



STATUTORY INSTRUMENTS.

S.I. No. 377 of 2014

PHARMACEUTICAL SOCIETY OF IRELAND (EDUCATION AND
TRAINING) (INTEGRATED COURSE) RULES 2014

PHARMACEUTICAL SOCIETY OF IRELAND (EDUCATION AND
TRAINING) (INTEGRATED COURSE) RULES 2014

PART 1

GENERAL PROVISIONS

Citation

1. These Rules may be cited as the Pharmaceutical Society of Ireland (Education and Training) (Integrated Course) Rules 2014.

Commencement

2. These Rules come into operation on 1 June 2015.

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) and the Health (Pricing and Supply of Medical Goods) Act 2013 (No. 14 of 2013);

“active drug substance” means any substance or mixture of substances intended to be used in the manufacture of a medicinal product and that, when used in its production, becomes an active ingredient of that product intended to exert a pharmacological, immunological or metabolic action with a view to restoring, correcting or modifying physiological functions or to make a medical diagnosis;

“Advisory Committee on Pharmaceutical Training” means the Committee established under Article 1 of Council Decision 85/434/EEC of 16 September 1985¹;

“Core Competency Framework for Pharmacists”, in respect of a person pursuing a qualification appropriate for practice, has the meaning assigned to it in Rule 5 and refers to such document which is for the time being in force;

¹OJ No. L 253, 24.9.1985, p. 43.

*Notice of the making of this Statutory Instrument was published in
“Iris Oifigiúil” of 12th August, 2014.*

“criteria” means the Accreditation Standards for the Five-Year Fully Integrated Masters Degree Programme in Pharmacy published under Rule 7 for the recognition and approval of five-year integrated programmes of education and training, leading to the award of a Masters degree in pharmacy and which are for the time being in force;

“marketing authorisation”, in respect of a medicinal product, has the meaning assigned to it in Regulation 4(1) of the Medicinal Products (Control of Advertising) Regulations 2007 (S.I. No. 541 of 2007);

“medical device” has the meaning assigned to it in section 1(1) (inserted by section 10(c) of the Irish Medicines Board (Miscellaneous Provisions) Act 2006 (No. 3 of 2006)) of the Irish Medicines Board Act 1995 (No. 29 of 1995);

“medicinal product” has the meaning assigned to it in section 2 of the Act and includes veterinary medicinal products within the meaning of section 18(2) of the Act;

“qualification appropriate for practice” has the meaning assigned to it in section 16(1) of the Act as referred to in section 14(1)(e) of the Act, as being one of the requirements essential for registration in the Register of Pharmacists;

“recognised institution” means a university or other higher education institution in the State that is recognised by the State as having an equivalent status to that of a university;

“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;

“training establishment” means any of the establishments referred to in Rule 14(1)(b) or in Rule 15(1);

“tutor pharmacist” means a registered pharmacist who has been recognised as a tutor pharmacist by the recognised institution under Rule 16.

Core Competency Framework for Pharmacists

4. (1) For the purposes of these Rules, the Council shall prepare, adopt and publish a framework document, which shall be known as the Core Competency Framework for Pharmacists.

(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.

(3) The content of the Core Competency Framework for Pharmacists shall be informed by the body of knowledge, the skills, and the values set out in the Schedule.

(4) The Council shall review and update the Core Competency Framework for Pharmacists 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 in professional development and learning.

(5) Where the Council proposes to amend the Core Competency Framework for Pharmacists, it shall publish its proposals on the Society's website and issue invitations to the relevant stakeholders to comment, within such reasonable period of time as specified by the Council, upon those proposals.

(6) The Council shall publish on the Society's website the Core Competency Framework for Pharmacists.

PART 2

QUALIFICATIONS APPROPRIATE FOR PRACTICE FOR THE PURPOSES OF SECTION 16(1) OF THE ACT

Qualifications appropriate for practice

5. A person who in accordance with these Rules holds a Masters degree in pharmacy that is recognised and approved by the Council in accordance with Part 3 shall be regarded as holding a qualification appropriate for practice.

