

STATUTORY INSTRUMENTS.

S.I. No. [ • ] of 2015

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PHARMACEUTICAL SOCIETY OF IRELAND (CONTINUING PROFESSIONAL  
DEVELOPMENT) RULES 2015

(Prn. [ • ])

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PHARMACEUTICAL SOCIETY OF IRELAND (CONTINUING PROFESSIONAL DEVELOPMENT) RULES 2015

The Council of the Pharmaceutical Society of Ireland, in exercise of the functions conferred on the said Society by section 11 of the Pharmacy Act 2007 (No. 20 of 2007) and for the purpose of discharging its functions under section 7(1)(d) of the Act, hereby makes the following rules:-

**PART 1**

**GENERAL PROVISIONS**

*Citation*

1. These Rules may be cited as the Pharmaceutical Society of Ireland (Continuing Professional Development) Rules 2015.

*Commencement*

2. (1) Subject to paragraph (2), these Rules shall come into operation on 1 January 2016.

(2) Rule 14, paragraphs (b), (c) and (d) of Rules 15 and 16, and paragraphs (a), (b) and (c) of Rule 18, shall come into operation on 1 January 2017.

*Interpretation*

3. In these Rules –

“Act” means the Pharmacy Act 2007 (No. 20 of 2007) as amended by the European Communities (Recognition of Professional Qualifications relating to the Profession of Pharmacist) (No. 2) Regulations 2008 (S.I. No. 489 of 2008), the Civil Partnership and Certain Rights and Obligations of Cohabitants Act 2010 (No. 24 of 2010), the European Communities (Recognition of Professional Qualifications relating to the Profession of Pharmacist) Regulations 2012 (S.I. No. 235 of 2012), the European Communities (Recognition of Professional Qualifications relating to the Profession of Pharmacist) Regulations 2013 (S.I. No. 377 of 2013), the Health (Pricing and Supply of Medical Goods) Act 2013 (No. 14 of 2013) and the European Union (Amendment of the Pharmacy Act 2007) Regulations 2015 (S.I. No. 86 of 2015);

“Codes of conduct for pharmacists” means the codes, drawn up by the Council in the discharge of its duty under section 7(2)(a)(iii) of the Act, and given effect to and maintained in compliance with section 12 of the Act;

“CPD” means the continuing professional development for pharmacists referred to in section 7(1)(d) of the Act;

“Core Competency Framework for Pharmacists” has the same meaning as assigned to it in Rule 4 of the Pharmaceutical Society of Ireland (Education and Training) (Integrated Course)

Rules 2014 (S.I. No 377 of 2014) and refers to such document which is for the time being in force;

“CPD system” means the CPD system developed and approved by the Council from time to time in the discharge of its functions under section 7(1)(d) of the Act;

“criteria” means the Accreditation Standards for CPD Programmes and Courses for Pharmacists published by the Council in accordance with Rule 5, and which are for the time being in force;

“ePortfolio” means the electronic CPD Portfolio established and maintained by the Institute of Pharmacy in the manner and form as may be approved by the Council from time to time and made available to each pharmacist by the Institute at the time the pharmacist first logs on to the website of the Institute, including any subsequent versions thereof.

“Executive Director” means the person appointed under Rule 4 by the Managing Body in respect of the activities of the Institute;

“Institute of Pharmacy” or “Institute” means the management arrangements put in place from time to time by the Council, to be known as the Irish Institute of Pharmacy, to arrange for the implementation and delivery of the CPD system and engagement by pharmacists with such system;

“Managing Body” means the body corporate appointed by the Council from time to time to provide the services of the Institute of Pharmacy as determined by the Council;

“Register of Pharmacists” and “Register of Retail Pharmacy Businesses” mean the relevant registers established under section 13(1) of the Act;

“registered pharmacist”, “supervising pharmacist” and “superintendent pharmacist” have the same meaning as in the Pharmaceutical Society of Ireland (Registration) Rules 2008 (S.I. No. 498 of 2008);

“Registrar” means the Registrar of the Pharmaceutical Society of Ireland, appointed pursuant to paragraph 13(1) of Schedule 1 to the Act;

“relevant state” has the meaning assigned to it in section 16(8) of the Act as amended by the European Communities (Recognition of Professional Qualifications relating to the Profession of Pharmacist) (No. 2) Regulations 2008 (S.I. No. 489 of 2008).

