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STATUTORY INSTRUMENTS

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**2010 No. 231**

**The Pharmacy Order 2010**

**PART 1**

Preliminary

**Citation and commencement**

1.—(1) This Order may be cited as the Pharmacy Order 2010.

(2) The following provisions come into force on the day after the day on which this Order is made—

- (a) this article;
- (b) articles 2, 3, 4(1), (2), (3)(b), (5) and (8) and 7 and Schedule 1; and
- (c) articles 65, 66, 69(1) to (4) and 70 and Schedules 5 and 6.

(3) Except as provided for by paragraph (2), the provisions of this Order which confer powers enabling rules or orders to be made, or which enable standards or requirements to be set by the Council, come into force on the making of this Order, but for the purpose only of the exercise of those powers.

(4) Rules under article 7(1) and (4) are not to come into force before the end of the period of two years beginning with the day on which this Order is made.

(5) Except as provided for by paragraphs (2) and (3), this Order comes into force on such day as the Privy Council may by order appoint.

(6) Different days may be appointed by an order under paragraph (5) for different provisions or different purposes.

**Extent**

2.—(1) Subject to paragraph (2), this Order extends to England and Wales and Scotland.

(2) The extent of any amendment, revocation, repeal or saving of any enactment set out in Schedules 4 and 6 is the same as that of the enactment amended, revoked, repealed or saved.

**Interpretation**

3.—(1) In this Order—

“the 2007 Order” means the Pharmacists and Pharmacy Technicians Order 2007(1);

“annotation” means an annotation in the Register;

“assessment team” means an assessment team appointed under rules made under article 55;

“competent authority” means any authority or body of a relevant European State designated by that State for the purposes of the Directive as competent, in connection with practice as a pharmacist or pharmacy technician—

- (a) to receive or issue evidence of qualifications or other information or documents; and
- (b) to receive applications and take the decisions referred to in the Directive;

“controlled drugs” has the meaning given in section 2(1)(a) of the Misuse of Drugs Act 1971<sup>(2)</sup> (controlled drugs and their classification);

“the Council” means the General Pharmaceutical Council established by article 4;

“the Directive” means Directive [2005/36/EC](#) of the European Parliament and of the Council of 7 September 2005 on the recognition of professional qualifications<sup>(3)</sup>, and references in this Order to the Directive, or to any provision of the Directive, are references to the Directive, or to that provision, as amended from time to time;

“electronic communication” has the meaning given in section 15(1) of the Electronic Communications Act 2000<sup>(4)</sup> (general interpretation);

“enactment” means an enactment contained in, or in an instrument made under—

- (a) an Act of Parliament;
- (b) an Act of the Scottish Parliament; or
- (c) a measure or Act of the National Assembly for Wales;

“European mutual recognition area” means the territory of the EEA States<sup>(5)</sup> and Switzerland;

“exempt person” means—

- (a) a national of a relevant European State other than the United Kingdom;
- (b) a national of the United Kingdom who is seeking access to, or is pursuing, the profession of pharmacist or pharmacy technician by virtue of an enforceable Community right; or
- (c) a person who is not a national of a relevant European State but who is, by virtue of an enforceable Community right, entitled to be treated, for the purposes of access to and pursuit of the profession of pharmacist or pharmacy technician, no less favourably than a national of a relevant European State;

“General Systems Regulations” means the European Communities (Recognition of Professional Qualifications) Regulations 2007<sup>(6)</sup>;

“improvement notice” means a notice served on any person under article 13;

“individual assessor” means an individual assessor appointed under rules made under article 55;

“inspector” means an inspector appointed by the Council under article 8(1);

“medical device” has the meaning given in regulation 2(2) of the Medical Devices Regulations 2002<sup>(7)</sup>;

“medicinal product” has the same meaning as it has in the Medicines Act 1968 by virtue of section 130 of that Act<sup>(8)</sup> (meaning of “medicinal product” and related expressions);

(2) [1971 c.38](#).

(3) OJ No. L255, 30.09.2005, p22, as amended by Council Directive [2006/100/EEC](#) of 20 November 2006, OJ No. L363 of 20.12.2006, p141.

(4) [2000 c.7](#).

(5) See Schedule 1 to the Interpretation Act [1978 \(c.30\)](#) for the definition of “EEA State” which was inserted by section 26(1) of the Legislative and regulatory Reform Act [2006 \(c.51\)](#).

(6) [S.I.2007/2781](#) as amended by [S.I.2009/1182](#).

(7) [S.I.2002/618](#). There are no relevant amendments.

(8) [1968 c.67](#). Section 130 was amended by section 12(2) of, and paragraph 3 of Schedule 1 to, the Animal Health and Welfare Act [1984 \(c.40\)](#) and by [S.I.1994/3119](#), [2005/50](#) and [2006/2407](#).

“medicinal product on a general sale list” means a medicinal product of a description, or falling within a class, specified in an order which is for the time being in force under section 51 of the Medicines Act 1968 **(9)**(general sale lists);

“the Pharmacy Acts” means the Pharmacy Act 1852**(10)**, the Pharmacy Act 1868**(11)**, the Pharmacy Act 1908**(12)**, the Pharmacy and Poisons Act 1933**(13)** and the Pharmacy Act 1954**(14)**;

“the Poisons Rules” means rules made by the Secretary of State under section 7 of the Poisons Act 1972**(15)** (poisons rules);

“prescribed” means prescribed by rules made by the Council;

“the Register” means the register established and maintained under article 19;

“registered pharmacist” means a person who is entered in Part 1 or 4 of the Register;

“registered pharmacy technician” means a person who is entered in Part 2 or 5 of the Register;

“registered pharmacy” means premises that are entered in Part 3 of the Register;

“registrant” means a registered pharmacist or a registered pharmacy technician;

“Registrar”, except where used in the expression “Registrar General”, is to be construed in accordance with article 18(1) and (6);

“Registrar General” means—

- (a) the Registrar General for England and Wales appointed under section 1 of the Registration Service Act 1953**(16)** (Registrar General); or
- (b) the Registrar General for Scotland appointed under section 1(1) of the Registration of Births, Deaths and Marriages (Scotland) Act 1965**(17)** (the Registrar General);

“regulatory body” means a regulatory body which has the function of authorising persons to practise as a member of a health or social care profession;

“relevant European State” means an EEA State or Switzerland;

“retail pharmacy business” has the meaning given in section 132 of the Medicines Act 1968**(18)** (general interpretation provisions);

“retail sale” is to be construed in accordance with section 131(3) of the Medicines Act 1968**(19)** (meaning of “wholesale dealing”, “retail sale” and related expressions);

“the Society” means the Royal Pharmaceutical Society of Great Britain;

“statutory committees” means the Committees of the Council listed in article 4(6);

“superintendent pharmacist” means a pharmacist who is a superintendent for the purposes of section 71(1) of the Medicines Act 1968**(20)** (business carried on by body corporate); and

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**(9)** See the Medicines (Products other than Veterinary Drugs) (General Sale List) Order 1984 (S.I.1984/769).

**(10)** 1852 c.56; repealed by the Pharmacy Act 1954 (c.61).

**(11)** 1868 c.121; repealed by the Pharmacy Act 1954.

**(12)** 1908 c.55; repealed by the Pharmacy Act 1954.

**(13)** 1933 c.25; repealed by the Statute Law Revision Act 1950 (c.6), by Schedule 4 to the Pharmacy Act 1954, by Schedule 6 to the Medicines Act 1968 (c.67) and by Schedule 2 to the Poisons Act 1972 (c.66).

**(14)** 1954 c.61; repealed by S.I.2007/289.

**(15)** 1972 c.66. The rules currently in force are S.I.1982/218. These Rules have been amended by S.I.1985/1077, 1968/10, 1986/1704, 1989/112 and 1992/2293.

**(16)** 1953 c.37. Section 1 was amended by section 68 of the Statistics and Registration Service Act 2007 (c.18).

**(17)** 1965 c.49. Section 1(1) was amended by the Scotland Act 1998 (c.46), section 125.

**(18)** 1968 c.67. There are no relevant amendments.

**(19)** 1968 c.67. The definition of retail sale was amended by paragraph 138(2) of Schedule 4 to the National Health Service Reorganisation Act 1973 (c.32), by paragraph 30 of Schedule 16 to the National Health Service (Scotland) Act 1978 (c.29) and by paragraphs 43 and 44 of Schedule 1 to the National Health Service (Consequential Provisions) Act 2006 (c.43).

**(20)** Section 71 is substituted by section 28 of the Health Act 2006 (as amended by S.I.2007/3101) from 1 October 2007 (see S.I.2008/2714(C.119)).

“supply in circumstances corresponding to retail sale” is to be construed in accordance with section 131(4) of the Medicines Act 1968.

(2) For the purposes of this Order, a person practises as a pharmacist or a pharmacy technician if, whilst acting in the capacity of or purporting to be a pharmacist or a pharmacy technician, that person undertakes any work or gives any advice in relation to the preparation, assembly, dispensing, sale, supply or use of medicines, the science of medicines, the practice of pharmacy or the provision of healthcare.

(3) For the purposes of articles 34 and 35, “emergency” means an emergency of the type described in subsection (1)(a) of section 19 of the Civil Contingencies Act 2004<sup>(21)</sup> (meaning of “emergency”), read with subsection (2)(a) and (b) of that section.

## PART 2

### The Council and its Committees

#### The Council and its Committees

4.—(1) There is to be a body corporate known as the General Pharmaceutical Council (“the Council”).

(2) The Council is to be constituted as provided for by an order of the Privy Council made under this article subject to the provisions of Schedule 1 to this Order.

(3) The principal functions of the Council are—

- (a) to establish and maintain a register of pharmacists, pharmacy technicians and premises at which a retail pharmacy business is, or is to be, carried on;
- (b) to set and promote standards for the safe and effective practice of pharmacy at registered pharmacies;
- (c) to set requirements by reference to which registrants must demonstrate that their fitness to practise is not impaired;
- (d) to promote the safe and effective practice of pharmacy by registrants (including, for example, by reference to any code of conduct for, and ethics relating to, pharmacy);
- (e) to set standards and requirements in respect of the education, training, acquisition of experience and continuing professional development that it is necessary for pharmacists and pharmacy technicians to achieve in order to be entered in the Register or to receive an annotation in the Register and to maintain competence; and
- (f) to ensure the continued fitness to practise of registrants.

(4) The Council has the functions conferred on it by this Order and such other functions as may be conferred on it by the Privy Council by order.

(5) Before making an order under paragraph (4), the Privy Council must consult the Council.

(6) The Council must have the following committees—

- (a) the Investigating Committee;
- (b) the Fitness to Practise Committee; and
- (c) the Appeals Committee,

and each of those committees has the functions assigned to it by or under this Order.

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(21) 2004 c.36.

(7) The Council may establish such other committees as it considers appropriate in connection with the discharge of its functions and may delegate any of its functions to them, except any power to make rules.

(8) Schedule 1 makes further provision about the Council, its committees, its staff, its publications and its accounts.

### **Standards and requirements: consultation and review**

5.—(1) Before setting any standards or requirements under this Order, the Council must consult such persons as it considers appropriate including, where it considers appropriate, persons appearing to it to represent—

- (a) registrants;
- (b) employers of registrants;
- (c) professional bodies or organisations appearing to the Council to represent registrants;
- (d) users of the services of registrants;
- (e) persons or bodies commissioning or funding the services provided by registrants or at registered pharmacies;
- (f) persons carrying on a retail pharmacy business at a registered pharmacy; and
- (g) persons or bodies providing, assessing, regulating or funding education and training for registrants or prospective registrants.

(2) The Council must keep the standards and requirements set under this Order under review and may vary or withdraw any of those standards and requirements whenever it considers it appropriate to do so.

(3) Paragraph (1) applies to the variation or withdrawal of standards or requirements as it applies to the setting of standards or requirements.

### **The Council's general duties**

6.—(1) The main objective of the Council (including its staff and committees) in exercising such of its functions as affect the health, safety or well-being of members of the public is to protect, promote and maintain the health, safety and well-being of members of the public, and in particular of those members of the public who use or need the services of registrants, or the services provided at a registered pharmacy, by ensuring that registrants, and those persons carrying on a retail pharmacy business at a registered pharmacy, adhere to such standards as the Council considers necessary for the safe and effective practice of pharmacy.

(2) In exercising its functions, the Council (including its staff and committees) must—

- (a) have proper regard to—
  - (i) the interests of persons using or needing the services of registrants in Great Britain,
  - (ii) the interests of all registrants and prospective registrants, and any differing interests of registered pharmacists and registered pharmacy technicians or groups within those professions, and
  - (iii) the interests of persons carrying on a retail pharmacy business at a registered pharmacy; and
- (b) co-operate, in so far as is appropriate and reasonably practicable, with persons concerned with—
  - (i) the employment (whether or not that employment is under a contract of service) of registrants,

- (ii) the education or training of registrants, prospective registrants or other health or social care professionals,
- (iii) the regulation of, or the co-ordination of the regulation of, other health or social care professionals,
- (iv) the regulation of health services, and
- (v) the provision, supervision or management of health services.

(3) In carrying out its duty to co-operate under paragraph (2)(b), the Council must have regard to any differing considerations relating to practising as a pharmacist or as a pharmacy technician which apply in England, Scotland or Wales.

(4) In paragraph (2), “other health care professionals” means persons regulated by a body, other than the Council, mentioned in section 25(3) of the National Health Service Reform and Health Care Professions Act 2002<sup>(22)</sup>.

## 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>(23)</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.

<sup>(22)</sup> 2002 c.17. Section 25(3) was amended by paragraph 17 of Schedule 10 to the Health and Social Care Act 2008 (c.14).

<sup>(23)</sup> 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.

- (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
    - (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>(24)</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>(25)</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

<sup>(24)</sup> 1968 c.67.

<sup>(25)</sup> 1972 c.66.

- (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.

### **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)(f) 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)(f), 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)(26) of that Act (conditional registration: Great Britain), 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(27) (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.

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

(27) 1978 c.30.

(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—

- (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>(28)</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;

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(28) 1971 c.80.

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.

(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<sup>(29)</sup> (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.

## **PART 4**

### **Registration**

#### **The Registrar**

**18.**—(1) The Council must appoint a fit and proper person to be Registrar.

(2) The Registrar is to have such functions as may be conferred by this Order or by rules under this Order or by any other enactment.

(3) The Council may delegate any of its functions to the Registrar, except any power to make rules.

(4) The Council may appoint a Deputy Registrar.

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(29) 1980 c.43.

(5) The Registrar and any Deputy Registrar are to hold and vacate office in accordance with the terms of their appointment.

(6) The Registrar may authorise a Deputy Registrar or an employee of the Council to act for the Registrar in any matter.

### **Establishment, maintenance of and access to the Register**

**19.**—(1) The Registrar must establish and maintain a register of pharmacists and pharmacy technicians and, for the purposes of section 74A of the Medicines Act 1968 (registration of premises: Great Britain) and section 74J of that Act (temporary registration with regard to emergencies involving loss of human life or human illness etc.)**(30)**, premises.

(2) The Register is to be divided into five parts as follows—

- (a) Part 1, relating to pharmacists other than visiting practitioners;
- (b) Part 2, relating to pharmacy technicians other than visiting practitioners;
- (c) Part 3, relating to premises;
- (d) Part 4, relating to pharmacists who are visiting practitioners; and
- (e) Part 5, relating to pharmacy technicians who are visiting practitioners.