PART 3

RECOGNITION AND APPROVAL OF PROGRAMMES OF EDUCATION AND TRAINING LEADING TO THE AWARD OF A MASTERS DEGREE IN PHARMACY

Recognition and approval of Masters degrees in pharmacy

6. Subject to the provisions of these Rules and for the purpose of Rule 5, the Council may recognise a Masters degree in pharmacy as a qualification appropriate for practice if the course of study leading to such Masters degree commenced after the date of coming into force of these Rules, and the Masters degree attests to training of at least five years' duration and incorporates—

- (a) not less than four years of full-time theoretical and practical training at a recognised institution, and
- (b) not less than twelve months of in-service practical training in accordance with Part 4,

and the said training (including the full-time theoretical and practical training and the in-service practical training) conforms to the criteria published under Rule 7.

Criteria for recognition and approval of five-year integrated programme of education and training leading to award of Masters degree in pharmacy

7. (1) The Council shall, for the purposes of this Part and in accordance with the procedures set out in this Rule, determine, approve and publish criteria for the recognition and approval of five-year integrated programmes of education and training, leading to the award of a Masters degree in pharmacy.

(2) The criteria referred to in paragraph (1) shall at least—

- (a) set out minimum requirements relating to the delivery of the programme including long-term commitment, staffing, premises, facilities, funding, policies, procedures and organisational structures,
- (b) incorporate, in an indicative syllabus, those subjects and branches of knowledge set out in the Schedule,
- (c) incorporate the competencies set out in the Core Competency Framework for Pharmacists,
- (d) incorporate a requirement to demonstrate a minimum standard of knowledge in relation 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, and
- (e) have regard to the National Framework of Qualifications kept and maintained in accordance with Section 43 of the Qualifications and Quality Assurance (Education and Training) Act 2012 (No. 28 of 2012).

(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, higher education 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 and issue invitations to the relevant stakeholders to comment, within such reasonable period of time as specified by the Council, upon those proposals.

(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 of five-year integrated programme of education and training leading to award of Masters degree in pharmacy

8. (1) A recognised institution which proposes to offer a five-year integrated programme of education and training leading to the award of a Masters degree in pharmacy for the purpose of Rule 5, shall—

- (a) make application in writing to the Registrar in the manner and form as may, from time to time, be prescribed by the Council, and
 - (b) satisfy the Council that the proposed programme of education and training and all matters relating to its delivery and processes of assessment, including staffing, premises, facilities, in-service practical training, funding and procedures, will conform with the criteria published under Rule 7.
- (2) Subject to the provisions of this Rule, the Council shall consider an application received under paragraph (1) and shall grant or refuse the application within a period of 120 days from the date the application is received.
- (3) Following receipt of an application under paragraph (1), the Council shall, by means of inspection or otherwise, confirm the accuracy of the information provided in the application and may give notice in writing to the applicant requesting it to provide further information in support of its application.
- (4) Where the Council gives a notice pursuant to paragraph (3), the period referred to in paragraph (2) shall be suspended from the date the notice is given and shall recommence only on receipt of the information requested.
- (5) The expiry of the period of 120 days referred to in paragraph (2) shall not be taken to mean that an implicit recognition or approval for the said degree has been granted by the Council.
- (6) On being satisfied that the proposed programme leading to the award of a Masters degree in pharmacy meets the requirements referred to in paragraph (1)(b), the Council shall grant its recognition and approval for the said degree.
- (7) In the grant of its recognition and approval to a recognised institution in respect of a Masters degree in pharmacy offered by it, the Council may attach such conditions as may be relevant and necessary.
- (8) On the recognition and approval of a Masters degree in pharmacy under this Rule, the Council shall publish a notice to that effect in *Iris Oifigiúil* and on the Society's website.
- (9) A recognised institution, in respect of which a Masters degree in pharmacy has been recognised and approved by the Council under this Rule, shall comply with the requirements set out in paragraph (1)(b) and any conditions that may be imposed by the Council under paragraph (7).
- (10) Where the Council has under Rule 7(5) published amended criteria, the recognised institutions responsible for the award of the Masters degrees in pharmacy, which have been recognised and approved by the Council under this Rule, shall make arrangements for compliance with the amended criteria by a date not later than the commencement of the subsequent academic year or by a date as may otherwise be specified by the Council.