## **PART 2**

### **ESTABLISHMENT OF THE INSTITUTE OF PHARMACY AND APPOINTMENT OF EXECUTIVE DIRECTOR**

4. (1) For the purpose of discharging its functions under section 7(1)(d) of the Act, the Council shall establish and maintain an Institute of Pharmacy which shall be hosted by a Managing Body which shall appoint, in consultation with the Society, the Executive Director.

(2) Subject to the policy direction of the Council, the Institute of Pharmacy, acting through the Executive Director, shall be responsible for the management and administration of the CPD functions set out in section 7(1)(d) of the Act and for the discharge of the duty of the Society referred to in section 7(2)(a)(iv) insofar as such duty relates to compliance by pharmacists with CPD as required by the code of conduct for pharmacists.

(3) The Executive Director shall be responsible for the day-to-day implementation and delivery by the Institute of the CPD system in accordance with the annual service plans approved by the Council.

### PART 3

#### RECOGNITION AND APPROVAL OF CPD PROGRAMMES AND COURSES FOR PHARMACISTS

*Criteria for recognition and approval of CPD programmes and courses for pharmacists*

5. (1) For the purpose of discharging its duty under section 7(2)(a)(iv) of the Act as it relates to registered pharmacists, the Council, in accordance with the procedures set out in this Rule, shall determine, approve and publish criteria for the recognition and approval of CPD programmes and courses of education and training, with a view to enabling pharmacists to better fulfil their obligations under their codes of conduct.

(2) The criteria referred to in paragraph (1) shall, in particular, make provision for any or all of the following –

- (a) set out minimum requirements appropriate to the development and delivery of the CPD programme or course including commitment, staffing, premises, facilities, infrastructure, policies, procedures, funding and organisational structures,
- (b) conform with such general and specific standards as may, from time to time, be established by the Council to facilitate the safe delivery by pharmacists of new services, including services where the acquisition of specialisation is necessary,
- (c) have regard to the competencies set out in the Core Competency Framework for Pharmacists,
- (d) have regard to the legislation and the law pertaining to pharmacy and medicinal products, the practice of pharmacy in the State, the obligations deriving from professional registration, professional codes of conduct and the ethical principles expected of a person practising as a pharmacist in the State,
- (e) require the subject matter to be current and of significant intellectual and practical content and deal primarily with matters relevant to the practice of pharmacy, including the improvement of the profession of pharmacy,
- (f) require that the CPD programmes and courses be developed and conducted by persons or bodies that have suitable qualifications and experience,
- (g) where appropriate, facilitate the participation by and cooperation with other health and social care professionals in CPD programmes and courses, and

- (h) require the CPD programmes and courses to be relevant to the pharmacist's immediate or long-term needs in relation to his or her professional development.

(3) The Council shall review the criteria referred to in paragraph (1) at intervals not exceeding five years having regard to national and international advancements in the theory and practice of pharmacy and healthcare, including advancements in relevant scientific and technical progress, and national policy in the areas of healthcare practice, pharmacy and professional development and learning.

(4) Where the Council proposes to amend the criteria referred to in paragraph (1), it shall publish its proposals on the Society's website with an invitation to the public to comment on the draft by such date as is specified in the invitation.

(5) The Council shall publish on the Society's website the criteria adopted in accordance with this Rule, or as may subsequently be amended under this Rule.

*Application for recognition and approval of CPD programmes and courses for pharmacists*

6. (1) Subject to the provisions of this Rule, and the policy of the Council in respect of the identification, selection and delivery of CPD programmes and courses for pharmacists that may be laid down from time to time by the Council, a person who proposes to offer such programme or course, shall –

- (a) make application in writing to the Executive Director for recognition and approval of a CPD programme or course by the Registrar in the manner and form as may, from time to time, be prescribed by the Institute,
- (b) satisfy the Institute that the proposed CPD programme or course will conform with the criteria published under Rule 5,
- (c) satisfy the Institute that the proposed CPD programme or course meets an identified and essential need and in conformity with any priorities for such programmes or courses that may from time to time be laid down by the Council, and
- (d) have paid to the Council any fee which may be payable in connection with that application.