(3) The Council may make such provision in rules in connection with the Register as it considers appropriate and may, in particular, make provision with regard to—

- (a) the form and keeping of the Register and the making of entries in, and alterations and corrections to, the Register;
  - (b) the recording of the date of a registrant's entry in the Register, or of that of a registered pharmacy, and of the period for which the entry is valid;
  - (c) the recording of home addresses of registrants;
  - (d) in any case where a retail pharmacy business carried on at a registered pharmacy is owned by a partnership or a body corporate, the recording of the address of the principal office of the partnership or the address of the registered or principal office of the body corporate;
  - (e) the recording of qualifications and specialisations of a registrant;
  - (f) the recording of any specialisations of a retail pharmacy business carried on at a registered pharmacy;
  - (g) the recording of continuing professional development matters;
  - (h) the recording of fitness to practise matters, including any warnings or advice given by, or undertakings agreed with, the Investigating Committee or the Fitness to Practise Committee;
  - (i) the recording of any improvement notices to which a person carrying on a retail pharmacy business at a registered pharmacy is subject;
  - (j) the recording of any conditions subject to which the entry of a registered pharmacy in the Register has effect; and
  - (k) the recording of the matters listed in sub-paragraphs (a) to (j), or of any other matters, in the Register in the Welsh language where appropriate.
- (4) Rules under paragraph (3) may provide—
- (a) for the marking of the Register so as to distinguish those registrants who are entered in Part 1 or 2 of the Register under article 34 from other registrants; and

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

- (b) for the marking of the Register so as to distinguish those registered pharmacies which are entered in Part 3 of the Register under section 74J of the Medicines Act 1968 (temporary registration with regard to emergencies involving loss of human life or human illness etc.) from other registered pharmacies.
- (5) The Registrar must, in such manner as the Registrar sees fit, compile lists comprising information in or derived from entries in the Register, but those lists must not include information in or derived from entries in respect of persons or premises whose entry in the Register is suspended.
- (6) The Council must determine the information that the lists are to contain, which may include—
- (a) a note specifying in which part of the Register a registrant is entered;
  - (b) the number of the entry of a registrant or of a registered pharmacy;
  - (c) the area (by reference to a city, town, district or country) in which a registrant lives or in which a registered pharmacy is located and contact details, but a registrant's home address must not be published without that registrant's consent;
  - (d) a note regarding any fitness to practise matters, including—
    - (i) any conditions to which a registrant's entry in the Register is subject,
    - (ii) any warnings or advice given by, or undertakings agreed with, the Investigating Committee or the Fitness to Practise Committee regarding a registrant's future conduct;
  - (e) a note in respect of any improvement notices to which a person carrying on a retail pharmacy business at a registered pharmacy is subject;
  - (f) a note in respect of any conditions subject to which the entry of a registered pharmacy in the Register has effect;
  - (g) a note in respect of a registrant's specialisations which are the subject of any annotations;
  - (h) a note in respect of the specialisations of a retail pharmacy business carried on at a registered pharmacy which are the subject of any annotations;
  - (i) a note to distinguish those registrants who are entered in Part 1 or 2 of the Register under article 34 from other registrants;
  - (j) a note to distinguish annotations made in respect of registrants under article 35 from other annotations made in respect of registrants who are qualified to order drugs, medicines and appliances in a specified capacity;
  - (k) a note to distinguish those registered pharmacies entered in Part 3 of the Register under section 74J(31) of the Medicines Act 1968 (temporary registration with regard to emergencies involving loss of human life or human illness etc.) from other registered pharmacies; and
  - (l) a note to distinguish annotations made under section 74K of the Medicines Act 1968(32) (temporary annotations with regard to emergencies involving loss of human life or human illness etc.) from other annotations of entries made in respect of registered pharmacies which are designated as registered pharmacies from which drugs, medicines and appliances may be ordered in a specified capacity.
- (7) The Council must publish the lists compiled by the Registrar under paragraph (5) and may do so in such manner as it considers appropriate.
- (8) If a registrant's entry in any part of the Register is suspended, the registrant must be treated as not being entered in that part of the Register, even though that part of the Register still contains the registrant's name, except—

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(31) Section 74J is inserted into the Act by paragraph 1(8) of Schedule 4 to this Order.

(32) Section 74K is inserted into the Act by paragraph 1(8) of Schedule 4 to this Order.

- (a) for the purposes of articles 28 to 31 and 43 and Part 6 (and rules under or that relate to those provisions); and
- (b) for such other purposes of this Order as the Council may prescribe.

(9) Accordingly, a person whose entry in any part of the Register is suspended is not to be treated for the purposes of any enactment other than this Order as being entered in that part.

### **Entitlement to entry in Part 1 or 2 of the Register: pharmacists and pharmacy technicians**

**20.**—(1) Subject to the provisions of, and rules under, this Order, a person (“P”) is entitled to be entered in Part 1 of the Register as a pharmacist or in Part 2 of the Register as a pharmacy technician if—

- (a) the Registrar is satisfied that—
  - (i) P is appropriately qualified within the meaning given in article 21 or, as the case may be, article 22,
  - (ii) P’s fitness to practise is not impaired, and
  - (iii) where necessary, P meets such additional requirements (if any) relating to education, training or experience as the Registrar considers are appropriate to P’s case; and
- (b) P has paid any fee prescribed under article 36(1)(a).

(2) Subject to the provisions of, and rules under, this Order, a person (“P”) is entitled to have P’s entry in Part 1 or, as the case may be, Part 2 of the Register renewed if—

- (a) the Registrar is satisfied that—
  - (i) P’s fitness to practise is not impaired, and
  - (ii) P meets the standard of proficiency for the safe and effective practice of pharmacy set under article 43(1) together with such additional requirements (if any) relating to continuing professional development as the Registrar considers are appropriate to P’s case; and
- (b) P has paid any fee prescribed under article 36(1)(a).

(3) A person is not entitled to be entered in Part 1 or 2 of the Register, or to have an entry in either of those parts renewed, if that person does not intend to practise as a pharmacist or, as the case may be, a pharmacy technician in Great Britain, the Channel Islands or the Isle of Man.

(4) The Registrar must treat a person who—

- (a) is an exempt person who has qualified as a pharmacist in a relevant European State other than the United Kingdom;
- (b) applies to be entered in Part 1 of the Register as a pharmacist; and
- (c) is entered in the register of pharmaceutical chemists for Northern Ireland,

as meeting the requirements of paragraph (1)(a)(i).

### **Pre-entry requirements in respect of qualifications and additional education, training or experience: pharmacists**

**21.**—(1) For the purposes of article 20(1)(a)(i), a person (“P”) is “appropriately qualified” as a pharmacist if—

- (a) P has a qualification awarded in Great Britain which has been approved by the Council as attesting to a standard of proficiency for the safe and effective practice of pharmacy that, in the Council’s opinion, it is necessary for a person to achieve in order to be entered in Part 1 of the Register (and so is also a recognised pharmacy qualification within other relevant European States);

- (b) P is an exempt person and has a qualification which the Privy Council has by order designated as being an approved qualification for the purpose of entry in Part 1 of the Register;
- (c) P is an exempt person—
  - (i) whose case falls within regulation 3(9)(a) or (e) of the General Systems Regulations,
  - (ii) to whom regulations 20 to 26 of those Regulations apply by reason of the operation of regulation 3(4) of those Regulations, and
  - (iii) who is permitted to pursue the profession of pharmacist in Great Britain by virtue of Part 3 of those Regulations; or
- (d) subject to paragraph (2), P has, elsewhere than in Great Britain, undergone training as a pharmacist, and—
  - (i) holds a qualification which has been approved by the Council as attesting to a standard of proficiency for the safe and effective practice of pharmacy that, in the Council's opinion, it is necessary for a person to achieve in order to be entered in Part 1 of the Register, or
  - (ii) holds a qualification which—
    - (aa) in the case where P is an exempt person who does not have a qualification referred to in sub-paragraph (b) and to whom sub-paragraph (c) does not apply, taken together with P's additional education, training or experience acquired elsewhere than in Great Britain (but at least in part within the European mutual recognition area) indicates that P has met the standard of proficiency for the safe and effective practice of pharmacy that, in the Council's opinion, it is necessary for a person to achieve in order to be entered in Part 1 of the Register, or
    - (bb) whether or not P is an exempt person, taken together with the additional education, training or experience that the Registrar requires P to undertake pursuant to article 20(1)(a)(iii), indicates that P has met the standard of proficiency for the safe and effective practice of pharmacy that, in the Council's opinion, it is necessary for a person to achieve in order to be entered in Part 1 of the Register.

(2) For the purposes of article 20(1)(a)(i), an exempt person who holds a qualification in pharmacy which—

- (a) was granted otherwise than in a relevant European State; and
- (b) has not previously been accepted by a relevant European State as qualifying that person to practise as a pharmacist in that State,

is “appropriately qualified” only if the qualification is evidence of training in pharmacy that meets, or under article 22(a) of the Directive (part-time training) is to be treated as meeting, the requirements of article 44 of the Directive (training as a pharmacist).

(3) An order under paragraph (1)(b) may provide that a qualification is only to be considered an approved qualification in such circumstances, or subject to such conditions, as are specified in the order.

(4) For the purposes of an application for entry in Part 1 of the Register, the Registrar must not require any exempt person to whom paragraph (1)(b), (c) or (d)(ii)(aa) applies to meet any requirements as to additional education, training or experience unless—

- (a) the application is for restoration to the Register; and
- (b) in so doing, the Registrar is acting in a manner that is consistent with the requirements of the EU Treaties and the Directive.

(5) In formulating its opinion under paragraph (1)(d)(ii) in relation to P, where P is an exempt person, the Council must—

- (a) if P holds a qualification granted outside of the European mutual recognition area which has been accepted by another relevant European State as qualifying P to practise as a pharmacist in that State, take into account the acceptance of that qualification; and
- (b) take into account all of P’s relevant qualifications, knowledge and experience, wherever acquired.

(6) For the purposes of article 20(1)(a)(iii), where P—

- (a) is a person to whom paragraph (1)(a) or (d)(i) or (ii)(bb) applies; and
- (b) is not an exempt person,

the Registrar may require P to meet requirements as to additional education which comprise or include reaching an adequate standard of proficiency in the knowledge and use of English.

**Pre-entry requirements in respect of qualifications and additional education, training or experience: pharmacy technicians**

22.—(1) For the purposes of article 20(1)(a)(i), a person (“T”) is “appropriately qualified” as a pharmacy technician if—

- (a) T has a qualification awarded in Great Britain which has been approved by the Council as attesting to a standard of proficiency for the safe and effective practice of pharmacy that, in the Council’s opinion, it is necessary for a person to achieve in order to be entered in Part 2 of the Register;
- (b) T is an exempt person and is permitted to pursue the profession of pharmacy technician in Great Britain by virtue of Part 3 of the General Systems Regulations; or
- (c) T has, elsewhere than in Great Britain, undergone training as a pharmacy technician, and—
  - (i) holds a qualification which has been approved by the Council as attesting to a standard of proficiency for the safe and effective practice of pharmacy that, in the Council’s opinion, it is necessary for a person to achieve in order to be entered in Part 2 of the Register, or
  - (ii) holds a qualification which—
    - (aa) in the case where T is an exempt person to whom sub-paragraph (b) does not apply, taken together with T’s additional education, training or experience acquired elsewhere than in Great Britain (but at least in part within the European mutual recognition area) indicates that T has met the standard of proficiency for the safe and effective practice of pharmacy that, in the Council’s opinion, it is necessary for a person to achieve in order to be entered in Part 2 of the Register,
    - (bb) whether or not T is an exempt person, taken together with the additional education, training or experience that the Registrar requires T to undertake pursuant to article 20(1)(a)(iii), indicates that T has met the standard of proficiency for the safe and effective practice of pharmacy that, in the Council’s opinion, it is necessary for a person to achieve in order to be entered in Part 2 of the Register.

(2) For the purposes of an application for entry in the Register as a pharmacy technician, the Registrar must not require any exempt person to whom paragraph (1)(b) or (c)(ii)(aa) applies to meet any requirements as to additional education, training or experience unless—

- (a) the application is for restoration to Part 2 of the Register; and

- (b) in so doing the Registrar is acting in a manner that is consistent with the requirements of the EU Treaties and the Directive.
- (3) In formulating its opinion under paragraph (1)(c)(ii) in relation to T, where T is an exempt person, the Council must—
  - (a) if T holds a qualification granted outside the European mutual recognition area which has been accepted by another relevant European State as qualifying T to practise as a pharmacy technician in that State, take into account the acceptance of that qualification; and
  - (b) take into account all T's relevant qualifications, knowledge and experience, wherever acquired.
- (4) For the purposes of article 20(1)(a)(iii), where T—
  - (a) is a person to whom paragraph (1)(a) or (c)(i) or (ii)(bb) applies; and
  - (b) is not an exempt person,

the Registrar may require T to meet requirements as to additional education which comprise or include reaching an adequate standard of proficiency in the knowledge and use of English.

**Form, manner and content of applications for entry or for renewal of an entry in the Register: pharmacists and pharmacy technicians**

**23.**—(1) The Council may make such provision in rules as it considers appropriate in connection with applications for entry, or for the renewal of an entry, in Part 1 of the Register as a pharmacist or in Part 2 of the Register as a pharmacy technician and may, in particular, make provision with regard to—

- (a) the form and manner in which applications are to be made (and the rules may provide that applicants must apply using application forms and presenting certificates that are in such form as the Council may determine from time to time);
  - (b) the time prior to an entry ceasing to be valid by which an application for the renewal of the entry must have been received by the Registrar;
  - (c) the information to be provided by or in respect of the applicant, including—
    - (i) the name under which the applicant practises or intends to practise,
    - (ii) the applicant's home address,
    - (iii) where the applicant is a national of the United Kingdom who is not an exempt person, proof of nationality;
    - (iv) where the applicant is an exempt person—
      - (aa) proof of nationality of a relevant European State, or
      - (bb) if the applicant is not a national of a relevant European State, proof of the Community right by virtue of which the applicant is an exempt person, and
    - (v) the information to be provided for the purposes of determining whether the applicant's fitness to practise is impaired; and
  - (d) consultation about the application with the Fitness to Practise Committee or the Investigating Committee.
- (2) The Registrar may, in relation to an applicant—
- (a) refuse to enter the applicant in the Register; or
  - (b) refuse to renew the entry of the applicant in the Register,

if the applicant fails to comply with, or if in respect of the applicant there is a failure to comply with, rules made under paragraph (1).

(3) If a registrant fails to comply with rules made under paragraph (1) in respect of an application for the renewal of an entry relating to the registrant in the Register, the failure may also be treated as misconduct for the purposes of article 51(1)(a) and the Registrar must consider, in accordance with article 52(1), whether or not to refer the matter to the Investigating Committee or (where rules under article 52(1) so provide) to the Fitness to Practise Committee.

(4) Paragraphs (5) to (8) apply to an exempt person (“E”)—

- (a) to whom article 21(1)(b) or (c) or article 22(1)(b) applies; and
- (b) who is making an application for entry in Part 1 or Part 2 of the Register.

(5) For the purpose of determining whether E’s fitness to practise is impaired, the Registrar must accept as sufficient evidence of E’s health a certificate which—

- (a) confirms that there is no problem with E’s physical or mental health that would impair E’s fitness to practise as a pharmacist or, as the case may be, a pharmacy technician; and
- (b) is required of a person who wishes to practise as a pharmacist or, as the case may be, a pharmacy technician in E’s attesting State.

(6) If no such certificate is required of such a person in E’s attesting State, the Registrar must, for the purpose of determining whether E’s fitness to practise is impaired, accept as sufficient evidence of E’s health a certificate which—

- (a) confirms that there is no problem with E’s physical or mental health that would impair E’s fitness to practise as a pharmacist or, as the case may be, a pharmacy technician; and
- (b) is issued by a competent authority in E’s attesting State.

(7) For the purpose of determining whether E’s fitness to practise is impaired, the Registrar must accept as sufficient evidence of E’s good character a certificate which—

- (a) attests to E’s good character or good repute; and
- (b) is issued by a competent authority in E’s attesting State.

(8) If no such certificate is issued by a competent authority in E’s attesting State, the Registrar must, for the purpose of determining whether E’s fitness to practise is impaired, accept as sufficient evidence of E’s good character a certificate (or certificates)—

- (a) attesting to the authenticity of a declaration on oath made by E—
  - (i) before a competent judicial or administrative authority, notary, or qualified professional body in E’s attesting State, and
  - (ii) attesting to E’s good character; and
- (b) issued by the authority, notary or body referred to in sub-paragraph (a)(i).

(9) In paragraphs (5) to (8) the “attesting State”, in relation to E, is—

- (a) the relevant European State in which E’s qualification in pharmacy was obtained; and
- (b) (if different), the relevant European State from which E comes to Great Britain.

(10) In paragraph (8)(a) “declaration on oath” includes a solemn declaration.

(11) The Registrar must not accept any certificate referred to in paragraph (5), (6), (7) or (8) if it is presented more than three months after the date on which it was issued.

#### **Notification by the Registrar: entry and renewal**

**24.—**(1) Paragraphs (2) to (4) apply where a person (“A”) applies under article 23 for entry in Part 1 of the Register as a pharmacist or in Part 2 of the Register as a pharmacy technician.