Duty of Council to review approved degrees

9. (1) Where the Council has recognised and granted its approval under Rule 8 to a Masters degree in pharmacy, it shall subsequently and at intervals not exceeding five years, review whether the programme of education and training being provided continues to conform with the requirements of Rule 8(1)(b) and any conditions that the Council may have imposed under Rule 8(4) in the grant of such recognition and approval.

(2) The review referred to in paragraph (1) shall be carried out in the manner set out in Rules 12 and 13.

Compliance by recognised institutions

10. (1) Notwithstanding the review to be conducted under Rule 9, where the Council has recognised and approved a Masters degree in pharmacy under Rule 8, the Council shall be entitled to arrange for such visits to a recognised institution as are from time to time necessary for the purpose of ensuring compliance with these Rules.

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

Visits to recognised institutions

11. (1) Where the Council considers an application received under Rule 8(1) or carries out a review under Rule 9 or a compliance visit under Rule 10, it shall appoint persons with relevant knowledge and experience, who shall be known as visitors, to visit the recognised institution concerned, including any of its proposed or associated training facilities and training establishments.

(2) A person appointed as a visitor under paragraph (1) shall not have an interest that is likely to influence the outcome of the application made under Rule 8(1), the review under Rule 9 or the compliance visit under Rule 10, as the case may be.

(3) It shall be the duty of visitors having visited the institution, including any of its proposed or associated training facilities as aforesaid, to report in writing to the Council as to whether in their opinion the standard of compliance and delivery of the Masters degree in pharmacy would satisfy or continue to satisfy the requirements specified under Rule 8.

(4) No person appointed as a visitor shall interfere with the giving of any instruction to any student in the course of his or her visit.

(5) The visitors, in their report to the Council on the institution concerned, may recommend that the Council—

- (a) grant its recognition and approval for the proposed Masters degree in pharmacy,
- (b) continue to grant its recognition and approval for the Masters degree in pharmacy,

- (c) grant its recognition and approval for the proposed Masters degree in pharmacy subject to certain conditions that they shall specify,
- (d) continue to grant its recognition and approval for the Masters degree in pharmacy subject to certain conditions that they shall specify,
- (e) defer its decision on the recognition and approval for the proposed Masters degree in pharmacy pending the resolution, to the satisfaction of the Council, of such issues of concern arising from their visit and consultation, touching upon the requirements of these Rules that they shall specify,
- (f) defer its decision on the continued recognition and approval for the Masters degree in pharmacy pending the resolution, to the satisfaction of the Council, of such issues of concern arising from their visit and consultation, touching upon the requirements of these Rules that they shall specify,
- (g) refuse to grant its recognition and approval for the proposed Masters degree in pharmacy on the basis of reasons which they shall specify, or
- (h) refuse to continue to grant its recognition and approval for the Masters degree in pharmacy on the basis of reasons which they shall specify.

Responses and resolutions following reporting of visits

12. (1) The Council, on receipt of a report of visitors under Rule 11, shall forthwith send a copy of the report to the institution concerned and such institution may, within such period (not being less than one month) as the Council shall specify at the time it sends the report to the institution, submit to the Council its comments and observations on the report.