(2) The Institute shall consider an application received under paragraph (1) and shall, within a period of 120 days from the date the complete application is received, make a recommendation to the Registrar to grant or refuse the application.

(3) Following receipt of an application under paragraph (1), the Institute shall confirm the completeness of the information provided in the application and, in consultation with such experts as may be required, conduct an evaluation of the application and, where further information or clarifications are necessary, the Institute may give notice in writing to the applicant requesting that it provide the further information or clarifications as sought in support of its application.

(4) Subject to Rule 7, in making its recommendation to the Registrar under paragraph (2), the Executive Director, on behalf of the Institute, shall submit an evaluation report, in support of the recommendation made, and which may include conditions subject to which the recognition and approval may be granted.

(5) On receipt of the evaluation report and recommendation referred to in paragraph (4) and on consideration thereof, the Registrar shall, within 150 days of receipt of the application by the Institute, grant or refuse to grant his or her recognition and approval for the said CPD programme or course. The duration of any such recognition and approval shall not exceed a period of three years.

(6) Where the Institute gives a notice pursuant to paragraph (3), the periods referred to in paragraphs (2) and (5) shall be suspended from the date the notice is given and shall recommence only on receipt of the information requested.

(7) The expiry of the period referred to in paragraph (5) shall not be taken to mean that an implicit recognition or approval for the said CPD programme or course has been granted by the Registrar.

(8) In the grant of his or her recognition and approval of a CPD programme or course, the Registrar may attach such conditions as may be set out in the evaluation report referred to in paragraph (4) as may be relevant and necessary.

(9) Where the Council has under Rule 5(5) published amended criteria, a body whose CPD programme or course for pharmacists has been recognised and approved by the Registrar under this Rule, shall forthwith, in consultation with the Institute, make arrangements for compliance with the amended criteria and shall promptly inform the Executive Director accordingly.

(10) In paragraph (4), “evaluation report” means a report of an evaluation of the application referred to in paragraph 1(a) which describes the manner in which the application meets or does not meet the criteria and which includes a recommendation, in respect of the duration of recognition and approval of the CPD programme or course, which shall not exceed a period of three years, or in respect of its rejection.

*Appeal by applicant to the Managing Body*

7. (1) The Executive Director, on behalf of the Institute, in compiling the evaluation report referred to in Rule 6, shall forward a copy of the draft report to the applicant to check its factual accuracy, together with a statement of any proposed conditions that may be under consideration with a view to their being attached to the proposed approval.

(2) The applicant may, within 5 working days of receipt of the draft evaluation report and proposals under paragraph (1), submit comments on the draft report and proposals and where such report and proposals are not in compliance with the application, the applicant may submit an appeal to the Managing Body in which circumstances the periods referred to in Rule 6(2) and (5) shall be suspended from the date the appeal is received by the Managing Body and shall recommence only on completion of the appeal process.

*Obligation on CPD programme or course provider to provide regular reports to the Institute*

8. (1) A provider, whose CPD programme or course has been granted recognition and approval by the Registrar, shall, in the manner and form established by the Institute, submit to the Institute a report on the delivery of the CPD programme or course as specified in the grant of approval by the Registrar.

(2) No material change to a CPD programme or course that has been recognised and approved by the Registrar shall be made without the prior approval of the Institute, following consultation with the Registrar.

#### **PART 4**

#### **CPD OBLIGATIONS OF PHARMACISTS**

9. (1) With a view to keeping abreast of relevant advances in scientific and technical progress and relevant legislative changes, and for the purpose of maintaining a level of competence in his or her ongoing practice as a pharmacist, and with a view to protecting, maintaining and promoting the health and safety of the public, every pharmacist shall undertake appropriate continuing professional development (CPD).