(2) The Registrar must, within the period of one month beginning with the date of receipt of the application—

- (a) acknowledge receipt of the application; and
  - (b) inform A of any missing document required for the purposes of the application.
- (3) The Registrar must, within the specified period, notify A—
- (a) of the result of the application; and
  - (b) if the Registrar refuses the application, of the reasons for the refusal, and of any right of appeal that A has to the Appeals Committee under article 40.
- (4) Any failure by the Registrar to inform A of the result of the application as required by paragraph (3)(a) is to constitute a decision by the Registrar to refuse the application which is to be taken as having been made at the end of the specified period.
- (5) In paragraphs (3) and (4) “the specified period” means—
- (a) the period of three months beginning with the relevant date; or
  - (b) if A’s application is made on the grounds that A is appropriately qualified by virtue of article 21(1)(c) or 22(1)(b), the period of four months beginning with the relevant date.
- (6) Paragraphs (7) to (9) apply where a person (“A”) applies under article 23 for the renewal of an entry in Part 1 of the Register as a pharmacist or in Part 2 of the Register as a pharmacy technician.
- (7) The Registrar must, within the period of one month beginning with the date of receipt of the application—
- (a) acknowledge receipt of the application; and
  - (b) inform A of any missing document required for the purposes of the application.
- (8) The Registrar must, within the specified period, notify A—
- (a) of the result of the application; and
  - (b) if the Registrar refuses the application, of the reasons for the refusal and of any right of appeal that A has to the Appeals Committee under article 40.
- (9) Any failure by the Registrar to inform A of the result of the application as required by paragraph (8)(a) is to constitute a decision by the Registrar to refuse the application which is to be taken as having been made at the end of the specified period.
- (10) In paragraphs (8) and (9) “the specified period” means the period of one month beginning with the relevant date.
- (11) In this article, “the relevant date” means—
- (a) the date on which the Registrar receives the application; or
  - (b) if any document required for the purposes of the application, or any fee which is payable in respect of that application by virtue of rules made under article 36(1)(a) (“the relevant fee”), is missing when the Registrar first receives the application, the date on which the Registrar first has all the documents required for those purposes together with the relevant fee.

### **Duration of entry**

- 25.—(1) The entry of a person entered in Part 1 or 2 of the Register pursuant to an application under article 23 is valid for the period of one year beginning with the date on which the entry was made.
- (2) Each renewal of such an entry pursuant to a further application under that article extends the validity of the entry for the period of one year beginning with the relevant date.
- (3) If the entry of a person in Part 1 or 2 of the Register ceases to be valid under this article then, except in such circumstances as may be prescribed, that person is to be treated for all purposes as

no longer being entered in that part of the Register and accordingly the Registrar must remove the entry from the Register.

(4) Where the Registrar removes the entry of a person from the Register under paragraph (3), the Registrar must send to that person at that person's last known home address a statement in writing giving that person notice of the removal and the reasons for it.

(5) In paragraph (2) the "relevant date"—

- (a) on the first renewal of an entry, means the first anniversary of the date on which the entry was made;
- (b) on a subsequent renewal of an entry, means the anniversary of the date on which the entry was made that occurs next after the making of the application for renewal.

### **Notice of entry in the Register**

**26.**—(1) Subject to paragraph (3), the Registrar must, where requested to do so by a registrant (other than one entered in the Register under article 34), or where an application for entry in the Register as a pharmacist or a pharmacy technician, or for the renewal of such an entry, is granted, issue to the registrant free of charge written notice of that registrant's entry in the Register.

(2) Notice of a registrant's entry in the Register issued under this article must be in such form as the Council determines from time to time and must include—

- (a) the number of the entry;
- (b) the period in respect of which the entry is valid;
- (c) the part of the Register in which the registrant is entered.

(3) The Registrar is not under a duty to issue further notice of a registrant's entry in the Register to a person to whom such notice has already been issued ("R"), whether under this article, article 32 of the 2007 Order, or one of the Pharmacy Acts, unless R—

- (a) satisfies the Registrar that the original notice, and any further notice already issued, has been lost or destroyed; or
- (b) changes the name under which R practises,

and pays to the Council any fee in respect of the further notice prescribed under article 36(1)(f).

(4) The Council may make such provision in rules as it considers appropriate in connection with the return of notices of a registrant's entry in the Register which—

- (a) incorrectly state the part of the Register in which the registrant is entered; or
- (b) incorrectly state the name under which the registrant practises.

### **Specialisations: registrants and registered pharmacies**

**27.**—(1) The Council may make such provision in rules as it considers appropriate in connection with annotations to entries in the Register to denote specialisations, and may in particular make provision with regard to—

- (a) the type of specialisations that are to be subject to annotations;
- (b) the form and manner in which applications for entering, renewing or restoring annotations in respect of specialisations, or for the removal of such annotations, are to be made (and the rules may provide that applicants must apply using application forms that are in such form as the Council may determine from time to time);
- (c) the circumstances in which annotations in respect of specialisations are to be entered, renewed, restored or removed by the Registrar;

- (d) the removal of annotations in respect of specialisations by the Registrar where a prescribed fee in respect of the renewal of the annotation has not been paid, after such warnings as may be prescribed;
- (e) the standards of proficiency for the safe and effective practice of pharmacy that it is necessary for a registrant to achieve in order for an annotation in respect of a specialisation to be made to an entry in the Register of a registrant; and
- (f) the standards provided for in rules made under article 7(1) that it is necessary to meet in connection with the carrying on of a retail pharmacy business at a registered pharmacy in order for an annotation in respect of a specialisation of the retail pharmacy business to be made to the entry in the Register of the registered pharmacy.

(2) Where the Registrar decides not to enter, renew or restore an annotation in respect of a specialisation of an entry in the Register of a registrant, or to remove such an annotation from the Register, the Registrar must send to that person at that person's last known home address a statement in writing giving that person notice of the decision and the reasons for it and of the right of appeal to the Appeals Committee under article 40.

(3) Where the Registrar decides not to enter, renew or restore an annotation in respect of a specialisation of an entry in the Register of a registered pharmacy, or to remove such an annotation from the Register, the Registrar must send to the person carrying on a retail pharmacy business at the registered pharmacy a statement in writing giving that person notice of the decision and the reasons for it and of the right of appeal to the Appeals Committee under article 40.

(4) The notice under paragraph (3) 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; or
- (c) where the retail pharmacy business is carried on by a body corporate, to that body corporate at its registered or principal office.

### **Registrants' duties with regard to their entries**

**28.**—(1) The Council may make such provision in rules as it considers appropriate in connection with the information to be provided by registrants with regard to their entries in Part 1 or 2 of the Register (provided the rules are consistent with paragraph (2)) and may, in particular, make provision with regard to the obligations of a registrant ("R") to inform the Registrar—

- (a) of the name under which R practises and of any changes to that name; and
- (b) of R's home address and of any changes to it.

(2) If the Registrar—

- (a) sends by first class post to R a notice addressed to R at R's last known home address enquiring whether R has—
  - (i) changed the name under which R practises,
  - (ii) ceased to practise as a pharmacist or, as the case may be, a pharmacy technician and intends to apply under article 31 for voluntary removal from the Register, or
  - (iii) changed home address,and receives no reply within a period of one month beginning on the day of posting the notice; and
- (b) upon the expiration of that period sends to R a second similar notice and receives no reply within one month beginning on the day of posting the notice,

the Registrar may remove R's entry from Part 1 or, as the case may be, Part 2 of the Register.

(3) If a registrant entered in Part 1 or 2 of the Register fails to comply with rules made under paragraph (1), the Registrar may remove the entry of that registrant from that part of the Register.

(4) Where the Registrar removes the entry of a person from a part of the Register pursuant to paragraph (2) or (3), the Registrar must send to that person at that person's last known home address a statement in writing giving that person notice of the removal and the reasons for it and of the right of appeal to the Appeals Committee under article 40.

### **Corrections to the Register**

**29.**—(1) The Registrar must keep the Register correct and up to date, and, in so doing—

- (a) must remove from the Register the entry of any registrant who has died; and
- (b) from time to time, must make the necessary alterations—
  - (i) to any of the particulars in a registrant's entry, and
  - (ii) to any of the particulars in the entry of a registered pharmacy.

(2) The Registrar General must, on registering the death of a person who the Registrar General believes to be a registrant, forthwith notify the Registrar of the death.

(3) If the Registrar determines—

- (a) that a entry of a registrant in Part 1 or 2 of the Register (except in a case where the entry was made under article 34) or in Part 4 or 5 of the Register has been fraudulently procured or incorrectly made, or
- (b) that the entry of a registered pharmacy in Part 3 of the Register has been fraudulently procured or incorrectly made,

the Registrar may remove the registrant or registered pharmacy from that part of the Register.

(4) The Council may make such provision in rules as it considers appropriate in connection with determinations by the Registrar under paragraph (3).

(5) Where the Registrar removes the entry of a person from a part of the Register pursuant to paragraph (3)(a), the Registrar must send to that person at that person's last known home address a statement in writing giving that person notice of the removal and the reasons for it and of the right of appeal to the Appeals Committee under article 40.

(6) Where the Registrar removes the entry of a registered pharmacy from Part 3 of the Register pursuant to paragraph (3)(b), the Registrar must send to the person carrying on a retail pharmacy business at the registered pharmacy a statement in writing giving that person notice of the removal and the reasons for it and of the right of appeal to the Appeals Committee under article 40.

(7) The notice under paragraph (6) 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; or
- (c) where the retail pharmacy business is carried on by a body corporate, to that body corporate at its registered or principal office.

### **Fitness to practise matters before entry or renewal of an entry**

**30.**—(1) The Registrar may remove the entry of a registrant from Part 1 or 2 of the Register if it is shown to the satisfaction of the Registrar that—

- (a) the fitness to practise of the registrant was impaired as a result of prescribed circumstances or because of a problem with the registrant's physical or mental health—
  - (i) at the time of the registrant's entry in that part of the Register, or
  - (ii) at the time of an application to renew the registrant's entry in that part of the Register;and
- (b) the registrant had not informed the Registrar of those circumstances or that problem before the time mentioned in paragraph (a)(i) or (ii).

(2) For the purposes of paragraph (1), the Council may make such provision in rules as it considers appropriate in connection with the information to be provided to the Registrar by or in respect of a registrant for the purpose of determining whether the registrant's fitness to practise was so impaired.

(3) If a registrant fails to comply, or if in respect of a registrant there is a failure to comply, with rules made under paragraph (2), the Registrar may remove the entry of that registrant from the part of the Register concerned.

(4) The Council may make such provision in rules as it considers appropriate in connection with the procedure to be followed by the Registrar before removing the entry of a registrant from Part 1 or 2 of the Register pursuant to paragraph (1) or (3).

(5) Where the Registrar removes the entry of a person from Part 1 or 2 of the Register pursuant to paragraph (1) or (3), the Registrar must send to that person at that person's last known home address a statement in writing giving that person notice of the removal and the reasons for it and of the right of appeal to the Appeals Committee under article 40.

### **Voluntary removal from the Register**

**31.**—(1) The Council may make such provision in rules as it considers appropriate in connection with applications by registrants for voluntary removal of an entry from any part of the Register and may, in particular, make provision with regard to—

- (a) the form and manner in which applications are to be made (and the rules may provide that applicants must apply using application forms that are in such form as the Council may determine from time to time);
- (b) the information to be provided by the applicant;
- (c) fitness to practise matters;
- (d) refusal of applications (in such circumstances as may be prescribed in the rules including where there are outstanding fitness to practise proceedings in respect of the applicant).

(2) Where the Registrar refuses an application for voluntary removal from any part of the Register, the Registrar must send to the applicant at the applicant's last known home address a statement in writing giving the applicant notice of the refusal and of the reasons for it.

### **Indemnity arrangements**

**32.**—(1) A registrant must have in force an adequate and appropriate indemnity arrangement that provides cover in relation to that registrant in respect of liabilities which may be incurred in practising as a pharmacist or, as the case may be, a pharmacy technician.

- (2) For the purposes of this article, an "indemnity arrangement" may comprise—
- (a) a policy of insurance;
  - (b) an arrangement made for the purposes of indemnifying a person; or
  - (c) a combination of the two.

(3) The Council may make rules about what is an adequate and appropriate indemnity arrangement for the purposes of this article.

(4) The Council may make such provision in rules as it considers appropriate in connection with the information to be provided to the Registrar—

(a) by or in respect of any person seeking to be entered in any part of the Register as a pharmacist or pharmacy technician (including on an application for restoration) for the purposes of determining whether, if that person is so entered, there will be in force an adequate and appropriate indemnity arrangement in relation to that person which commences, at the latest, on the date on which that person is entered in that part of the Register;

(b) by or in respect of a registrant for the purposes of determining whether, at any time, there is in force an adequate and appropriate indemnity arrangement in relation to that registrant.

(5) Rules under paragraph (4)(b) may require the information to be provided—

(a) at the request of the Registrar; or

(b) on such dates or at such intervals as the Registrar may determine, either generally or in relation to individual registrants or registrants of a particular description.

(6) The Council may also make rules requiring a registrant to inform the Registrar if there ceases to be in force an adequate and appropriate indemnity arrangement in relation to that registrant.

(7) Where there is a failure to comply with rules under paragraph (4) by or in respect of a person who is entered, or is seeking to be entered, in any part of the Register, the Registrar may refuse to enter the person in, or to restore the person's entry to, that part of the Register.

(8) If a registrant is in breach of paragraph (1), or fails to comply with rules under paragraph (4) (b) or (6), or there is a failure to comply with rules under paragraph (4)(b) in respect of a registrant—

(a) the Registrar may remove that person's entry from Part 1, 2, 4 or 5 of the Register (as the case may be); or

(b) the breach or failure may be treated as misconduct for the purposes of article 51(1)(a) and the Registrar must consider, in accordance with article 52(1), whether or not to refer the matter to the Investigating Committee or (where rules under article 52(1) so provide) to the Fitness to Practise Committee.

(9) Where the Registrar—

(a) refuses to enter a person in any part of the Register, or to restore a person's entry to any part of the Register pursuant to paragraph (7); or

(b) removes a person's entry from any part of the Register, pursuant to paragraph (8)(a),

the Registrar must send to the person at the person's last known home address a statement in writing giving the person notice of the decision and the reasons for it and of the right of appeal to the Appeals Committee under article 40.

### **Visiting pharmacists and pharmacy technicians from relevant European States**

**33.** Schedule 2 has effect in respect of visiting pharmacists and visiting pharmacy technicians from relevant European States.

### **Temporary entry with regard to emergencies involving loss of human life or human illness etc.**

**34.—**(1) If the Secretary of State advises the Registrar that an emergency has occurred, is occurring or is about to occur and that action should be considered under this article, the Registrar may enter in Part 1 or 2 of the Register—

- (a) a person as a pharmacist or a pharmacy technician if the Registrar considers that the person is a fit, proper and suitably experienced person to be so entered in the Register with regard to the emergency; or
  - (b) the persons comprising a specified group of persons as pharmacists or, as the case may be, pharmacy technicians if the Registrar considers that the group is comprised of persons who may reasonably be considered fit, proper and suitably experienced persons to be so entered in the Register with regard to the emergency.
- (2) The Registrar may enter in Part 1 or Part 2 of the Register by virtue of paragraph (1)(b) all of the persons comprising a specified group of persons without first identifying each person in the group.
- (3) The entry of a person in Part 1 or 2 of the Register under this article is subject to such conditions as the Registrar may specify, and the Registrar may at any time vary the conditions to which a person's entry under this article is subject (including by adding to the conditions or removing any conditions).
- (4) The entry of any person in Part 1 or 2 of the Register by virtue of paragraph (1)(b) as one of a specified group may be subject to the same conditions as the entries of other members of the group or it may be subject to different conditions.
- (5) The entry of a person in Part 1 or 2 of the Register under this article ceases to have effect if revoked by the Registrar, which—
- (a) the Registrar must do if the Secretary of State advises the Registrar that the circumstances that led the Secretary of State to advise the Registrar as mentioned in paragraph (1) no longer exist;
  - (b) the Registrar may do for any other reason at any time including where the Registrar has grounds for suspecting that the person's fitness to practise may be impaired.
- (6) The entry of a person in Part 1 or 2 of the Register by virtue of paragraph (1)(b) as one of a specified group may be revoked without revoking the entries of the other members of the group, or it may be revoked by virtue of a decision to revoke the entries of all the members of the group.
- (7) Articles 20 to 25, 27 and 30, Part 5 and Part 6 (except articles 48 to 50) do not apply to persons entered in Part 1 or 2 of the Register under this article.
- (8) If a person breaches any condition to which the person's entry in Part 1 or 2 of the Register under this article is subject, anything done by that person in breach of the condition is to be treated as not being done by a registered pharmacist or, as the case may be, by a registered pharmacy technician.
- (9) The Registrar may make available information to assist with the identification of persons entered in Part 1 or 2 of the Register under this article in such manner as the Registrar sees fit.

**Temporary annotations with regard to emergencies involving loss of human life or human illness etc.**

**35.—**(1) If the Secretary of State advises the Registrar that an emergency has occurred, is occurring or is about to occur and that action should be considered under this article, the Registrar may annotate—

- (a) the entry of a registrant in Part 1 or 2 of the Register to indicate that the registrant is qualified to order drugs, medicines and appliances in a specified capacity, notwithstanding that the registrant is not so qualified, if the Registrar considers that the registrant is a fit, proper and suitably experienced person to order drugs, medicines and appliances in that capacity with regard to the emergency; or
- (b) the entries of a specified group of registrants in Part 1 or 2 of the Register to indicate that they are qualified to order drugs, medicines and appliances in a specified capacity, notwithstanding that they are not so qualified, if the Registrar considers that the group is

comprised of registrants who are of a type who may reasonably be considered fit, proper and suitably experienced persons to order drugs, medicines and appliances in that capacity with regard to the emergency.

