this article—

- (a) may be accompanied by a police constable or by such other persons as the inspector considers necessary;
- (b) may bring into the premises such equipment as the inspector considers necessary.

(7) If an inspector enters any unoccupied premises by virtue of this article, the inspector must leave the premises as effectively secured against unauthorised entry as the premises were found.

(8) In the application of this article to Scotland, a reference to a justice of the peace includes a reference to the sheriff and to a magistrate.

### **Powers of an inspector**

**11.**—(1) An inspector may, upon entering any premises by virtue of article 10 —

- (a) inspect the premises and any plant, machinery or equipment at the premises;
- (b) search the premises;
- (c) inspect and remove from the premises any substance, article or product (whether or not appearing to the inspector to be a medicinal product);
- (d) take and remove from the premises samples of any substance, article or product;
- (e) carry out any examinations and tests and make any enquiries (including such enquiries of any person as the inspector considers it appropriate to make relating to the fitness

to practise of a registrant who is or has been employed on the premises to provide pharmaceutical services);

- (f) require any person holding or accountable for any documents or records (whether or not kept at the premises being inspected) to produce them for inspection at the premises.

(2) The power conferred by paragraph (1)(g) includes power to require any documents or records that are kept by means of a computer or other electronic device to be produced in a form in which they are legible and may be taken away.

(3) If an inspector requires documents or records to be produced for inspection by virtue of the power conferred by paragraph (1)(g), the inspector may—

- (a) take copies of or extracts from such documents or records;
- (b) take possession of the documents or records or of the computer or other electronic device in which the documents or records are stored and retain them for as long as the inspector considers necessary;
- (c) require access to any computer or other electronic device or to any associated apparatus or material that is or has been used in connection with the documents or records and inspect and check the operation of the computer, electronic device, apparatus or material.

(4) The power conferred by paragraph (3)(c) includes power to require any person having charge of, or otherwise concerned with the operation of, the computer, device, apparatus or material to afford such assistance as the inspector may reasonably require.

(5) An inspector also has power to do anything which is calculated to facilitate the discharge of the inspector's functions or which is incidental or conducive to the discharge of those functions.

### **Obstruction: offences**

12. Any person who—

- (a) intentionally obstructs an inspector exercising functions under article 10 or 11;
- (b) without reasonable cause, fails to give an inspector exercising any functions under this Order any assistance or information that the inspector may reasonably require from that person for the performance of those functions;
- (c) furnishes to an inspector exercising any functions under this Order any information that the person knows to be false or misleading; or
- (d) fails to produce a document or record when required to do so by an inspector exercising any functions under this Order,

commits an offence and is liable, on summary conviction, to a fine not exceeding level 3 on the standard scale.

### **Improvement notices**

13.—(1) If an inspector has reasonable grounds for believing that there is—

- (a) a failure in connection with the carrying on of a retail pharmacy business at a registered pharmacy entered in the Register under section 74A of the Medicines Act 1968 (registration or premises: Great Britain) to meet the standards that are provided for in rules made under article 7(1); or
- (b) a failure to comply with conditions to which the entry of a registered pharmacy entered in the Register under section 74A of the Medicines Act 1968 is subject by virtue of section 74D(1)(4) of that Act (conditional registration: Great Britain),

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(4) Sections 74A and 74D are inserted into the Act by paragraph 1(8) of Schedule 4 to this Order.

the inspector may serve a notice on the person carrying on the retail pharmacy business at the registered pharmacy (in this Order referred to as an “improvement notice”).

- (2) An improvement notice must—
  - (a) state the inspector’s grounds for believing that there is a failure referred to in paragraph (1) (a) or (b);
  - (b) specify the measures that the person to whom the notice is addressed must take in order to rectify that failure;
  - (c) require that person to take those measures, or measures that the inspector agrees are at least equivalent to them, within the period specified in the notice which may not be less than 28 days beginning with the day on which the notice is served; and
  - (d) state—
    - (i) that there is a right of appeal to a magistrates’ court or to the sheriff under article 16, and
    - (ii) the period within which such an appeal may be brought.
- (3) An improvement notice is served by an inspector—
  - (a) on an individual—
    - (i) if it is delivered to that individual personally,
    - (ii) if it is left at that individual’s proper address, or
    - (iii) if it is sent by first class post or otherwise delivered to that individual at that individual’s proper address;
  - (b) on a partnership—
    - (i) if it is delivered personally to a partner in the partnership,
    - (ii) if it is delivered personally to a person having control or management of the partnership business, or
    - (iii) if it is sent by first class post or otherwise delivered to the partnership’s proper address;
  - (c) on a body corporate—
    - (i) if it is delivered personally to the secretary or clerk of that body,
    - (ii) if it is sent by first class post or otherwise delivered to that body’s proper address.
- (4) For the purposes of paragraph (3), and of section 7 of the Interpretation Act 1978<sup>(5)</sup> (which defines “service by post”) in its application to that paragraph, the proper address of a person is—
  - (a) in the case of an individual, to that individual’s home address in the Register;
  - (b) in the case of a partnership, the address of the principal office of the partnership;
  - (c) in the case of a body corporate, the address of the registered or principal office of the body.
- (5) An improvement notice is treated as having been served, where the notice is sent by post, at the time at which the notice would be delivered in the ordinary course of post or, where the notice has been left at an address, it is treated as having been served on the next working day following the day on which it was left at that address.
- (6) The Council may make rules providing for an improvement notice which is required to be served on any person under this article to be served by an electronic communication.
- (7) Rules under paragraph (6) must secure that—