(2) The CPD undertaken shall be systematic, self-directed and needs-based and be outcomes-focussed, based on a process of continual learning and development with application in his or her professional practice as a pharmacist.

(3) For the purpose of this Rule, every pharmacist shall on a regular basis carry out a self-assessment of his or her learning needs, having regard to the Core Competency Framework for Pharmacists, with a view to identifying learning activities appropriate to the needs of his or her professional practice the outcome of which shall form the basis of his or her learning profile. Such learning profile shall also include learning identified and experienced in the course of his or her professional practice and any other learning that may be identified with a view to enhancing his or her professional practice.

(4) Every pharmacist shall, in undertaking his or her CPD activities, engage in such activities as may have been identified in his or her learning profile, and reflect on the impact of those activities having regard to the objectives of undertaking appropriate CPD as set out in paragraph (1).

#### **PART 5**

#### **ENGAGEMENT WITH THE INSTITUTE**

10. (1) Subject to paragraph (2), every person whose name is entered in the Register of Pharmacists shall also be registered with the Institute of Pharmacy and such registration with the said Institute shall be valid for so long as the person's name is entered in the Register of Pharmacists.

(2) The Council shall, on a person's first registration as a pharmacist, or, as the case may require, on the first continued registration as a pharmacist following the commencement of these Rules, including on the re-registration or restoration of a person to the Register of Pharmacists, inform the pharmacist of his or her registration with the Institute of Pharmacy,

subsequent to which the responsibility for ongoing engagement with the Institute of Pharmacy shall remain with the pharmacist.

11. Every pharmacist, in undertaking his or her CPD activities, shall use, as an aid, the ePortfolio made available by the Institute of Pharmacy for that purpose, the contents of which as generated by the pharmacist shall be the sole property of the pharmacist concerned and, accordingly, subject to his or her absolute control.

12. There shall be paid to the Council any annual fee that may be established by the Council, in respect of registration with the Institute of Pharmacy in conformity with Rule 10(1), the purpose of which is to contribute to the cost of making CPD programmes and courses available to pharmacists on behalf of the Institute.

*Reporting on and supervision of CPD activity*

13. (1) Subject to the provisions of this Rule, a pharmacist shall submit a report on his or her CPD activities, at the request of the Executive Director, to the Institute and shall cooperate with the Executive Director in the review and evaluation of that report and any feedback that may be provided by the Executive Director, within any timescale that may be laid down by the Executive Director.

(2) The report referred to in paragraph (1), which shall include a record extracted from a recent self-assessment of the nature referred to in Rule 9(3), shall be prepared in accordance with guidelines laid down by the Institute with the approval of the Council and may include such extracts from the ePortfolio as the pharmacist may consider relevant.

(3) The annual selection of pharmacists for the purpose of report submission and review referred to in paragraph (1) shall approximate to one-fifth of those pharmacists on the Register of Pharmacists with a view to ensuring that each pharmacist will be subject to a request to submit a report on his or her CPD activities referred to in paragraph (1), once in every five years. In making the annual selection, persons whose primary qualifications as a pharmacist have been obtained in the State, or in another relevant state, within the previous three years from the date of making the selection, shall be excluded from the list of registered pharmacists to be considered for the purpose of that annual selection.

(4) The request referred to in paragraph (1) shall be made not later than the 30th of September in each year and shall give not less than three months' notice of the date by which the report on CPD activities shall be received by the Institute.

(5) The review and evaluation of the report referred to in paragraph (1) shall be carried out by the Institute having regard to the objectives and requirements set out in Rule 9 and in compliance with any guidelines established by the Institute with the approval of the Council.

(6) The outcome of the review and evaluation of the report referred to in paragraph (1) carried out under this Rule shall be conveyed to the pharmacist concerned by the Executive Director in the form of a certificate within the timescales set down by the Institute.

*Practice review for patient-facing pharmacists*

14. (1) Subject to the provisions of this Rule, from the selection of pharmacists made under Rule 13(1), the Institute shall select at random not less than ten per cent of that cohort, to be requested by the Executive Director on behalf of the Institute, to undergo a practice review.



