



STATUTORY INSTRUMENTS.

S.I. No. 553 of 2015



PHARMACEUTICAL SOCIETY OF IRELAND (CONTINUING
PROFESSIONAL DEVELOPMENT) RULES 2015

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The Council of the Pharmaceutical Society of Ireland, in exercise of the powers conferred on the said Society by section 11 of the Pharmacy Act 2007 (No. 20 of 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. 532 of 2014), and for the purpose of discharging its functions under section 7(1)(d) of that Act, with the consent of the Minister of State at the Department of Health, 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 come into operation on 1 January 2016.

(2) Rule 12 and paragraphs (a)(iii), (b) and (c)(i) of Rule 15 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 Union (Recognition of Professional Qualifications relating to the Profession of Pharmacist) Regulations 2012 (S.I. No. 235 of 2012), the European Union (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);

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

*Notice of the making of this Statutory Instrument was published in
“Iris Oifigiúil” of 22nd December, 2015.*

“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;

“Codes of conduct” 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;

“Core Competency Framework for Pharmacists” has the meaning 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;

“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 for use by pharmacists pursuant to Rule 10(1);

“Executive Director” means the person for the time being appointed by the Managing Body pursuant to Rule 4(3);

“Institute of Pharmacy” or “Institute” means the Irish Institute of Pharmacy, established by the Council pursuant to Rule 4(1);

“Managing Body” means the body corporate appointed for the time being by the Council pursuant to Rule 4(2);

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

“registered pharmacist” means a person whose name is entered in the Register of Pharmacists;

“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 Regulation 6 of the European Communities (Recognition of Professional Qualifications relating to the Profession of Pharmacist) (No. 2) Regulations 2008;

“superintendent pharmacist” has the meaning assigned to it in Rule 3 of the Pharmaceutical Society of Ireland (Registration) Rules 2008 (S.I. No. 494 of 2008);

“supervising pharmacist” has the meaning assigned to it in Rule 3 of the Pharmaceutical Society of Ireland (Registration) Rules 2008.

PART 2

ESTABLISHMENT OF INSTITUTE OF PHARMACY AND
APPOINTMENT OF EXECUTIVE DIRECTOR*Establishment of Institute and appointment of Managing Body and Executive Director*

4. (1) For the purpose of discharging its functions under section 7(1)(d) of the Act, the Council shall establish, in the form of a management arrangement, the Irish Institute of Pharmacy, which shall arrange for the implementation and delivery of the CPD system, as determined by the Council, and the engagement by pharmacists with such system.

(2) The Council shall, from time to time, appoint a corporate body as the Managing Body of the Institute, which body shall provide facilities and services for the Institute of Pharmacy.

(3) The Managing Body shall, in consultation with the Society, appoint a person as Executive Director of the Institute, which person shall be responsible for the management and administration of the Institute, including the particular functions assigned to such person under these Rules.

(4) Subject to the policy direction of the Council, the Institute shall be responsible for the implementation and delivery of the CPD system in accordance with annual service plans approved by the Council and for the discharge of the duty of the Society referred to in section 7(2)(a)(iv) of the Act insofar as such duty relates to compliance by pharmacists with CPD as required by the codes of conduct for pharmacists.

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 shall, in accordance with the procedures set out in this Rule, determine, approve and publish criteria, under the title of the Accreditation Standards for CPD Programmes and Courses for Pharmacists, 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 pharmacists' immediate or long-term needs in relation to their 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) Prior to the approval of the criteria referred to in paragraph (1), and where the Council proposes to amend such approved criteria, the Council shall publish its proposals on the Society's website with an invitation to the public to comment on the draft criteria or amendments 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.

Identification, selection and delivery of CPD programmes and courses for pharmacists

6. (1) The Council shall agree a policy, from time to time, in respect of the identification, selection and delivery of CPD programmes and courses for pharmacists.

(2) The recognition and approval of CPD programmes and courses for pharmacists, in accordance with the policy referred to in paragraph (1), shall be carried out by the Registrar and such recognition and approval shall be for a limited duration which shall not exceed a period of three years.

(3) CPD programmes and courses shall conform to the criteria, in accordance with the policy referred to in paragraph (1).

(4) The Council shall publish guidelines, in accordance with the policy referred to in paragraph (1), providing for—

- (a) the manner and form of the application by persons seeking recognition and approval of programmes and courses,
- (b) the application procedure,
- (c) the conditions for approval and recognition of programmes and courses,
- (d) the appeals process,
- (e) fees payable to the Council in connection with the application, and
- (f) any other relevant matter.

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

7. (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

CPD obligations of pharmacists

8. (1) With a view to keeping abreast of relevant advances in scientific and technical progress and clinical practice, including 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 CPD.

(2) The CPD undertaken shall be systematic, self-directed, needs-based and 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.

(4) Every pharmacist shall create and maintain a learning profile, as part of his or her ePortfolio, which shall detail the learning activities identified pursuant to paragraph (3), as well as 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.

(5) Every pharmacist shall, in undertaking his or her CPD activities, engage in such activities as may have been identified in the learning profile referred to in paragraph (4), 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 INSTITUTE

Registration of pharmacists with Institute

9. (1) Subject to paragraph (2), every person whose name is entered in the Register of Pharmacists shall also be registered with the Institute 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, subsequent to which the responsibility for ongoing engagement with the Institute shall remain with the pharmacist.

ePortfolios

10. (1) The Institute shall establish and maintain an electronic CPD portfolio, to be known as an "ePortfolio", in such manner and form as may be approved by the Council from time to time, for each pharmacist registered with the Institute, which shall be accessible by pharmacists through the website of the Institute.