(2) The Registrar may make the annotation in such a way as to distinguish registrants whose entries are annotated by virtue of paragraph (1) from registrants in respect of whose entries the annotation is made otherwise than by virtue of paragraph (1).

(3) Annotations made by virtue of paragraph (1)—

- (a) must be removed by the Registrar if the Secretary of State advises the Registrar that the circumstances that led the Secretary of State to advise the Registrar as mentioned in paragraph (1) no longer exist;
- (b) may be removed by the Registrar at any time, including where the Registrar has grounds for suspecting that the person's fitness to order drugs, medicines and appliances may be impaired.

(4) A registrant whose entry in Part 1 or 2 of the Register is annotated by virtue of paragraph (1) (b) as one of a specified group may have that annotation removed without the Registrar removing the equivalent annotations of the other members of the group or by virtue of a decision to remove the annotations made by virtue of paragraph (1)(b) of all the members of the group.

### **Fees in connection with entry**

**36.**—(1) Subject to paragraph (3), the Council may make rules with respect to the charging of fees in connection with the entry in the Register of a person or of premises at which a retail pharmacy business is, or is to be, carried on, and in particular with respect to—

- (a) applications for entry to, or for the renewal of an entry in, the Register of a person or premises under article 23 or, as the case may be, under section 74A of the Medicines Act 1968<sup>(33)</sup> (registration of premises: Great Britain);
  - (b) applications for the restoration of an entry to the Register pursuant to—
    - (i) article 37 (including provision for additional fees to be charged in connection with the application),
    - (ii) article 57,
    - (iii) under section 74C(1) of the Medicines Act 1968<sup>(34)</sup> (supplementary provision in respect of registration of premises: Great Britain), and
    - (iv) section 74I(1) of the Medicines Act 1968<sup>(35)</sup> (supplementary provision in respect of change of ownership of retail pharmacy business: Great Britain);
  - (c) amendments to the Register (including any amendments required to reflect the transfer of ownership of the retail pharmacy business carried on at a registered pharmacy or the voluntary removal of a registered pharmacy from the Register);
  - (d) applications for entering annotations in, or restoring annotations to, the Register;
  - (e) applications for the renewal of annotations in the Register; and
  - (f) issuing further notices of a registrant's entry in the Register pursuant to article 26(3).
- (2) The Council must publish any such rules in such manner as it sees fit.
- (3) Rules under paragraph (1) must not provide for fees to be charged in respect of the entry or the renewal of an entry of a person in Part 4 or 5 of the Register.

<sup>(33)</sup> Section 74A is inserted into the Act by paragraph 1(8) of Schedule 4 to this Order.

<sup>(34)</sup> Section 74C is inserted into the Act by paragraph 1(8) of Schedule 4 to this Order.

<sup>(35)</sup> Section 74I is inserted into the Act by paragraph 1(8) of Schedule 4 to this Order.

(4) Rules under paragraph (1) may provide for a fee not to be charged, or to be waived in whole or in part, in prescribed cases or circumstances (which may include cases or circumstances defined by reference to the discretion of the Registrar).

(5) Rules under paragraph (1) may also, in relation to the entry of registered pharmacies in the Register, provide for—

- (a) fees to be charged by reference to different periods; and
- (b) fees to be charged by reference to the location of a registered pharmacy.

(6) Before making rules under paragraph (1), the Council must consult such persons as it considers appropriate including, where it considers appropriate, persons appearing to it to represent—

- (a) registrants;
- (b) professional bodies or organisations recognised by the Council as representing registrants;
- (c) persons carrying on a retail pharmacy business at a registered pharmacy; or
- (d) persons or bodies commissioning or funding the services provided by registrants or at registered pharmacies.

### **Restoration to the Register of persons or premises removed from the Register**

**37.—**(1) Where the entry of a person in the Register has been removed from the Register—

- (a) under article 25(3) pursuant to a decision by the Registrar under article 23(2)(b) to refuse to renew that entry;
- (b) pursuant to article 28(2) or (3);
- (c) pursuant to article 29(3);
- (d) pursuant to article 30(1) or (3);
- (e) pursuant to rules made under article 31;
- (f) pursuant to article 32(8)(a); or
- (g) by reason of a failure by that person to comply with the requirements or conditions of the framework adopted by the Council under article 43(4)(a) or by reason of a false declaration made by that person about compliance with those requirements or conditions,

the Registrar may, upon an application being made to the Registrar by that person, restore that person to the Register in such circumstances as may be prescribed.

(2) Where the entry of a registered pharmacy has been removed from the Register—

- (a) under article 14(4)(a) because the person who was carrying on a retail pharmacy business at the registered pharmacy failed to comply with the provisions of an improvement notice; or
- (b) under rules made under section 74G of the Medicines Act 1968<sup>(36)</sup> (voluntary removal from the register: Great Britain),

the Registrar may, upon an application being made to the Registrar by the person who, immediately prior to the removal, was carrying on the retail pharmacy business at the registered pharmacy, restore that pharmacy to the Register in such circumstances as may be prescribed.

(3) The Council may make such provision in rules as it considers appropriate in connection with applications for restoration pursuant to paragraphs (1) and (2) and may, in particular, make provision with regard to—

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<sup>(36)</sup> 1968 c.67. Section 74G is inserted into the Act by paragraph 1(8) of Schedule 4 to this Order.

- (a) the form and manner in which applications are to be made (including rules to the effect that applicants must apply using application forms that are in such form as the Council may determine from time to time);
  - (b) the information to be provided by the applicant; and
  - (c) in the case of applications for restoration made in respect of individuals—
    - (i) fitness to practise matters;
    - (ii) whether any, and if so what, additional education, training or experience is required before restoration, and the rules may make provision for these issues to be determined in individual cases by the Registrar,
    - (iii) whether, and if so what, continuing professional development is required after restoration, and the rules may make provision—
      - (aa) for these issues to be determined in individual cases by the Registrar, and
      - (bb) enabling the Registrar to determine that the application for restoration is to be granted subject to the applicant agreeing to comply with such undertakings with regard to continuing professional development as the Registrar considers appropriate; and
  - (d) refusal of applications (including where the applicant has not paid the fee prescribed under article 36(1)(b)).
- (4) Where a person who has agreed to comply with an undertaking pursuant to rules made under paragraph (3)(c)(iii)(bb) breaches that undertaking, that breach may be treated as misconduct for the purposes of article 51(1)(a) and the Registrar must consider, in accordance with article 52(1), whether or not to refer the matter to the Investigating Committee or (where rules under article 52(1) so provide) the Fitness to Practise Committee.
- (5) Where the Registrar refuses an application for restoration to Part 1, 2, 4 or 5 of the Register, the Registrar must send to the applicant at the applicant's last known home address a statement in writing giving the applicant notice of the decision and the reasons for it and of the right of appeal to the Appeals Committee under article 40.
- (6) Where the Registrar refuses an application for restoration to Part 3 of the Register, the Registrar must send to the person who, immediately prior to the removal of the entry of the registered pharmacy, was carrying on a retail pharmacy business at the registered pharmacy a statement in writing giving that person notice of the decision and the reasons for it and of the right of appeal to the Appeals Committee under article 40.
- (7) The notice under paragraph (6) must be sent—
- (a) where the person who was carrying on the business is an individual, to that individual at that individual's home address in the Register;
  - (b) where the person who was carrying on the business is a partnership, to that partnership at its principal office; or
  - (c) where the person who was carrying on the business is a body corporate, to that body corporate at its registered or principal office.

### **Offences relating to the Register**

- 38.**—(1) A person who makes a false representation as to being—
- (a) entered in the Register as a pharmacist;
  - (b) entered in the Register as a pharmacy technician; or
  - (c) entered in any part of the Register with a particular annotation,

commits an offence.

(2) A person who—

- (a) uses the title “pharmacist” or “fferyllydd” (its equivalent in the Welsh language) without being entered as a pharmacist in Part 1 or 4 of the Register;
- (b) uses the title “pharmacy technician” or “technegydd fferylliaeth” (its equivalent in the Welsh language) without being entered as a pharmacy technician in Part 2 or 5 of the Register; or
- (c) uses a title in respect of a particular annotation, which is a prescribed specialist title, where that person does not have an entry in any part of the Register with that particular annotation,

commits an offence.

(3) For the purposes of paragraph (2)(c), “prescribed specialist title” means—

- (a) in the case of a pharmacist, a title for a pharmacist which the Council prescribes by rules as being a title that is only to be used by a registrant with a particular annotation; and
- (b) in the case of a pharmacy technician, a title for a pharmacy technician which the Council prescribes by rules as being a title that is only to be used by a registrant with a particular annotation.

(4) A person who practises—

- (a) as a pharmacist while not being entered as such in Part 1 or 4 of the Register; or
- (b) as a pharmacy technician while not being entered as such in Part 2 or 5 of the Register,

commits an offence.

(5) A person who exhibits any notice or certificate which—

- (a) purports to be a notice of entry issued under article 26 in respect of a pharmacist but which is not a notice of entry issued under that article in respect of a pharmacist;
- (b) purports to be a certificate of registration issued under one of the Pharmacy Acts in respect of a pharmaceutical chemist but which is not a certificate of registration issued under one of those Acts in respect of a pharmaceutical chemist; or
- (c) purports to be a certificate of registration issued under the 2007 Order in respect of a pharmacist but which is not a certificate of registration issued under that Order in respect of a pharmacist,

commits an offence.

(6) A person who exhibits any notice or certificate which—

- (a) purports to be a notice of entry issued under article 26 in respect of a pharmacy technician but which is not a notice of entry issued under that article in respect of a pharmacy technician;
- (b) purports to be a certificate of registration issued under the 2007 Order in respect of a pharmacy technician but which is not a certificate of registration issued under that Order in respect of a pharmacy technician,

commits an offence.

(7) A person who, for fraudulent purposes—

- (a) uses or lends to, or allows to be used by, another person—
  - (i) a notice of entry or certificate of registration in respect of a pharmacist or a pharmaceutical chemist (whether issued under article 26 or one of the Pharmacy Acts or the 2007 Order), or

- (ii) a notice of entry or certificate of registration in respect of a pharmacy technician issued under article 26 or the 2007 Order; or
- (b) makes or possesses any document closely resembling such a notice or certificate, commits an offence.
- (8) Any person who commits an offence under paragraph (1), (2) or (4) is liable on summary conviction to a fine not exceeding level 5 on the standard scale.
- (9) Any person who commits an offence under paragraph (5), (6) or (7) is liable on summary conviction to a fine not exceeding level 3 on the standard scale.
- (10) 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.

### **Appealable decisions**

- 39.**—(1) Subject to paragraph (2), the following decisions are appealable decisions for the purposes of article 40—
- (a) a decision under Part 3 of the General Systems Regulations to require an exempt person to whom article 21(1)(c) or 22(1)(b) applies to complete an adaptation period, or pass an aptitude test, before deciding whether that person is “appropriately qualified” for the purposes of article 20(1)(a)(i);
- (b) a decision by the Registrar to refuse to enter a person in Part 1 or 2 of the Register as a pharmacist or a pharmacy technician (excluding restoration cases);
- (c) a decision by the Registrar to refuse to enter a person in Part 4 or 5 of the Register (excluding restoration cases);
- (d) a decision by the Registrar under article 23(2)(b) to refuse to renew an entry of a registrant in Part 1 or 2 of the Register;
- (e) a decision by the Registrar under paragraph 5 or 14 of Schedule 2 to refuse to renew the entry of a visiting practitioner in Part 4 or 5 of the Register;
- (f) a decision by the Registrar to refuse to enter, renew or restore an annotation in any part of the Register in respect of a specialisation pursuant to rules under article 27(1);
- (g) a decision by the Registrar to remove an annotation in respect of a specialisation from any part of the Register pursuant to rules under article 27(1);
- (h) a decision by the Registrar to remove the entry of a registrant from Part 1 or 2 of the Register pursuant to article 28(2) or (3);
- (i) a decision by the Registrar to remove the entry of a registrant from Part 1, 2, 4 or 5 of the Register or a registered pharmacy from Part 3 of the Register pursuant to article 29(3) (a) or (b);
- (j) a decision by the Registrar to remove the entry of a registrant from Part 1 or 2 of the Register pursuant to article 30(1) or (3);

- (k) a decision by the Registrar to remove an entry of a registrant from Part 1 or 2 of the Register under article 32(8)(a);
  - (l) a decision by the Registrar to refuse an application for restoration of a person's entry in Part 1, 2, 4 or 5 of the Register but only if the decision is for a reason that does not relate to a person's fitness to practise;
  - (m) a decision by the Registrar in accordance with rules made by the Council under article 43(7) to suspend the entry of a registrant in the Register or to remove such an entry from the Register on the ground that the registrant has failed to comply with the requirements or conditions of the framework adopted by the Council under article 43(4)(a) or has made a false declaration about compliance with those requirements or conditions;
  - (n) a decision by the Council under article 47(6)(a) or (b) to refuse to approve, or to withdraw approval from, any education, training, qualification, test or institution or other provider or to impose probationary or remedial measures on an institution or other provider;
  - (o) a decision by the Registrar to refuse to enter a person in Part 2 of the Register under paragraph 6(2) of Schedule 5 on the ground that the person does not have the requisite knowledge, skill and experience for practising as a pharmacy technician in Great Britain;
  - (p) a decision by the Registrar under section 74A of the Medicines Act 1968(37) (registration of premises: Great Britain) to refuse to enter premises in Part 3 of the Register or to refuse to renew the entry of premises in Part 3 of the Register;
  - (q) a decision by the Registrar under section 74H of the Medicines Act 1968(38) (change of ownership of retail pharmacy business: Great Britain) not to restore an entry of premises to Part 3 of the Register;
  - (r) a decision by the Registrar under paragraph (4) of article 14 to suspend or remove an entry of premises in Part 3 of the Register; and
  - (s) a decision which, by virtue of rules under this Order, may be appealed to the Appeals Committee.
- (2) A decision is not an appealable decision if it was taken—
- (a) because of a failure to pay any fee prescribed under article 36(1); or
  - (b) because the applicant is not appropriately qualified, in circumstances where the applicant contends that the applicant's qualifications should be approved by the Council pursuant to article 21(1)(d)(i) or 22(1)(c)(i).

### **Appeals to the Appeals Committee**

**40.**—(1) Except as provided for by paragraphs (2) and (3), a person in respect of whom an appealable decision has been made may appeal against it to the Appeals Committee by giving notice of appeal to the Registrar within 28 days beginning with the date on which the written statement of the reasons for the decision was sent.

(2) In the case of an appealable decision to which paragraph (4) or (9) of article 24 applies, the person in respect of whom that decision has been made may appeal against it to the Appeals Committee by giving notice of appeal to the Registrar within 28 days beginning with the date on which the application is, by virtue of that paragraph, taken to have been refused by the Registrar.

(3) In the case of an appealable decision to which paragraph (6)(a) or (b) of article 47 applies, the institution or other provider on which probationary or remedial measures have been imposed or from or in relation to which approval has been withdrawn or refused may bring an appeal to the Appeals Committee by giving notice of appeal to the Council within 28 days beginning with the date

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(37) Section 74A is inserted into the Act by paragraph 1(8) of Schedule 1 to this Order.

(38) Section 74H is inserted into the Act by paragraph 1(8) of Schedule 4 to this Order.

on which the decision is made or within such longer period as the Council may, in the circumstances of any particular case, allow.

(4) Where, on an application by a person in respect of whom an appealable decision to which paragraph (1) relates has been made, the Registrar is satisfied that that person did not receive the written statement of the reasons for the decision within 14 days of the statement being sent, the Registrar may by authorisation in writing extend the time for giving notice of appeal under paragraph (1).

(5) Where an appealable decision to which paragraph (3) relates has been taken, the decision to impose probational or remedial measures on, or to refuse approval of or withdraw approval from, an institution or other provider does not take effect—

(a) until the period for bringing an appeal in respect of the decision has expired, but if the period for bringing an appeal has been extended under paragraph (4), that extended period is, for the purposes of this paragraph, to be treated as a period for bringing an appeal (notwithstanding that this may require reversal of the action taken); and

(b) where an appeal is brought within the period for bringing an appeal, until the date on which the appeal is finally disposed of, or is abandoned or fails by reason of its non-prosecution.