(2) The practice review referred to in paragraph (1), which shall be prepared in accordance with guidelines laid down by the Institute with the approval of the Council, shall consist of a direct evaluation, conducted by the Institute, of the knowledge, skills and judgement of the pharmacist, against a standard established in consultation with peer pharmacists practising in patient-facing roles, having regard to the Core Competency Framework for Pharmacists, with particular reference to those competencies dealing with patient care, including clinical knowledge, the ability to gather and interpret appropriately information from patients, patient management and education and communication (including counselling) skills. In line with the said guidelines, the practice review shall take account of the review of the report on the pharmacist's CPD activities referred to in Rule 13(1).

(3) The random selection of pharmacists under paragraph (1) shall exclude those pharmacists who do not practise in a patient-facing role.

(4) A pharmacist practising in a patient-facing role referred to in paragraphs (2) and (3) shall include a superintendent pharmacist, a supervising pharmacist and any other registered pharmacist engaged or employed in a retail pharmacy business or in the pharmacy department of a hospital, including on a casual or occasional basis.

(5) The outcome of the practice review carried out under this Rule shall be conveyed to the pharmacist concerned by the Executive Director in writing within three months from the date the review concluded.

(6) Where the outcome of the practice review is deemed unsatisfactory by the Institute, the Executive Director and the Institute shall cooperate with the pharmacist concerned in a process with a view to enabling him or her to address any deficiency in his or her knowledge, skills or judgement as may have been identified in the course of the review and following which the pharmacist may be required to undergo not more than two further practice reviews as referred to in paragraph (2).

(7) Notwithstanding paragraph (1), where the Council or the Registrar has identified a pharmacist acting in a patient-facing role whose ability or competence to practice may be considered deficient in a material respect, the Institute shall include, at the request of the Council or the Registrar, such persons to undergo a practice review as provided for in paragraph (1). The outcome of such review shall be notified by the Executive Director to the Council or to the Registrar, as the case may be.

(8) In this Rule, patient-facing role includes the exercise of personal control of a retail pharmacy business by a pharmacist and includes the discharge of such role by way of the supervision and control of other registered pharmacists in such business.

15. The Executive Director shall refer to the Registrar relevant information in connection with the following:

- (a) failure by a pharmacist to cooperate with the Executive Director under Rule 13 or to submit a report by the date specified by the Executive Director and, in the absence of an appropriate response to a reminder within a reasonable time, to be specified in the reminder;

- (b) where a pharmacist has completed the process set out in Rule 14(6) and has failed to achieve the required standard;
- (c) failure by a pharmacist to participate in the practice review under Rule 14; or
- (d) refusal on the part of a pharmacist to cooperate with the Executive Director with respect to the operation of Rule 14.

16. The following may give rise to a complaint under section 35(1)(f) of the Act:

- (a) failure by a pharmacist to cooperate with the Executive Director under Rule 13 or to submit a report by the date specified by the Executive Director and, in the absence of an appropriate response to a reminder within a reasonable time, to be specified in the reminder;
- (b) where a pharmacist has completed the process set out in Rule 14(6) and has failed to achieve the required standard;
- (c) failure by a pharmacist to participate in the practice review under Rule 14; or
- (d) refusal on the part of a pharmacist to cooperate with the Executive Director with respect to the operation of Rule 14.

## PART 6

### AMENDMENTS TO EXISTING RULES

*Amendments to the Pharmaceutical Society of Ireland (Education and Training) (Integrated Course) Rules 2014*

17. The provisions of the Pharmaceutical Society of Ireland (Education and Training) (Integrated Course) Rules 2014 (S.I. No. 377 of 2014) are amended by:

- (a) in Rule 4, the substitution of the following for paragraph (2):

“(2) The Core Competency Framework for Pharmacists shall set out the competencies, including knowledge, skills, attitudes and values, that are to be attained by a person who has pursued the programmes of education and training referred to in Rule 7 leading to a qualification appropriate for practice, and shall include the competencies against which pharmacists will evaluate their development and learning needs for the purposes of their continuing professional development as referred to in section 7(1)(d) of the Act.”,

and

- (b) in Rule 9, the substitution of the following for paragraph (2):

“(2) the review referred to in paragraph (1) shall be carried out in the manner set out in Rules 11 and 12”.

