DRAFT STATUTORY INSTRUMENTS

2010 No.

The Pharmacy Order 2010

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.
- (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.)(1), 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;

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

- (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
 - (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(2) 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
- (1) a note to distinguish annotations made under section 74K of the Medicines Act 1968(3) (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—
 - (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

⁽²⁾ Section 74J is inserted into the Act by paragraph 1(8) of Schedule 4 to this Order.

⁽³⁾ Section 74K is inserted into the Act by paragraph 1(8) of Schedule 4 to this Order.

- (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 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) Thas, 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 practise 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 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 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

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(4) (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(5) (supplementary provision in respect of registration of premises: Great Britain), and
 - (iv) section 74I(1) of the Medicines Act 1968(6) (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.
- (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);

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

⁽⁵⁾ Section 74C is inserted into the Act by paragraph 1(8) of Schedule 4 to this Order.

⁽⁶⁾ Section 74I is inserted into the Act by paragraph 1(8) of Schedule 4 to this Order.

- (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(7) (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—
 - (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)(ii)(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(7)(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(8) (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(9) (change of ownership of retail pharmacy business: Great Britain) not to restore an entry of premises to Part 3 of the Register;

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

⁽⁹⁾ Section 74H is inserted into the Act by paragraph 1(8) of Schedule 4 to this Order.

- (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 probational or remedial measures have been imposed or from 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 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 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 which approval has been withdrawn, 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.