(6) Where an appealable decision has been taken to remove an entry or an annotation in respect of a person or a registered pharmacy from any part of the Register, or to refuse to renew such an entry or annotation in any part of the Register, the decision does not take effect—

(a) until the period for bringing an appeal in respect of the decision has expired, but if the period for bringing an appeal has been extended under paragraph (4), that extended period is, for the purposes of this paragraph, to be treated as the period for bringing an appeal (notwithstanding that this may require reversal of the action taken); and

(b) where an appeal is brought within the period for bringing an appeal, until the date on which the appeal is finally disposed of, or is abandoned or fails by reason of its non-prosecution.

(7) Having considered the appeal, the Appeals Committee may—

(a) dismiss the appeal;

(b) allow the appeal and quash the decision appealed against;

(c) substitute for the decision appealed against any other decision that the person taking the decision could have taken; or

(d) remit or refer the case to the Registrar for disposal of the matter in accordance with the Appeals Committee's directions.

(8) The Appeals Committee must, as soon as reasonably practicable, send to the person bringing the appeal a statement in writing giving the person notice of the Committee's decision and the reasons for it and of any right of appeal under article 41(1).

(9) Except as provided in paragraph (10), the statement referred to in paragraph (8) must be sent—

(a) where the appellant is an individual, to that individual at that individual's home address in the Register;

(b) where the appellant is a partnership, to that partnership at its principal office; and

(c) where the appellant is a body corporate, to that body corporate at its registered or principal office.

(10) Where the appellant is an institution or other provider on which probational or remedial measures have been imposed or from or in relation to which approval has been withdrawn or refused, the statement referred to in paragraph (8) must be sent to that institution or other provider at the last known address of that institution or other provider.

(11) Subject to paragraph (12), the Appeals Committee must, as soon as reasonably practicable, publish, in such manner as it sees fit, its decision and the reasons for it.

(12) If the Appeals Committee has allowed the appeal, or has taken a decision or issued a direction that has the effect of allowing the appeal, it is not required to publish its decision and the reasons for it unless the person making the appeal so requests.

(13) For the purposes of paragraphs (5) and (6) an appeal is finally disposed of once all rights in relation to the appeal have been exhausted.

(14) In this article any reference to a person in respect of whom an appealable decision has been made is, in a case where the decision relates to a registered pharmacy, or to premises that have been or would have been a registered pharmacy, to be construed as a reference to the applicant for registration or, as the case may be, to the person who is or has been carrying on a retail pharmacy business at the premises.

### **Appeals from the Appeals Committee**

**41.**—(1) Except where the Appeals Committee has allowed an appeal, or has taken a decision or issued a direction that has the effect of allowing the appeal, a person in respect of whom a decision by the Appeals Committee has been taken may appeal against that decision to the relevant court.

(2) Notice of any appeal under this article must be filed at, or in Scotland lodged in, the relevant court and served on the Council, in accordance with rules of court, within 28 days beginning with the date on which the written notice of the reasons for the decision was sent, or within such longer period as the relevant court may, in accordance with the rules of court, allow.

(3) In this article, “the relevant court” means—

- (a) in the case of an appeal relating to an individual domiciled in Scotland or to premises in Scotland, the sheriff in whose sheriffdom the individual is domiciled or the premises are located; and
- (b) in any other case, the county court (the Central London County Court if the person making the appeal is not domiciled in Great Britain).

(4) Having considered an appeal under this article, the relevant court may—

- (a) dismiss the appeal;
- (b) allow the appeal and quash the decision appealed against;
- (c) substitute for the decision appealed against any other decision that the Appeals Committee could have taken; or
- (d) remit or refer the case to the Registrar for disposal of the matter in accordance with the relevant court’s directions,

and may make such order as to costs or, in Scotland, expenses as the relevant court thinks fit.

## **PART 5**

### **Education, training and acquisition of experience and continuing professional development**

#### **Education, training and acquisition of experience**

**42.**—(1) In connection with its general function under article 4(3)(e), in so far as that function relates to the education, training and acquisition of experience of registrants and prospective registrants, the Council must—

- (a) except in the case of persons who are appropriately qualified by virtue of article 21(1)(b) or (c) or article 22(1)(b), set the standards of proficiency for the safe and effective practice of pharmacy which it is necessary for a person to achieve in order to be entered in Part 1 or 2 of the Register as a pharmacist or, as the case may be, a pharmacy technician; and
  - (b) set—
    - (i) the standards of education, training and experience that providers of education and training must meet in order to enable a person undertaking such education or training, or acquiring such experience, to achieve the standards referred to in subparagraph (a) having regard, in particular, to the outcomes to be achieved, and
    - (ii) any requirements to be satisfied for admission to, and continued participation in, education and training for prospective pharmacists or prospective pharmacy technicians, which may include requirements as to fitness to practise unimpaired by health.
- (2) The Council must publish the standards and requirements set under this article, as they exist from time to time, in such manner as it considers appropriate.
- (3) The Council must—
- (a) ensure that all providers in Great Britain concerned with the education and training of prospective pharmacists and prospective pharmacy technicians are notified of the standards and requirements set under paragraph (1)(b)(i) and (ii); and
  - (b) take appropriate steps to satisfy itself that those standards and requirements are met.
- (4) The Council may—
- (a) approve, or arrange with others to approve, courses of education or training which the Council is satisfied confer, or would confer, on persons completing them successfully the standards of proficiency referred to in paragraph (1)(a);
  - (b) approve, or arrange with others to approve, such other courses of education or training as the Council considers appropriate;
  - (c) approve, or arrange with others to approve, qualifications which are granted following success in an examination, or some other assessment, taken as part of an approved course;
  - (d) approve, or arrange with others to approve, such tests of competence, or tests of proficiency in the knowledge and use of English, as the Council may require; or
  - (e) approve, or arrange with others to approve—
    - (i) institutions,
    - (ii) other providers, including tutors,  
of postgraduate education and training which leads to an approved qualification, if the Council considers that they are properly organised and equipped for conducting the whole or part of an approved course;
  - (f) approve, or arrange with others to approve, premises as being suitable for postgraduate education and training which leads to an approved qualification.
- (5) In connection with paragraph (4), the Council may approve, or arrange with others to approve—
- (a) a course of education or training run outside Great Britain which is intended to lead to an approved qualification;
  - (b) an institution or other provider of a course of education or training to which subparagraph (a) refers.
- (6) The Council must publish a statement of—

- (a) the criteria by reference to which the standards of education, training and experience referred to in paragraph (1)(b)(i) are set; and
- (b) the criteria that will be taken into account in deciding whether to grant approval under paragraph (4),

as they exist from time to time.

(7) The Council must publish and maintain a list of the courses of education and training, qualifications and institutions or other providers (including tutors)—

- (a) which are for the time being approved under this Order; or
- (b) which have been approved under this Order but which are no longer so approved,

together with a record of the periods in respect of which approval was given.

(8) References in this Part to an approved course of education and training, an approved qualification, an approved test or an approved institution or other provider are references to such a course, qualification, test, institution or other provider approved under paragraph (4).

### **Continuing professional development**

**43.**—(1) In connection with its general function under article 4(3)(e), in so far as that function relates to the continuing professional development of registrants, the Council must—

- (a) set the standards of proficiency for the safe and effective practice of pharmacy which it is necessary for a registrant to maintain in order to have an entry in Part 1 or 2 of the Register renewed; and
- (b) set the standards of continuing professional development which it is necessary for a registrant to maintain in order to continue to meet the standards of proficiency referred to in sub-paragraph (a).

(2) The Council must publish the standards set under this article, as they exist from time to time, in such manner as it considers appropriate.

(3) The Council must—

- (a) consult such persons as it considers appropriate about the development of criteria by reference to which compliance with the standards set under paragraph (1)(b) is to be monitored; and
- (b) publish those criteria as they exist from time to time in such manner as it considers appropriate.

(4) The Council must—

- (a) adopt and maintain a framework relating to the requirements and conditions to be met by registrants in respect of their continuing professional development; and
- (b) require registrants—
  - (i) to complete an annual declaration regarding their compliance with such requirements and conditions in respect of their continuing professional development as they are obliged to meet by that framework, and
  - (ii) to submit records about any continuing professional development undertaken by them to the Registrar for review.

(5) The framework adopted by the Council under paragraph (4)(a)—

- (a) must include provision relating to—
  - (i) the amount and type of continuing professional development that a registrant is required to undertake,

- (ii) the information to be provided by a registrant about the continuing professional development that the registrant has undertaken and the form and manner in which that information is to be provided,
  - (iii) the times at which information about the continuing professional development that a registrant has undertaken is to be provided (including any continuing professional development that relates to an annotation in respect of a particular specialisation that is to be recorded in the Register),
  - (iv) the keeping of records about the continuing professional development undertaken by registrants; and
- (b) must require that any continuing professional development that is undertaken by a registrant in accordance with it is relevant to—
- (i) the safe and effective practice of pharmacy, and
  - (ii) a learning need for the individual registrant that is relevant to the current scope of the practice of pharmacy including any specialisation of that individual registrant and the environment in which they practise;
- (c) in so far as it relates to a person (“P”) who is a registrant only as a result of being entered in Part 4 or 5 of the Register—
- (i) may not impose requirements on P if P is required to undertake, in P’s home State, continuing professional development in relation to the profession of pharmacist or, as the case may be, pharmacy technician; and
  - (ii) where they impose requirements on P—
    - (aa) must take account of the fact that P is fully qualified to pursue the profession in P’s home State, and
    - (bb) must specify that continuing professional development which P is required to undertake by the requirements may be undertaken outside Great Britain.
- (6) The Council must publish the framework adopted by it under paragraph (4)(a), as it exists from time to time, in such manner as it considers appropriate.
- (7) The Council must make such provision in rules as it considers appropriate with respect to registrants who fail to comply with any requirements of the framework adopted by the Council under paragraph (4)(a).
- (8) Rules under paragraph (7) must—
- (a) make provision about the circumstances in which the Registrar may remove the entry of a registrant from the Register, or impose such other remedial measures as may be prescribed in the rules, where the registrant—
    - (i) has failed to comply with the requirements or conditions of the framework adopted by the Council under paragraph (4)(a) relating to the continuing professional development of registrants; or
    - (ii) has made a false declaration about compliance with those requirements or conditions;
  - (b) where the framework adopted by the Council under paragraph (4)(a) makes provision in respect of a person (“P”) who is a registrant only as a result of being entered in Part 4 or 5 of the Register, secure that any sanction imposed in relation to P by reference to that provision is appropriate and proportionate in view of P’s continued lawful establishment in P’s home State as a pharmacist or, as the case may be, a pharmacy technician;

- (c) make provision for the Registrar to send a statement in writing to the registrant concerned at the registrant's last known home address giving that registrant notice of the removal and the reasons for it and of right of appeal to the Appeals Committee under article 40; and
- (d) make provision for the suspension of a registrant's entry in the Register pending the outcome of any appeal against a decision to remove the registrant from the Register.

(9) In this article "home State", in relation to a registrant entered in Part 4 or 5 of the Register, means the relevant European State in which the registrant is lawfully established as a pharmacist or, as the case may be, a pharmacy technician.

### **Specific obligations and powers of the Council in respect of education and training**

**44.**—(1) In the exercise of its function under article 4(3)(e), the Council must—

- (a) determine—
  - (i) programmes or courses in respect of, or any combination of, education, training or experience required in order to obtain an annotation in respect of a specialisation,
  - (ii) the amount and type of education, training and experience required in order to obtain an annotation in respect of a specialisation,
  - (iii) the education, training and experience that is necessary to address fitness to practise matters;
- (b) hold or cause to be held assessments in respect of—
  - (i) approved qualifications, or any education, training or experience leading to an approved qualification,
  - (ii) additional education, training or experience required for the purposes of article 20(1)(a)(iii), and
  - (iii) becoming and acting as tutors of, or in relation to, any education, training or experience leading to an approved qualification or any additional education, training or experience required for the purposes of article 20(1)(a)(iii),

and determine the arrangements under which those assessments are to be held (including arrangements for dealing with disciplinary matters with regard to candidates and prospective candidates);

- (c) appoint or arrange for the appointment of persons ("examiners") to carry out or oversee assessments of the type mentioned in paragraph (b), and pay them 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; and
- (d) establish, publish and maintain lists of premises that are to be used as training establishments.

(2) The duty imposed by paragraph (1)(c) does not prevent the Council from determining arrangements under which assessments of the type mentioned in paragraph (1)(b) are to be held which do not involve examiners.

### **Visitors**

**45.**—(1) The Council may appoint persons ("visitors") to visit any place at which, or any institution or other provider by which, or under whose direction—

- (a) any relevant course of education or training is, or is proposed to be, given;
- (b) any examination or other assessment is, or is proposed to be, held in connection with any such course; or

- (c) any test of competence is, or is proposed to be, conducted in connection with any such course or for any other purposes connected with this Order.
- (2) For the purposes of this article, “test of competence” includes such tests of proficiency in the knowledge and use of English as the Council may require.
- (3) In this article, “relevant course of education or training” means—
- (a) any course of education or training which forms, or is intended to form, part of an approved course of education or training; or
  - (b) any course which a registrant may be required to undergo for the purpose of applying for an annotation in respect of a specialisation to be made to an entry in a part of the Register in accordance with rules made by the Council under article 27.
- (4) No visitor may exercise the functions of a visitor under this Order in relation to—
- (a) any place at which that visitor regularly gives instruction in any subject; or
  - (b) any institution or other provider with which that visitor has, in the opinion of the Council, a significant connection.
- (5) A person is not prevented from being a visitor merely because that person is a member of the Council or any of its committees; but no person may be a visitor if that person is employed by the Council.
- (6) Visitors must be selected with due regard to the profession with which the education and training they are to report on is concerned and at least one of the visitors must be entered in a part of the Register which relates to that profession.
- (7) Where a visitor visits any place or institution or other provider in the exercise of the functions of a visitor under this article, the visitor—
- (a) must report to the Council—
    - (i) on the nature, content and quality of the instruction given, or to be given, and the facilities provided, or to be provided, at that place or by that institution or provider, and
    - (ii) on such other matters (if any) as the Council may require; and
  - (b) may, having regard to the contents of the report in so far as it relates to the matters referred to in sub-paragraph (a)(i), send a copy of the report to the inspectorate established under article 8(1).
- (8) Requirements of the kind mentioned in paragraph (7)(a)(ii) may be imposed by the Council—
- (a) generally in relation to all visits made to a specified kind of place or institution or other provider or in respect of a specified type of course; or
  - (b) specifically in relation to a particular visit.
- (9) Where a visitor reports to the Council in accordance with paragraph (7)(a), the Council must on receipt of the report—
- (a) send a copy of it to the institution or other provider concerned; and
  - (b) notify that institution or other provider of the period within which it may make observations on the report.
- (10) The period specified by the Council in a notice given under paragraph (9)(b) must not be less than one month beginning with the date on which a copy of the report is sent to the institution or other provider concerned under paragraph (9)(a).
- (11) The Council must not take any steps in the light of any report made under paragraph (7) before the end of the specified period mentioned in paragraph (10).

(12) The Council must publish such reports together with, at the request of the institution or other provider concerned, the response of that institution or provider to the report.

(13) The Council may make such provision in respect of visitors as it may reasonably determine—

- (a) for the payment of allowances, including the payment of allowances to employers of visitors, for the purposes of enabling visitors to perform functions under this article; and
- (b) for the reimbursement of such expenses as visitors may reasonably have incurred in the course of carrying out their functions under this article.

### **Information to be given by institutions or other providers**

**46.**—(1) This article applies to any institution or other provider in Great Britain by which, or under whose direction, whether inside or outside Great Britain—

- (a) any relevant course of education or training is, or is proposed to be, given; or
- (b) any test of competence is, or is proposed to be, conducted in connection with any such course or for any other purpose connected with this Order.

(2) In paragraph (1), “test of competence” and “relevant course of education or training” have the same meaning as in article 45.

(3) Whenever required to do so by the Council, any institution or other provider to which this article applies must give to the Council such information and assistance as the Council may reasonably require in connection with the exercise of its functions under this Order.

(4) Where an institution or other provider refuses any reasonable request for information made by the Council under this article, the Council may, in accordance with article 47, refuse to approve or withdraw approval from, any course of education or training, qualification, test or institution or other provider to which the information relates.

### **Refusal or withdrawal of approval of courses, qualifications and institutions**

**47.**—(1) Paragraph (2) applies to a case where, as a result of any visitor’s report or other information acquired by the Council, the Council is of the opinion that—

- (a) the standards set under article 42(1)(b)(i) are not, or will not, be met by an institution or other provider; or
- (b) an institution or other provider is not observing the requirements referred to in article 42(1)(b)(ii).