*Amendments to the Pharmaceutical Society of Ireland (Registration) Rules 2008*

18. The Pharmaceutical Society of Ireland (Registration) Rules 2008 (S.I. No. 494 of 2008) are amended –

- (a) by inserting in Rule 3(1) the following after the definition of ‘Council’:

“‘Executive Director’, ‘Institute of Pharmacy’ and ‘patient-facing role’ have the same meaning as in the Pharmaceutical Society of Ireland (Continuing Professional Development) Rules 2015 (S.I. No. XX of 2015)”;

(b) by inserting in Rule 11 the following after paragraph (7):

“(8) Where the name of a pharmacist is entered into the Register of Pharmacists for the first time, or by way of continued registration, and such applicant declares that he or she is not practising in a patient-facing role, the Registrar shall forward the name of the said pharmacist to the Executive Director of the Institute of Pharmacy for the purpose of Rule 14(3) of the Pharmaceutical Society of Ireland (Continuing Professional Development) Rules 2015 (S.I. No. XX of 2015).”

(c) by substituting the following for paragraph 3. of Schedule 2:

“3. The professional capacity as a pharmacist in which he or she is practising and a statement indicating whether or not he or she is practising in a patient-facing role (within the meaning of the term in Rule 14 of the Pharmaceutical Society of Ireland (Continuing Professional Development) Rules 2015 (S.I. No. XX of 2015), including on a casual or occasional basis.”.

(d) by inserting the following after paragraph 7. of Schedule 2:

“7A. A statement –

(a) confirming his or her engagement with the Institute of Pharmacy referred to in Rule 3 of the Pharmaceutical Society of Ireland (Continuing Professional Development) Rules 2015 (S.I. No. XX of 2015) in his or her undertaking and reporting of the CPD activities as required under Parts 4 and 5 of those Rules, and

(b) indicating whether or not he or she has, within the previous 12 months, been requested by the Executive Director to submit a report on his or her CPD activities referred to in Rule 13(1) of the aforementioned Rules and where such request has been responded to, evidence issued by the Institute under Rule 13(5) of the said Rules showing that the outcome has been satisfactory.”

*Amendments to the Pharmaceutical Society of Ireland (Retail Pharmacy Businesses) (Registration) Rules 2008*

19. Schedule 1 to the Pharmaceutical Society of Ireland (Retail Pharmacy Businesses) (Registration) Rules 2008 (S.I. No. 495 of 2008) is amended by the substitution of the following for sub-paragraph (b) of paragraph 12:

“(b) are enabled to adequately engage with the Irish Institute of Pharmacy referred to in Rule 3 of the Pharmaceutical Society of Ireland (Continuing Professional Development) Rules 2015 (S.I. No. XX of 2015) in his or her undertaking of appropriate CPD activities as required under Parts 4 and 5 of those Rules”.

The Council of the Pharmaceutical Society of Ireland, in exercise of the functions conferred on the said Society by section 11 of the Pharmacy Act 2007 (No. 20 of 2007) and for the purpose of discharging its functions under section 7(1)(d) of the Act, hereby makes the following rules:-

Dated this                      day of                      2015

\_\_\_\_\_  
President

\_\_\_\_\_  
Registrar

I, in exercise of the powers conferred on me by section 11(5) of the Pharmacy Act 2007 (as adapted by the Health and Children (Alteration of Name of Department and Title of Minister) Order 2011 (S.I. No. 219 of 2011)) and the Health (Delegation of Ministerial Functions) Order 2014 (S.I. No. XXX of 2014), consent to the making of the above Rules.

Given under my hand

[Day] [Month] 2015

LEO VARADKAR  
Minister for Health

**EXPLANATORY NOTE**

*(This note is not part of the Instrument and does not purport to be a legal interpretation).*