(2) Every pharmacist, in undertaking his or her CPD activities, shall use, as an aid, his or her ePortfolio, 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.

Reporting on and supervision of CPD activity

11. (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 reasonable timescale that may be laid down by the Executive Director.

(2) The report referred to in paragraph (1) shall include the up-to-date learning profile of the pharmacist created pursuant to Rule 8(4), as well as such other extracts from his or her ePortfolio as the pharmacist may consider relevant, and shall be prepared in accordance with guidelines laid down by the Institute with the approval of the Council.

(3) The selection of pharmacists for the purpose of report submission and review referred to in paragraph (1) shall be such as to ensure 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.

(4) 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.

(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 8 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 within the timescales set down by the Institute and, where such review and evaluation are satisfactory, the said outcome shall be issued in the form of a certificate.

Practice review for patient-facing pharmacists

12. (1) Subject to the provisions of this Rule and prior consultation with the Institute, the Council shall publish, from time to time, guidelines providing for an annual practice review, overseen by the Institute, of a randomly selected sample of pharmacists.

(2) The guidelines referred to in paragraph (1) shall provide for—

- (a) the procedure for random selection of pharmacists for review,
- (b) the review procedures,
- (c) the process where the outcome of the practice review is deemed unsatisfactory by the Institute, and

(d) any other relevant matters.

(3) The pharmacists selected pursuant to the guidelines referred to in paragraph (1) shall participate in the practice review referred to in that paragraph and shall cooperate with the Executive Director in the operation of this Rule.

(4) The practice review referred to in paragraph (1) 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 and about 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 11(1).

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

(6) 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 the timeframe provided for that purpose in the guidelines referred to in paragraph (1).

(7) In this Rule, "practising in a patient-facing role" means carrying out the role of a pharmacist in the delivery, or the oversight of the delivery, of care and services to members of the public, including patients, whether in a retail pharmacy business or in the pharmacy department of a hospital, or any other relevant location, including on a casual or occasional basis, and includes the role carried out by 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.

Referral of information by Executive Director to Registrar

13. The Executive Director shall refer to the Registrar relevant information in connection with any contravention by a pharmacist of Rule 11(1) or (2) or Rule 12(3).

PART 6

AMENDMENTS TO EXISTING RULES

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

14. The provisions of the Pharmaceutical Society of Ireland (Education and Training) (Integrated Course) Rules 2014 are amended—

(a) in Rule 4, by substituting for paragraph (2) the following:

“(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, by substituting for paragraph (2) the following:

“(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

15. The Pharmaceutical Society of Ireland (Registration) Rules 2008 are amended—

(a) in Rule 3(1)—

(i) by inserting after the definition of “certificate of registration” the following definition:

“‘CPD Rules’ means the Pharmaceutical Society of Ireland (Continuing Professional Development) Rules 2015 (S.I. No. 553 of 2015);”,

(ii) by inserting after the definition of “Council” the following definitions:

“‘Executive Director’ has the meaning assigned to it in Rule 3 of the CPD Rules;

‘Institute of Pharmacy’ has the meaning assigned to it in Rule 3 of the CPD Rules;”, and

(iii) by inserting after the definition of “old Society” the following definition:

“‘patient-facing role’ has the meaning assigned to it in Rule 12(7) of the CPD Rules;”,

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

“(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 12(5) of the CPD Rules.”, and

(c) in Schedule 2—

(i) by substituting for paragraph 3 the following:

“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.”, and

(ii) by inserting after paragraph 7 the following:

“7A. A statement—

(a) confirming his or her engagement with the Institute of Pharmacy in his or her undertaking and reporting of the CPD activities as required under Parts 4 and 5 of the CPD 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 11(1) of the CPD Rules and where such request has been responded to, evidence issued by the Institute of Pharmacy under Rule 11(6) of the CPD Rules showing that the outcome has been satisfactory.”.

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

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

“(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. 553 of 2015) in his or her undertaking of appropriate CPD activities as required under Parts 4 and 5 of those Rules”.

I, Kathleen Lynch, Minister of State at the Department of Health, consent to the making of the foregoing Rules.

GIVEN under my hand,
15 December 2015.

KATHLEEN LYNCH,
Minister of State at the Department of Health.



GIVEN under the Official Seal of the Pharmaceutical Society of
Ireland,
15 December 2015.

ANN FRANKISH,
President.

DAMHNAIT GAUGHAN,
Registrar.

EXPLANATORY NOTE

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

These Rules set out the system of continuing professional development (CPD) for pharmacists, the role of the Irish Institute of Pharmacy to oversee the management and operation of the CPD system on behalf of the PSI, the associated quality assurance review processes, and the recognition and approval of CPD programmes and courses for pharmacists.

These Rules also amend the Pharmaceutical Society of Ireland (Education and Training) (Integrated Course) Rules 2014, the Pharmaceutical Society of Ireland (Registration) Rules 2008 and the Pharmaceutical Society of Ireland (Retail Pharmacy Businesses) (Registration) Rules 2008.

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

These Rules come into operation on 1 January 2016, except for the rules in relation to practice review for patient-facing pharmacists which come into operation on 1 January 2017.

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