(2) In a case to which this paragraph applies, the Council may—

- (a) impose such probationary or remedial arrangements (including action plans for providers of new courses) or such conditions as may be prescribed; or
- (b) refuse to approve, or withdraw approval from, any course of education or training, qualification, test, or institution or other provider to which that opinion relates.

(3) If the Council is considering taking any action under paragraph (2)(a) or (b), the Council must act in accordance with paragraphs (4) to (6).

(4) The Council must—

- (a) notify the institution or other provider concerned of its opinion, setting out its reasons; and
- (b) inform the institution or other provider of the period within which it may make observations on the matters raised, which must not be less than one month beginning with the date on which the reasons are sent to the institution or other provider under subparagraph (a).

(5) The Council may take no further steps before the expiry of the period about which the institution or other provider has been informed under paragraph (4)(b).

(6) If, taking account of any visitor's report or other information acquired by the Council together with any observations submitted by the institution or other provider under paragraph (4), the Council decides that it is appropriate to—

- (a) impose probationary or remedial arrangements or conditions on the institution or other provider; or
- (b) refuse or withdraw approval,

it must send to the institution or other provider concerned at the last known address of the institution or provider a statement in writing giving the institution or other provider notice of the decision and the reasons for it and of the right of appeal to the Appeals Committee under article 40.

(7) A decision under paragraph (6) has effect from the date of the decision or from such later date as may be specified in the decision.

(8) Where, under this article, approval of a course of education or training or an institution or other provider is withdrawn, the Council must use its best endeavours to secure that any person who, at that time, is undertaking that course or is studying at that institution or with that other provider is given the opportunity to attend an approved course conducted by an approved institution or other provider.

(9) Where, under this article, approval of a qualification, a course of education or training or an institution or other provider is withdrawn, that withdrawal does not affect the entitlement of any person to be entered in a part of the Register on the basis of the award of a qualification to that person before the date on which the decision withdrawing approval from that qualification, the course of education or training which led to the award of that qualification or, as the case may be, the institution or other provider that conducted the course that led to the award of that qualification, had effect.

## PART 6

### Fitness to practise

#### **Standards of conduct and performance**

**48.**—(1) The Council must—

- (a) set standards relating to the conduct, ethics and performance expected of registrants; and
- (b) make provision in rules regarding the criteria to which the Fitness to Practise Committee is to have regard when deciding, in the case of any registrant, whether or not the requirements as to fitness to practise are met in relation to that registrant.

(2) The Council must publish the standards set under this article, as they exist from time to time, in such manner as it considers appropriate.

(3) Where any registrant is alleged to have failed to comply with standards set under this article, that failure—

- (a) is not, of itself, to be taken to constitute misconduct on the registrant's part; but
- (b) is to be taken into account in any proceedings against the registrant under this Order.

#### **Disclosure of information: general**

**49.**—(1) For the purpose of assisting the Council (including its staff and its committees) in carrying out functions in respect of the fitness to practise of a registrant, or of assisting the Registrar

in carrying out functions in respect of identifying any person entered in the Register by virtue of article 34(1)(b), a person authorised by the Council may require—

- (a) a registrant (except the registrant in respect of whom the information or document is sought); or
- (b) any other person,

who, in the opinion of the authorised person, is able to supply information or produce any document which appears to be relevant to the discharge of any such function, to supply the information or produce the document.

(2) Nothing in paragraph (1) requires or permits—

- (a) any disclosure of information which is prohibited by or under any enactment, but where that prohibition arises because the information is in a form which allows for the identification of an individual, the person authorised by the Council may require that information to be put in a form which does not allow for the identification of that individual; or
- (b) the supplying of information or production of a document which a person could not be compelled to produce in civil proceedings in the High Court or the Court of Session under article 58 .

(3) In determining, for the purposes of paragraph (2)(a), whether a disclosure of personal data is prohibited, it is to be assumed, for the purposes of section 35(1) of the Data Protection Act 1998(39) (disclosures required by law or made in connection with legal proceedings etc.), that the disclosure of personal data is required by paragraph (1).

(4) If a person fails to supply any information or to produce any document within 14 days of being required to do so under paragraph (1), or within such longer period as the Council in the circumstances of a particular case may allow, the Council may seek an order of the relevant court requiring the information to be supplied or the document to be produced.

(5) For the purposes of this article, the “relevant court” means—

- (a) in a case where the person in respect of whom the information or document is sought is domiciled in Scotland, the sheriff in whose sheriffdom that person is domiciled; and
- (b) in any other case, the county court (the Central London County Court if the person in respect of whom the information or document is sought is not domiciled in Great Britain).

### **Disclosure of fitness to practise matters in the public interest**

**50.**—(1) The Council may, if it considers it to be in the public interest to do so, publish or disclose to any person—

- (a) information which relates to a particular pharmacist’s or pharmacy technician’s fitness to practise, whether the matter to which the information relates arose before or after the entry in the Register of that pharmacist or pharmacy technician, or arose in Great Britain or elsewhere; or
- (b) information of a particular description related to fitness to practise in relation to every pharmacist or pharmacy technician, or to every pharmacist or pharmacy technician of a particular description.

(2) For the purposes of paragraph (1)(b), the Council need not consider whether it is in the public interest to publish or disclose the information in question in relation to each individual pharmacist or pharmacy technician to whom it relates.

**Impairment of fitness to practise**

**51.**—(1) A person’s fitness to practise is to be regarded as “impaired” for the purposes of this Order only by reason of—

- (a) misconduct;
- (b) deficient professional performance (which includes competence);
- (c) adverse physical or mental health which impairs their ability to practise safely and effectively or which otherwise impairs their ability to carry out the duties of a pharmacist or a pharmacy technician in a safe and effective manner;
- (d) failure to comply with a reasonable requirement imposed by an individual assessor or an assessment team in connection with carrying out a professional performance assessment;
- (e) a conviction in the British Islands for a criminal offence;
- (f) a conviction elsewhere than in the British Islands for an offence which, if committed in England, Wales or Scotland, would constitute a criminal offence;
- (g) an order under section 246(2) or (3) of the Criminal Procedure (Scotland) Act 1995<sup>(40)</sup> discharging the person absolutely (admonition and absolute discharge);
- (h) having accepted a conditional offer under section 302 of the Criminal Procedure (Scotland) Act 1995<sup>(41)</sup> (fixed penalty: conditional offer by procurator fiscal);
- (i) having agreed to pay a penalty under section 115A of the Social Security Administration Act 1992<sup>(42)</sup> (penalty as alternative to prosecution);
- (j) a police caution in the British Islands;
- (k) having agreed to be bound over to keep the peace by a magistrates’ court in England or Wales;
- (l) a determination made by a regulatory body in the United Kingdom responsible under any enactment for the regulation of a health or social care profession to the effect that the person’s fitness to practise as a member of a profession regulated by that body is impaired, or a determination by a regulatory body elsewhere to the same effect;
- (m) the Independent Barring Board including the person in a barred list (within the meaning of the Safeguarding Vulnerable Groups Act 2006<sup>(43)</sup> or the Safeguarding Vulnerable Groups (Northern Ireland) Order 2007<sup>(44)</sup>); or
- (n) the Scottish Ministers including the person in the children’s list or the adults’ list (within the meaning of the Protection of Vulnerable Groups (Scotland) Act 2007<sup>(45)</sup>).

(2) The demonstration towards a patient or customer, or a prospective patient or customer, by a pharmacist or pharmacy technician of attitudes or behaviour from which that person can reasonably expect to be protected may be treated as misconduct for the purposes of paragraph (1)(a).

(3) References in this article to a conviction include a conviction by court martial.

(4) A person’s fitness to practise may be regarded as impaired because of matters arising—

- (a) outside Great Britain; and
- (b) at any time.

<sup>(40)</sup> 1995 c.46.

<sup>(41)</sup> Section 302 was amended by section 406(1) of and Schedule 17, paragraph 133(1) and (2) to, the Communications Act 2003 (c.21), by paragraph 16 of Schedule 7 to the Wireless Telegraphy Act 2006 (c.36) and by section 50(1) of the Criminal Proceedings etc. (Reform) (Scotland) Act 2007 (asp 6).

<sup>(42)</sup> 1992 c.5. Section 115A was inserted by section 60 of the Social Security Administration (Fraud) Act 1997 (c.47) and amended by section 14 of the Social Security Fraud Act 2001 (c.11).

<sup>(43)</sup> 2006 c.47.

<sup>(44)</sup> S.I.2007/1351 (N.I.11).

<sup>(45)</sup> 2007 asp14.

(5) The Council may make such provision in rules as it considers appropriate in connection with the information to be provided to the Registrar by a registrant about fitness to practise matters that arise while the registrant is entered in any part of the Register.

(6) If a registrant fails to comply with rules under paragraph (5), the failure may be treated as misconduct for the purposes of paragraph (1)(a) and the Registrar must consider, in accordance with article 52(1), whether or not to refer the matter to the Investigating Committee or (where rules under article 52(1) so provide) the Fitness to Practise Committee.

### **Initial action in respect of allegations**

52.—(1) Where—

- (a) an allegation is made to the Council against a registrant that the registrant’s fitness to practise is impaired; or
- (b) the Council has information that calls into question a registrant’s fitness to practise, even though no allegation to that effect has been made to the Council,

the Registrar must, except in such cases and subject to such considerations as the Council may prescribe, refer the matter (referred to in this article as “the allegation”) to the Investigating Committee.

(2) Rules under paragraph (1) may provide for—

- (a) an allegation not to be referred where it is of a type that the Council has stated in threshold criteria, which it has published and which it may amend from time to time, should not be referred; and
- (b) an allegation to be referred, in prescribed cases, directly by the Registrar to the Fitness to Practise Committee.

(3) Where the Registrar—

- (a) refers an allegation directly to the Fitness to Practise Committee under rules made by virtue of paragraph (2)(b); and
- (b) is of the opinion that the Fitness to Practise Committee should consider making an interim order under article 56,

the Registrar must notify the Committee accordingly.

(4) Where the Registrar refers an allegation to the Fitness to Practise Committee under rules made by virtue of paragraph (2)(b), the Registrar must inform the registrant who is the subject of the allegation and the person, if any, who made the allegation of that decision.

(5) Once a decision has been taken to refer the allegation to the Investigating Committee or (where rules so provide) the Fitness to Practise Committee, the Registrar must, as soon as is reasonably practicable—

- (a) require from the registrant who is the subject of the allegation details of any person—
  - (i) by whom the registrant is employed or engaged to provide services in, or in relation to, any area of pharmacy, or
  - (ii) with whom the registrant has arrangements to provide such services;
- (b) notify the Secretary of State, the Scottish Ministers and the Welsh Ministers of the investigation of the registrant’s fitness to practise;
- (c) notify the Department of Health, Social Services and Public Safety in Northern Ireland of the investigation of the registrant’s fitness to practise where the registrant is also entered in the register of pharmaceutical chemists for Northern Ireland or the register of visiting

pharmaceutical chemists made out and maintained under Articles 6 and 9 of the Pharmacy (Northern Ireland) Order 1976(46); and

- (d) notify any person of whom the Registrar is aware—
- (i) by whom the registrant is employed or engaged to provide services in, or in relation to, any area of pharmacy, or
  - (ii) with whom the registrant has arrangements to provide such services, of the investigation of the registrant’s fitness to practise.

(6) Where a registrant fails to comply with a requirement imposed under paragraph (5)(a) within 14 days of the requirement being imposed, or within such longer period as the Registrar may in the circumstances of the particular case allow—

- (a) the failure may be treated as misconduct for the purposes of article 51(1)(a) and the Registrar may refer the matter to the Committee that is considering the allegation in respect of the registrant; and
  - (b) the Registrar may seek an order of the relevant court requiring the requested details to be supplied.
- (7) For the purposes of this article, the “relevant court” means—
- (a) in a case where the registrant is domiciled in Scotland, the sheriff in whose sheriffdom that registrant is domiciled; and
  - (b) in any other case, the county court (the Central London County Court if the registrant is not domiciled in Great Britain).

### **Consideration by the Investigating Committee**

**53.**—(1) Where an allegation or a matter (referred to in this article as “the allegation”) is referred to the Investigating Committee by—

- (a) the Registrar under article 52(1) or (6)(a); or
- (b) an individual assessor or an assessment team under rules made under article 55(3)(c),

the Committee must decide whether the allegation ought to be considered by the Fitness to Practise Committee.

(2) If the Investigating Committee decides that the allegation need not be considered by the Fitness to Practise Committee, then unless the person who is the subject of the allegation (referred to in this article as “the person concerned”) has requested a referral under paragraph (3)—

- (a) the Investigating Committee may give—
  - (i) a warning to the person concerned in connection with any matter arising out of or related to the allegation and give a direction that details of the warning be recorded in the Register,
  - (ii) advice to the person concerned in connection with any matter arising out of, or related to, the allegation, and
  - (iii) advice to any other person or other body involved in its investigation of the allegation on any issue arising out of, or related to, the allegation; and
- (b) the Registrar must inform the person concerned and the person who made the allegation, if any, of the Investigating Committee’s decision and any action it is taking under sub-paragraph (a).

(3) If the Investigating Committee determines that the allegation ought to be considered by the Fitness to Practise Committee or the person concerned has requested a referral under this paragraph—

- (a) the Investigating Committee must refer the allegation to the Fitness to Practise Committee;
- (b) where the Investigating Committee considers that the Fitness to Practise Committee should consider making an interim order under article 56, it must notify the Fitness to Practise Committee accordingly; and
- (c) the Registrar must inform the person concerned and the person who made the allegation, if any, of the Investigating Committee’s decision to refer the allegation to the Fitness to Practise Committee.

(4) If, having considered the allegation, the Investigating Committee considers that the Council should consider exercising any of its powers to bring criminal proceedings under any enactment, it must notify the Registrar accordingly.

### **Consideration by the Fitness to Practise Committee**

**54.**—(1) Where an allegation or matter (referred to in this article as “the allegation”) is referred to the Fitness to Practise Committee by the Registrar—

- (a) under rules made by virtue of article 52(2)(b);
- (b) under article 52(6)(a);
- (c) by the Investigating Committee under article 53; or
- (d) by an individual assessor or an assessment team under rules made under article 55(3)(c),

the Fitness to Practise Committee must determine whether or not the fitness to practise of the person in respect of whom the allegation is made (referred to in this article as “the person concerned”) is impaired.

(2) If the Fitness to Practise Committee determines that the fitness to practise of the person concerned is impaired, it may—

- (a) give a warning to the person concerned in connection with any matter arising out of, or related to, the allegation and give a direction that details of the warning be recorded in the Register;
- (b) give advice to any other person or other body involved in the investigation of the allegation on any issue arising out of, or related to, the allegation;
- (c) give a direction that the entry in the Register of the person concerned be removed;
- (d) give a direction that the entry in the Register of the person concerned be suspended, for such period not exceeding 12 months as may be specified in the direction; or
- (e) give a direction that the entry in the Register of the person concerned be conditional upon that person complying, during such period not exceeding 3 years as may be specified in the direction, with such requirements specified in the direction as the Committee thinks fit to impose for the protection of the public or otherwise in the public interest or in the interests of the person concerned.