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(5) 1978 c.30.

- (a) an improvement notice cannot be served by an electronic communication unless the person consents in writing to the receipt of notices from the Council by electronic communication and the communication is sent to the number or address specified by that person when giving consent;
- (b) an electronic communication received outside of a person's normal business hours is to be taken to have been served on the next working day.

(8) In this article "working day" means a day which is not a Saturday or Sunday, Christmas Day, Good Friday or a day which is a bank holiday under the Banking and Financial Dealings Act 1971<sup>(6)</sup> in the part of Great Britain in which the premises to which the notice relates are located.

### **Non-compliance with improvement notices**

14.—(1) A person carrying on a retail pharmacy business at a registered pharmacy who fails to comply with the terms of an improvement notice served under article 13 commits an offence and is liable on summary conviction to a fine not exceeding level 5 on the standard scale.

(2) Where an inspector is reasonably satisfied that a person carrying on a retail pharmacy business at a registered pharmacy has failed to comply with the terms of an improvement notice served under article 13, the inspector must give notice of that fact in writing to the Registrar.

(3) The obligation imposed by paragraph (2) applies whether or not proceedings are to be brought against the person for an offence under paragraph (1).

(4) Upon receipt of a notice given under paragraph (2), the Registrar may—

- (a) remove the entry of the registered pharmacy from the Register; or
- (b) suspend that entry pending compliance by the person with such requirements or conditions as the Registrar considers it necessary to impose.

(5) Where under paragraph (4) the Registrar removes or suspends the entry of a registered pharmacy, the Registrar must send to the person carrying on the retail pharmacy business a statement in writing giving that person notice of the removal or suspension and the reasons for it and of the right of appeal to the Appeals Committee under article 40.

(6) The notice under paragraph (5) must be sent—

- (a) where the retail pharmacy business is carried on by an individual, to that individual at that individual's home address in the Register;
- (b) where the retail pharmacy business is carried on by a partnership, to that partnership at its principal office;
- (c) where the retail pharmacy business is carried on by a body corporate, to that body corporate at its registered address or principal office.

(7) Proceedings for an offence under this article may be begun—

- (a) in England and Wales, at any time within the period of 6 months beginning with the date on which evidence sufficient in the opinion of the Council to justify a prosecution came to the Council's knowledge;
- (b) in Scotland, at any time within the period of 6 months beginning with the date on which evidence sufficient in the opinion of the prosecutor to justify a prosecution came to the prosecutor's knowledge;

but no proceedings may be begun after the expiry of the period of two years beginning with the date of the commission of the offence.

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(6) 1971 c.80.

(8) For the purposes of paragraph (7), the date of the commission of the offence is the day after the day on which the period specified under paragraph (2)(c) of article 13 expires.

#### **Offences committed by partnerships**

**15.**—(1) Proceedings for an offence under article 14 alleged to have been committed by a partnership must be brought in the name of the partnership (and not in that of any of the partners).

(2) Rules of court relating to the service of documents are to have effect as if the partnership were a body corporate.

(3) In proceedings for an offence brought against a partnership, Schedule 3 to the Magistrates' Courts Act 1980(7) (corporations) applies as it applies in relation to a body corporate.

(4) A fine imposed on a partnership on its conviction for an offence is to be paid out of the assets of the partnership.

#### **Appeals against improvement notices**

**16.**—(1) Any person on whom an improvement notice is served may appeal to a magistrates' court or, in Scotland, to the sheriff.

(2) The procedure on appeal to a magistrates' court under paragraph (1) is by way of complaint, and the Magistrates' Courts Act 1980 applies to the proceedings.

(3) An appeal to the sheriff under paragraph (1) is by summary application.

(4) The period within which an appeal may be brought is 28 days beginning with the date on which the notice was served.

(5) The court may suspend an improvement notice pending the determination or abandonment of an appeal.

#### **Powers of a court on appeal**

**17.** On an appeal against an improvement notice, the court may either cancel the notice or confirm it, with or without modification.