(3) Where the Fitness to Practise Committee has given a direction under this article, other than a direction that the entry in the Register of the person concerned be removed, it may, if it thinks fit, following a review—

- (a) where the entry in the Register of the person concerned is suspended, give a direction that—
  - (i) the entry be removed from the Register,

- (ii) the suspension of the entry be extended for such further period not exceeding 12 months as may be specified in the direction, starting from the time when the period of suspension would otherwise expire,
  - (iii) the entry be suspended indefinitely, if the suspension has already been in force throughout a period of at least two years,
  - (iv) in the case of an indefinite suspension, terminate the suspension, provided that the review takes place in the circumstances provided for in paragraph (4), or
  - (v) on expiry or termination of the period of suspension (including a period of suspension that was expressed to be indefinite), the entry be conditional upon that person complying, during such period not exceeding 3 years as may be specified in the direction, with such requirements specified in the direction as the Committee thinks fit to impose for the protection of the public or otherwise in the public interest or in the interests of the person concerned;
- (b) where the entry in the Register of the person concerned is conditional upon that person complying with requirements specified in a direction given under this article, give a direction that—
- (i) the period specified in the direction for complying with the requirements be extended for such further period not exceeding 3 years as may be specified in the direction, starting from the time when the earlier period would otherwise expire,
  - (ii) the requirements be added to, removed or otherwise varied in such manner as may be specified in the direction,
  - (iii) the entry instead be suspended (for example, where that person has failed, whether wholly or partly, to comply with the requirements), for such period not exceeding 12 months as may be specified in the direction, or
  - (iv) the entry be removed from the Register, if that person has failed, whether wholly or partly, to comply with the requirements.
- (4) If the Fitness to Practise Committee gives a direction under paragraph (3)(a)(iii), the Committee must review the direction if—
- (a) the person concerned asks it to do so; and
  - (b) at least two years have elapsed—
    - (i) since the direction took effect, or
    - (ii) if the direction has already been reviewed by the Committee, since the conclusion of the last review by the Committee.
- (5) If the Fitness to Practise Committee determines that the fitness to practise of the person concerned is not impaired—
- (a) the Committee may give—
    - (i) a warning to the person concerned in connection with any matter that the Committee considers necessary or desirable taking into account the Committee’s findings and give a direction that details of the warning be recorded in the Register,
    - (ii) advice to the person concerned in connection with any such matter, and
    - (iii) advice to any other person or other body involved in the investigation of the allegation on any issue arising out of, or related to, the allegation;
  - (b) the Registrar must inform the person concerned and the person who made the allegation, if any, of the Committee’s decision and any action it is taking under sub-paragraph (a); and

- (c) the Committee must, if the person concerned so requests, publish in such manner as it sees fit a statement summarising its determination, or may publish such a statement if that person consents.
- (6) If the person concerned is entered in more than one part of the Register, the Fitness to Practise Committee—
  - (a) must make separate determinations under this article in relation to each part of the Register; and
  - (b) may give a direction under paragraph (2) or (3) in relation to only one part of the Register or different directions in relation to different parts of the Register,but may otherwise deal with the matter as a single case.
- (7) If the Fitness to Practise Committee determines under this article that a person's fitness to practise is impaired solely by reason of adverse physical or mental health, it may not give a direction under paragraph (2)(c), (3)(a)(i) or (3)(b)(iv) that the entry in the Register in respect of that person be removed.
- (8) If the Fitness to Practise Committee gives a warning or a direction under this article, the Registrar must on its behalf send to the person concerned at the last known home address of that person a statement in writing giving the person notice of the reasons for the warning or the direction and of any right of appeal under article 58.
- (9) If, having considered the allegation, the Fitness to Practise Committee considers that the Council should consider exercising any of its powers to bring criminal proceedings under any enactment, it must notify the Registrar accordingly.

### **Professional performance assessments**

- 55.—**(1) The Council may make rules about the circumstances in which the Registrar, the Investigating Committee and the Fitness to Practise Committee are authorised to give directions requiring an assessment of the standard of a registrant's professional performance by an individual assessor or an assessment team.
- (2) The circumstances that may be prescribed under paragraph (1) include circumstances arising during proceedings of either Committee.
  - (3) The Council may make such provision as it considers appropriate in rules in connection with the composition of assessment teams and the functions of and procedures to be followed by individual assessors and assessment teams and may, in particular, make provision with regard to—
    - (a) the Council entering into arrangements with other bodies for those bodies to provide individual assessors or assessment teams to carry out the assessments;
    - (b) allowing an assessment by an individual assessor or an assessment team to include an assessment of the standard of a registrant's professional performance both at any time before the assessment and at the time of the assessment; and
    - (c) referring to the Investigating Committee or the Fitness to Practise Committee a case where an individual assessor or an assessment team considers that a registrant has failed to comply with a reasonable requirement that has been imposed on that registrant by the individual assessor or the assessment team.
  - (4) An individual assessor or an assessment team, in connection with carrying out an assessment of the standard of a registrant's professional performance—
    - (a) may require the production of, and inspect and take copies of, any records (in whatever form they are held) arising out of or related to the registrant's professional practice; and
    - (b) where such records are kept otherwise than in legible form, may require a copy of them to be given in legible form.

- (5) Nothing in, or in rules under, this article requires or permits—
- (a) any disclosure of information which is prohibited by or under any enactment, but where that prohibition arises because the information is in a form which allows for the identification of an individual, an individual assessor or an assessment team, when requiring the production of records under paragraph (4)(a), may require that the records be put in a form which does not allow for the identification of that individual; or
  - (b) the production of records which a person could not be compelled to produce in civil proceedings in the High Court or the Court of Session under article 58.
- (6) In determining, for the purposes of paragraph (5)(a), whether a disclosure of personal data is prohibited, it is to be assumed, for the purposes of section 35(1) of the Data Protection Act 1998<sup>(47)</sup> (disclosures required by law or made in connection with legal proceedings etc.), that the disclosure of personal data is required by paragraph (4).
- (7) If a person fails to produce any records within 14 days of being required to do so under paragraph (4), the Registrar, the Investigating Committee or the Fitness to Practise Committee on whose behalf the individual assessor or assessment team is carrying out the assessment in connection with which the records are being sought, may seek an order of the relevant court requiring the records to be produced.
- (8) For the purposes of this article, the “relevant court” means—
- (a) in a case where records are being sought in relation to a registrant who is domiciled in Scotland, the sheriff in whose sheriffdom that registrant is domiciled; and
  - (b) in any other case, the county court (the Central London County Court in the case of a registrant who is not domiciled in Great Britain).

### Interim orders

- 56.**—(1) Where the Fitness to Practise Committee is satisfied that it is necessary for the protection of members of the public or is otherwise in the public interest or is in the interests of the registrant for an entry in the Register relating to a registrant to be suspended or to be made subject to conditions, the Committee may make an order—
- (a) that the entry in question be suspended for such period not exceeding 18 months as may be specified in the order (an “interim suspension order”); or
  - (b) that the entry in question be conditional upon the registrant complying, during such period not exceeding 18 months as may be specified in the order, with such requirements specified in the order as the Committee thinks fit to impose (an “order for interim conditional entry”).
- (2) Subject to paragraph (7), where the Fitness to Practise Committee has made an order under paragraph (1), the Committee—
- (a) must review it within the period of 6 months beginning with the date on which the order was made, and must after that, for so long as the order continues in force, further review it—
    - (i) before the end of the period of 6 months beginning with the date of the decision of the immediately preceding review, or
    - (ii) if, after the end of the period of 3 months beginning with the date of the decision of the immediately preceding review, the person concerned requests an earlier review, as soon as practicable after that request; and
  - (b) may review it where new evidence relevant to the order has become available after it was made.

<sup>(47)</sup> 1998 c.29.

(3) Where an interim suspension order or an order for interim conditional entry has been made in relation to any person under any provision of this article (including this paragraph) the Fitness to Practise Committee may—

- (a) revoke the order;
- (b) add to, remove or otherwise vary any condition imposed by the order; or
- (c) if satisfied that to do so is necessary for the protection of members of the public or is otherwise in the public interest—
  - (i) replace an order for interim conditional entry with an interim suspension order having effect for the remainder of the term of the previous order, or
  - (ii) replace an interim suspension order with an order for interim conditional entry having effect for the remainder of the term of the previous order.

(4) If an order is made, revoked or varied under any provision of this article, the Registrar must without delay send to the person in respect of whose entry in the Register it relates at the last known home address of that person a statement in writing giving the person notice of the order, the revocation or, as the case may be, the variation.

(5) The Council may apply to the relevant court for an order made by the Fitness to Practise Committee under paragraph (1) or (3) to be extended or, if it has been extended, further extended, and on such application the relevant court may extend, or further extend, for up to 12 months the period for which the order has effect.

(6) Any reference in this article to an interim suspension order, or to an order for interim conditional entry, includes a reference to such an order as extended under paragraph (5).

(7) For the purposes of paragraph (2), the first review after the relevant court's extension of an order made by the Fitness to Practise Committee, or after a replacement order made by the Fitness to Practise Committee under paragraph (3)(c), must take place—

- (a) if the order (or the order which has been replaced) has not been reviewed at all under paragraph (2), within the period of 6 months beginning with the date on which the relevant court ordered the extension or on which the replacement order under paragraph (3)(c) was made; and
- (b) if the order (or the order which has been replaced) has been reviewed under paragraph (2), within the period of 3 months beginning with that date.

(8) A registrant who is aggrieved by the decision of the Fitness to Practise Committee to make or vary an order under this article may appeal against that decision to the relevant court, and the court may—

- (a) in the case of an interim suspension order, terminate the suspension;
- (b) in the case of an order for interim conditional entry, revoke the order or remove or vary any condition imposed by the order; and
- (c) in either case, substitute for the period specified in the order (or in the order extending it) some other period which could have been specified in the order when it was made (or in the order extending it),

but unless the court otherwise directs, the order remains in force pending the outcome of the appeal.

(9) The decision of the relevant court on any application under paragraph (8) is final.

(10) If an order is made in relation to any person under this article and that order remains in effect immediately before the determination in respect of the allegation against that person under article 54(1), the Fitness to Practise Committee must revoke the order once it has been determined whether or not the person's fitness to practise is impaired.

(11) In this article, "the relevant court" means—

- (a) in a case relating to a registrant who is domiciled in Scotland, the Court of Session; and
- (b) in any other case, the High Court.

**Restoration of names to the Register: fitness to practise**

57.—(1) Subject to paragraph (2)—

- (a) a person whose entry has been removed from one or more parts of the Register, in accordance with a direction under article 54(2)(c) or (3)(a)(i) or (b)(iv) may apply to the Registrar under this article for restoration to any part of the Register from which that person's entry has been removed; and
- (b) the Registrar must refer that application to the Fitness to Practise Committee.

(2) An application may not be made under paragraph (1)—

- (a) before the expiration of five years from the date of removal; or
- (b) within 12 months of the date of an earlier application under paragraph (1) relating to the same entry.

(3) The Council may make such provision in rules in connection with applications for restoration by virtue of paragraph (1) as it considers appropriate and may, in particular, make provision with regard to—

- (a) the form and manner in which applications for restoration are to be made (and the rules may provide that applicants must apply using application forms that are in such form as the Council may determine from time to time);
- (b) the information to be provided by the applicant, including—
  - (i) the name under which the applicant intends to practise, and
  - (ii) the applicant's home address;
- (c) whether any, and if so what, additional education, training or continuing professional development is required before restoration (and the rules may make provision for these issues to be determined in individual cases by the Registrar);
- (d) fitness to practise matters; and
- (e) refusal of applications (including where the applicant has not paid the fee prescribed under article 36(1)(b)).

(4) An application under this article may not be granted unless the person applying for restoration provides such evidence of fitness to practise as the Fitness to Practise Committee directs.

(5) Where the Fitness to Practise Committee refuses an application for restoration, the Registrar must send to the applicant at the applicant's last known home address a statement in writing giving the applicant notice of the decision and of the reasons for it.

(6) If the Fitness to Practise Committee grants the application, it may give a direction that the person's entry in the part or parts of the Register to which it has been restored be conditional upon that person complying, during such period not exceeding 3 years as may be specified in the direction, with such requirements specified in the direction as the Committee thinks fit to impose for the protection of the public or otherwise in the public interest or in the interests of the person concerned.

(7) Where the Fitness to Practise Committee gives a direction under paragraph (6), that direction must, for the purposes of article 54(3), be treated as a direction under article 54.

(8) If the application under this article relates to more than one part of the Register, the Fitness to Practise Committee—

- (a) must make separate determinations under this article in relation to each part of the Register; and

(b) may give a direction under paragraph (6) in relation to only one part of the Register or different directions in relation to different parts of the Register, but may otherwise deal with the matter as a single case.

(9) If—

- (a) the Fitness to Practise Committee refuses an application under this article (“the current application”);
- (b) it had refused a previous application under this article made by the same person, whether relating to the same part of the Register as the current application or to another part or parts of the Register; and
- (c) since the time when the previous application was refused, the person has not been entered in the part of the Register to which the current application and the previous application relate, or (if they relate to different parts) has not been entered in any of those parts of the Register,

the Fitness to Practise Committee may direct that the person may make no further application under this article in respect of the part or parts of the Register to which the current application and the previous application (or each of two or more previous applications falling within sub-paragraphs (b) and (c)) relate.

(10) If the Fitness to Practise Committee gives a direction under paragraph (6) or (9), the Registrar must on its behalf send to the applicant at the applicant’s last known home address a statement in writing giving the applicant notice of the decision and the reasons for it and, in the case of a direction under paragraph (9), of the right of appeal under article 58.

### **Appeals against appealable fitness to practise decisions**

**58.**—(1) The following decisions are appealable fitness to practise decisions for the purposes of this Part—

- (a) a decision of the Fitness to Practise Committee under article 54 to give a direction to remove the entry of a person from one or more parts of the Register;
- (b) a decision of the Fitness to Practise Committee under article 54 to give a direction for suspension or for conditional entry (including a direction extending a period of earlier suspension or of conditional entry or making a period of suspension indefinite);
- (c) a decision of the Fitness to Practise Committee under article 54 to give a direction to vary the conditions imposed by a direction for conditional entry; and
- (d) a decision of the Fitness to Practise Committee to give a direction under article 57(9) that a person may make no further applications under that article in respect of one or more parts of the Register.

(2) A person in respect of whom an appealable fitness to practise decision has been made may appeal against that decision to the relevant court.

(3) Notice of any appeal under this article must be filed at, or in Scotland lodged in, the relevant court and served on the Council, in accordance with rules of court, within 28 days beginning with the date on which the written notice of the reasons for the decision was sent, or within such longer period as the relevant court may, in accordance with rules of court, allow.

(4) In this article, “the relevant court” means—

- (a) in a case where the person making the appeal is domiciled in Scotland, the Court of Session; and
- (b) in any other case, the High Court.

(5) Having considered the appeal, the relevant court may—

- (a) dismiss the appeal;
  - (b) allow the appeal and quash the direction in respect of which the appeal is made;
  - (c) substitute for the direction in respect of which the appeal is made any other direction that the Fitness to Practise Committee could have given; or
  - (d) remit or refer the case to the Registrar or the Fitness to Practise Committee for disposal of the matter in accordance with the relevant court's directions,
- and may make such order as to costs or, in Scotland, expenses as the relevant court thinks fit.

### **The taking effect of directions in respect of appealable fitness to practise decisions**

**59.**—(1) Where an appealable fitness to practise decision is taken in respect of a direction, that direction does not take effect—

- (a) until the period for bringing an appeal in respect of the direction has expired; or
- (b) where an appeal is brought within the period for bringing an appeal, until the date on which the appeal is finally disposed of, is abandoned or fails by reason of its non-prosecution.

(2) Where, by virtue of paragraph (3) of article 58, the time for bringing an appeal in respect of the direction has been extended by the relevant court in accordance with rules of court—

- (a) paragraph (1) applies to the direction as if the references to the period for bringing an appeal were references to that period as so extended; and
- (b) if the relevant court allows an appeal to be brought after the expiration of the period for bringing an appeal specified in paragraph (3) of article 58, the direction is deemed not to have taken effect on the expiration of that period.

(3) Where, within the period for bringing an appeal (which includes that period as extended by virtue of article 58(3)), an appeal is brought against an appealable fitness to practise decision in respect of a direction (“the later direction”) that extends, varies or replaces an earlier direction, the earlier direction continues to have effect until the date on which the appeal is finally disposed of, is abandoned or fails by reason of its non-prosecution.

(4) Where, as a result of an extension of an earlier direction pursuant to paragraph (3), a later direction takes effect on a date after it was due to take effect, the period for which the later direction was originally expressed to have effect (howsoever expressed) is treated as commencing—

- (a) on the date on which it was originally due to take effect; or
- (b) if this would mean that the later direction would in practice expire before it commences, on the date on which the appeal is finally disposed of, is abandoned or fails by reason of its non-prosecution.

(5) For the purposes of paragraphs (3) and (4), an appeal is finally disposed of once all rights in relation to the appeal have been exhausted.

### **Interim measures pending a direction taking effect**

**60.**—(1) Paragraph (2) applies where, under article 54, the Fitness to Practise Committee gives—

- (a) a direction to remove a registrant's entry from one or more parts of the Register; or
- (b) a direction for suspension.

(2) If the Fitness to Practise Committee is satisfied that to do so is necessary for the protection of members of the public or is otherwise in the public interest or in the interests of the registrant, it may order that the entry of the registrant who is the subject of the direction in the part or parts of the Register to which the direction relates be suspended forthwith, pending the coming into force of the direction.

(3) Paragraph (4) applies where the Fitness to Practise Committee gives a direction for conditional entry under article 54.

(4) If the Fitness to Practise Committee is satisfied that to do so is necessary for the protection of members of the public or is otherwise in the public interest or in the interests of the registrant, it may order that the entry of the registrant who is the subject of the direction in the part or parts of the Register to which the direction relates, be conditional upon that registrant complying, pending the coming into force of the direction, with such requirements specified in the order as the Committee thinks fit to impose.

(5) If the direction referred to in paragraph (1) or (3) relates to the entry of the registrant in more than one part of the Register, the Fitness to Practise Committee may make an order under paragraph (2) or, as the case may be, (4) in relation to only one part of the Register and may impose different requirements under paragraph (4) in relation to the registrant's entry in different parts of the Register.

(6) Where the Fitness to Practise Committee makes an order under paragraph (2) or (4), the Registrar must send to the registrant who is the subject of the order at that registrant's last known home address a statement in writing giving that registrant notice of the contents of the order and of the right of appeal under paragraph (7).

(7) A registrant who is aggrieved by a decision of the Fitness to Practise Committee to make an order under this article may appeal against that decision to the relevant court, and the court may—

- (a) dismiss the appeal;
- (b) in the case of an order under paragraph (2), terminate the suspension; and
- (c) in the case of an order under paragraph (4), revoke the order or remove or vary any condition imposed by the order,

and the decision of the relevant court on any application under this paragraph is final.

(8) In this article, "the relevant court" means—

- (a) in a case where the person making the appeal is domiciled in Scotland, the Court of Session; and
- (b) in any other case, the High Court.

## PART 7

### Proceedings

#### Rules in respect of proceedings

**61.**—(1) Subject to the following provisions of this Part, the Council must make such provision as it considers appropriate in rules in connection with the procedure to be followed and rules of evidence to be observed by—

- (a) the Investigating Committee;
- (b) the Fitness to Practise Committee (whether exercising functions under this Order or the Medicines Act 1968<sup>(48)</sup>); and
- (c) the Appeals Committee.

(2) The rules under paragraph (1) in respect of the Fitness to Practise Committee or the Appeals Committee must, and in respect of the Investigating Committee may, include provision—

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(48) 1968 c.67.

- (a) for securing that, where a hearing is to be held, notice of when and where the hearing is to be held is given, at such time and in such manner as may be specified in the rules, to any person to whom the proceedings relate;
  - (b) for securing that the person concerned (which for the purposes of this article, where appropriate, includes an individual who, or body corporate which, is subject to disqualification proceedings under Part 4 of the Medicines Act 1968) and the Council are, if they so require, entitled to be heard by the committee—
    - (i) at any hearing, or
    - (ii) in fitness to practise proceedings or on any other occasion when the committee is considering making an interim suspension order or an order for interim conditional entry;
  - (c) for allowing the person concerned and the Council to be represented at any hearing, or in fitness to practise proceedings or on any other occasion when the committee is considering making an interim suspension order or an order for interim conditional entry, by—
    - (i) a person with a general qualification (within the meaning of section 71 of the Courts and Legal Services Act 1990<sup>(49)</sup> (offences)),
    - (ii) an advocate in Scotland, or a solicitor with rights of audience to appear in the Court of Session or in the High Court of Justiciary by virtue of section 25A of the Solicitors (Scotland) Act 1980<sup>(50)</sup> (rights of audience in the Court of Session etc.), or
    - (iii) a person of such other description as may be specified in rules, if the rules so allow and the person concerned or the Council so elects;
  - (d) for proceedings before the committee to be held in public, except and to the extent that rules provide otherwise; and
  - (e) in respect of reviewing directions under article 54—
    - (i) which are due to expire,
    - (ii) in circumstances where the committee is considering varying the requirements specified in the direction, or
    - (iii) in the case of a direction for suspension or for conditional entry—
      - (aa) at the request of the Registrar or the person concerned, or
      - (bb) upon new evidence becoming available.
- (3) The rules under paragraph (1) may include provision—
- (a) in respect of preliminary consideration of a case before a committee (including considering representations from the person concerned and the Council during its preliminary consideration);
  - (b) following preliminary consideration of a case—
    - (i) in the case of an appeal before the Appeals Committee, allowing the Appeals Committee, in prescribed circumstances, to allow the appeal or take a decision which has the effect of allowing the appeal,
    - (ii) in fitness to practise proceedings, allowing the Fitness to Practise Committee, in prescribed circumstances, to make a finding that the fitness to practise of the person concerned is not impaired, and

<sup>(49)</sup> 1990 c.41.<sup>(50)</sup> 1980 c.46. Section 25A was inserted by section 24 of the Law Reform (Miscellaneous Provisions) (Scotland) Act 1990 (c.40) and amended by paragraph 31 of Schedule 4 to the Criminal Procedure and Consequential Provisions (Scotland) Act 1995 (c.40), by S.S.I.1999/1042 and by S.S.I.2001/121.

- (iii) in a disqualification case, allowing the Fitness to Practise Committee, in prescribed circumstances, to dismiss the case;
- (c) in respect of consensual disposal of a fitness to practise case following preliminary consideration of it, including provision—
  - (i) enabling the Investigating Committee or the Fitness to Practise Committee, in prescribed circumstances, to agree with the person concerned that the person concerned will comply with such undertakings as the committee considers appropriate, and
  - (ii) with respect to the procedure to be followed when any such undertakings are breached (the rules may provide that the breach may be treated as misconduct for the purposes of article 51(1)(a) and for the matter to be dealt with as a misconduct allegation that is before the committee);
- (d) in respect of consensual disposal of a disqualification case following preliminary consideration of it, including provision—
  - (i) enabling the Fitness to Practise Committee, in prescribed circumstances, to agree with the individual or body corporate that the individual or body corporate will comply with such undertakings as the Committee considers appropriate, and
  - (ii) with respect to the procedure to be followed where any such undertakings are breached;
- (e) in respect of case management meetings (and the rules may provide that the preliminary consideration of a case is to take place at a case management meeting) and directions, including provision with respect to the procedure to be followed where case management directions are breached;
- (f) in respect of cancelling, postponing or adjourning hearings and staying proceedings in appropriate circumstances;
- (g) enabling the Appeals Committee to refer a case before it to the Investigating Committee or the Fitness to Practise Committee for advice;
- (h) enabling the Fitness to Practise Committee to draw such inference as seems appropriate to it in the particular circumstances of the case if the person concerned fails—
  - (i) during fitness to practise proceedings, to submit to any examination or assessment required or directed to be carried out in accordance with the rules made under this article or article 55, or
  - (ii) to co-operate with the Committee;
- (i) enabling the committee during the course of proceedings, to make such inquiries as it considers appropriate;
- (j) enabling the Fitness to Practise Committee, following consideration of a disqualification case, instead of issuing a direction under section 80 of the Medicines Act 1968<sup>(51)</sup> (disqualification and removal from the Register)—
  - (i) to agree with the individual or body corporate that the individual or body corporate will comply with such undertakings as the Committee considers appropriate (and the rules may include provision with respect to the procedure to be followed where any such undertakings are breached), and
  - (ii) to dispose of the matter by giving advice or a warning; and

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(51) 1968 c.67.

- (k) for the award of, and in respect of the assessment of, costs or expenses, and may require the committee to have regard to a person's ability to pay when considering the making of an award against the person under the rules.
- (4) An award of costs may, by leave of the High Court, be enforced in the same manner as an order of the High Court to the same effect.
- (5) An award of expenses may, by leave of the Court of Session, be enforced in the same manner as a decree of the Court of Session to the same effect.
- (6) The rules under paragraph (1) may make provision—
  - (a) as to the form which is to be used for any document (and may provide that documents specified in the rules are to be in such form as the Council may determine from time to time); and
  - (b) for documents or certificates to be sent or received as an electronic communication.

### **Procedure for the Fitness to Practise Committee and the Appeals Committee**

- 62.**—(1) For the purposes of proceedings under this Order in England and Wales—
- (a) the Fitness to Practise Committee or the Appeals Committee may administer oaths; and
  - (b) the Fitness to Practise Committee, the Appeals Committee or any party to proceedings before either of those committees may apply for the issue of a witness summons directing a person to attend the proceedings in order to give evidence or to produce a document.
- (2) No person may be compelled under any such summons to give any evidence or to produce any document which that person could not be compelled to give or produce on the trial of an action.
- (3) Section 36 of the Senior Courts Act 1981<sup>(52)</sup> (subpoena issued by High Court to run throughout the United Kingdom), which provides a special procedure for the issue of such a summons so as to be in force throughout the United Kingdom, applies in relation to any proceedings under this Order in England and Wales as it applies in relation to causes and matters in the High Court.
- (4) For the purposes of any such proceedings in Scotland, the Fitness to Practise Committee or the Appeals Committee may administer oaths and the Court of Session has, on the application of any party to the proceedings, the like power as in any action in that court—
- (a) to grant warrant for the citation of witnesses and havers to give evidence or to produce documents before the committee, and for the issue of letters of second diligence against any witness or havers failing to appear after due citation;
  - (b) to grant warrant for the recovery of documents; and
  - (c) to grant commissions to persons to take the evidence of witnesses or to examine havers and receive their exhibits and productions.
- (5) Where—
- (a) several sittings of the Fitness to Practise Committee or the Appeals Committee are required to enable the committee to dispose of the case; or
  - (b) on an appeal to the relevant court under article 58, the case is remitted to the Fitness to Practise Committee to dispose of the case in accordance with directions given by the court,
- the validity of the proceedings on the case before the committee may not be called into question by reason only that members of the committee who were present at a former meeting were not present at a later meeting of the committee or that members present at a later meeting were not present at a former meeting of the committee.

(52) 1981 c.54 as amended by section 59(5) of and Schedule 11 to the Constitutional Reform Act 2005 (c.4). Section 36 has been amended by the Courts and Legal Services Act 1990 (c.41), Schedule 17, paragraph 13.

### **Legal advisers**

**63.**—(1) The Council may do either or both of the following—

- (a) appoint suitably qualified and experienced barristers, solicitors or advocates to be legal advisers;
- (b) make rules which provide for it to enter into arrangements with another person for that person to appoint on behalf of the Council suitably qualified and experienced barristers, solicitors or advocates to be legal advisers.

(2) Legal advisers appointed under this article may not be a member of the Council or of a statutory committee.

(3) Legal advisers appointed under this article may be appointed either generally or for any proceedings or particular class of proceedings and are to hold and vacate office in accordance with the terms of the instrument under which they are appointed.

(4) The Council may make rules as to the functions of legal advisers appointed under this article.

### **Clinical and other specialist advisers**

**64.**—(1) The Council may do either or both of the following in connection with proceedings under this Order—

- (a) appoint registered medical practitioners to be clinical advisers;
- (b) make rules which provide for it to enter into arrangements with another person for that person to appoint on behalf of the Council registered medical practitioners to be clinical advisers.

(2) The Council may do either or both of the following in connection with proceedings under this Order—

- (a) appoint persons to act as specialist advisers on issues on which, in the Council's opinion, specialist knowledge is required;
- (b) make rules which provide for it to enter into arrangements with another person for that person to appoint on behalf of the Council persons to be specialist advisers.

(3) Persons appointed to be—

- (a) clinical advisers must have specialist expertise in a particular field or fields; and
- (b) specialist advisers must have particular expertise in the speciality for which they are appointed.

(4) If clinical advisers are appointed under paragraph (1), their appointment is for the purpose of giving advice to—

- (a) the Investigating Committee or the Fitness to Practise Committee on health related issues under consideration by the committee in the proceedings before it; and
- (b) the Council or any of its other committees on health related issues.

(5) If specialist advisers are appointed under paragraph (2), their appointment is for the purpose of giving advice to—

- (a) one or more of the statutory committees on issues falling within their speciality which are under consideration by the committee in the course of proceedings before it; and
- (b) the Council or any of its other committees on issues falling within their speciality or related to it.

(6) Advisers appointed under this article may not be a member of the Council or of a statutory committee.

- (7) Advisers appointed under this article—
- (a) may be appointed generally; or
  - (b) may be appointed for the purpose of any proceedings or particular class of proceedings,
- and are to hold and vacate office in accordance with the terms of the instrument under which they are appointed.
- (8) The Council may make rules as to the functions of advisers appointed under this article.

## PART 8

### Miscellaneous

#### General fees

**65.**—(1) Subject to paragraph (2), the Council may charge such fees as it may reasonably determine in connection with the exercise of its functions, or the functions of its statutory committees.

(2) No fee may be charged, pursuant to paragraph (1), in connection with the exercise of a function where provision is made elsewhere in this Order for the charging of a fee in connection with the exercise of that function.

#### Rules

**66.**—(1) Any power to make rules under this Order may be exercised—

- (a) so as to make different provision—
  - (i) with respect to different cases or different classes of cases, or
  - (ii) in respect of the same case or class of case for different purposes;
- (b) in relation to all cases to which the power extends or in relation to those cases subject to specified exceptions; or
- (c) so as to make any supplementary, incidental, consequential, transitional, transitory or saving provision as the Council considers necessary or expedient.

(2) The Council must ensure that its rule making powers under this Order are exercised in such a way so as to ensure that its rules are and remain consistent with the requirements of the EU Treaties and the Directive.

(3) Before making rules under Parts 3 to 7 of this Order, the Council must consult such persons or organisations as it considers appropriate including—

- (a) Primary Care Trusts in England;
- (b) Local Health Boards in Wales;
- (c) Health Boards in Scotland;
- (d) persons carrying on a retail pharmacy business at a registered pharmacy;
- (e) professional bodies or organisations appearing to the Council to represent registrants;
- (f) the Council for Healthcare Regulatory Excellence;
- (g) such other regulatory bodies as the Council considers relevant; and
- (h) other persons, bodies or organisations representing members of the public and patients.

(4) No rules made under this Order, except rules made solely under article 36 (or article 36 together with paragraph (1)), can come into force until approved by order of the Privy Council.

(5) The Privy Council may approve rules submitted to them for approval either in the form submitted to them or subject to such modifications as appear necessary to them.

#### **The Directive: designation of competent authority etc.**

**67.**—(1) The Council is designated as the competent authority in Great Britain for the purposes of the Directive so far as it relates to the professions of pharmacist and pharmacy technician.

(2) Accordingly, the Council must in Great Britain carry out (in particular) the functions specified in Schedule 3.

(3) The Council is designated as the competent authority in Great Britain for the award of evidence of formal qualifications in pharmacy listed in relation to the United Kingdom in Annex V, point 5.6.2 of the Directive.

(4) Subject to paragraph (5), the Secretary of State may give directions to the Council in connection with its functions specified in Schedule 3, and it is the duty of the Council to comply with any such directions.

(5) Directions given under paragraph (4) may be as to matters of administration only.

(6) In Schedule 3—

“non-UK pharmacy qualification” means a qualification in pharmacy that is awarded to a person by a competent authority of a relevant European State other than the United Kingdom; and

“GB pharmacy qualification” means a qualification in pharmacy that is awarded to a person by a competent authority in Great Britain.

#### **Amendments, repeals and revocations**

**68.** The amendments, repeals and revocations contained in Schedule 4 have effect.

#### **Transitional, transitory and saving provisions**

**69.**—(1) The transitional provisions contained in Schedule 5 have effect.

(2) The savings contained in Schedule 6 have effect.

(3) In connection with the commencement of any provision of this Order, the Privy Council may by order make such transitional, transitory or saving provisions as it considers appropriate.

(4) The power to make an order under paragraph (3) may be exercised—

(a) so as to make different provision—

(i) with respect to different cases or different classes of cases, or

(ii) in respect of the same case or class of case for different purposes;

(b) in relation to all cases to which the power extends or in relation to all those cases subject to specified exceptions; or

(c) so as to make any supplementary, incidental or consequential provisions which the Privy Council considers necessary or expedient.

#### **Privy Council procedures etc.**

**70.**—(1) Any power vested in the Privy Council to make an order under this Order may be exercised by any two or more members of the Privy Council.

(2) Any power of the Privy Council to make an order under this Order is exercisable by statutory instrument and, except for an order made solely in respect of approving rules under article 19, 27,

31 or 36 (or any of those articles together with article 66(1)), an order of the Privy Council under this Order is subject to annulment in pursuance of a resolution of either House of Parliament or of the Scottish Parliament.

(3) Paragraph (2) and article 66(4) do not preclude the inclusion of rules under article 19, 27, 31 or 36 in a set of rules which is to be approved by an order of the Privy Council that is subject to annulment in pursuance of a resolution of either House of Parliament or of the Scottish Parliament.

(4) For the purposes of section 1 of the Statutory Instruments Act 1946<sup>(53)</sup> (definition of “Statutory Instrument”), any power of the Privy Council to make an order under this Order is to be taken to be conferred by an Act of Parliament.

(5) Any act of the Privy Council under this Order is sufficiently signified by an instrument signed by the Clerk of the Privy Council.

(6) Where an order or act of the Privy Council under this Order is signified by an instrument purporting to be signed by the Clerk of the Privy Council, that is evidence, and in Scotland, sufficient evidence, of—

- (a) the fact that the order was duly made, or the act duly done; and
- (b) the order’s terms.

*Judith Simpson*  
Clerk of the Privy Council

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<sup>(53)</sup> 1946 c.36. Section 1(1A) was inserted by paragraph 2 of Schedule 12 to the Government of Wales Act 1998 (c.38) and substituted by paragraph 2 of Schedule 10 to the Government of Wales Act 2006 (c.32).