(2) Subject to paragraph (3), the Council may, on consideration of a report of visitors under Rule 11 and of any comments and observations received from the institution concerned, by resolution—

- (a) grant its recognition and approval for the proposed Masters degree in pharmacy,
- (b) continue to grant its recognition and approval for the Masters degree in pharmacy,
- (c) grant its recognition and approval for the proposed Masters degree in pharmacy subject to certain conditions that it shall specify,
- (d) continue to grant its recognition and approval for the Masters degree in pharmacy subject to certain conditions that it shall specify,
- (e) defer its decision on the recognition and approval for the proposed Masters degree in pharmacy pending the resolution, to the satisfaction

of the Council, of such issues of concern touching upon the requirements of these Rules that they shall specify,

- (f) defer its decision on the continued recognition and approval for the Masters degree in pharmacy pending the resolution, to the satisfaction of the Council, of such issues of concern touching upon the requirements of these Rules that they shall specify,
- (g) refuse to grant its recognition and approval for the proposed Masters degree in pharmacy on the basis of reasons which it shall specify, or
- (h) refuse to continue to grant its recognition and approval for the Masters degree in pharmacy on the basis of reasons which it shall specify.

(3) Where the Council proposes to adopt a resolution that, for any reason arising from the requirements of these Rules, would have the effect of refusing to grant its recognition and approval for a proposed Masters degree in pharmacy, or of refusing to continue the recognition and approval of a previously recognised and approved Masters degree in pharmacy, it shall notify the institution accordingly and any such notification shall include:

- (a) a statement of the proposal of the Council,
- (b) a statement setting out in detail the reasons on which the said proposals are based, and
- (c) a statement that the institution has the right to make representations to the Council in response to the notification, within such reasonable period of time as specified by the Council,

and the Council shall, after consideration of any representations it may receive from the institution concerned, decide whether to grant recognition and approval or confirm or alter its proposal to refuse to grant or to continue to grant its recognition and approval, as the case may be.

(4) Where a resolution under paragraph (2)(g) or (h) is adopted by the Council, no person who is subsequently awarded a Masters degree in pharmacy by the institution concerned shall be entitled to make application or to present for registration as a pharmacist, on the basis of a Masters degree in pharmacy granted by the said institution after the date specified in the resolution.

(5) If the Council is satisfied, on the basis of representations made by the institution concerned, that effective provision has been made so as to comply with the requirements and conditions subject to which the recognition and approval of a Masters degree in pharmacy under Rule 8 had been granted, the Council may revoke a resolution under paragraph (2)(g) or (h) and such revocation shall not entitle a person to be registered as a pharmacist on the basis of a Masters degree in pharmacy granted by the institution concerned during the period from the date specified in the resolution until the coming into force of the revocation of the resolution.

(6) Notwithstanding paragraph (4), any student enrolled on a Masters degree in pharmacy that is impacted by a resolution adopted by virtue of paragraph (2)(g) or (h), shall be facilitated by the Council in transferring to another such degree programme that is recognised and approved by the Council under Rule 8, and, where such arrangements are to be facilitated, the Council shall satisfy itself that those arrangements, including any remedial measures that may be deemed necessary, are appropriate to meet the circumstances presented.

Obligation on recognised institutions to provide annual report and to notify material changes

13. (1) A recognised institution, in respect of which a Masters degree in pharmacy has been recognised and approved by the Council under Rule 8, shall on an annual basis provide the Registrar with a report to include matters relating to the programme of education and training for such degree, to its delivery and assessment, to any material changes that might be considered relevant to the continued recognition and approval of the said degree, to the institution concerned, and to the requirements and conditions, subject to which the recognition and approval under Rule 8 had been granted.

(2) Notwithstanding paragraph (1), at any time a recognised institution, in respect of which a Masters degree in pharmacy has been recognised and approved by the Council under Rule 8, shall notify the Registrar of any proposed material change to its programme of education and training for such degree, to its delivery or to the institution concerned, any of which might reasonably be considered relevant to the continued recognition and approval of the said degree, and shall provide an explanation as to how the said change is such as would enable the requirements and conditions, subject to which the recognition and approval under Rule 8 had been granted, to continue to be met.

(3) Failure to notify the Registrar in respect of the material changes referred to in paragraph (2) may, at the sole discretion of the Council, be deemed a basis for the making of a resolution pursuant to Rule 12(2)(d), (f) or (h) and, should the Council propose to make such a resolution, it shall follow the procedure for such resolution as set out at Rule 12(3). The adoption of such a resolution shall have the consequences set out at Rule 12(4). The Council may, at its sole discretion, revoke such resolution provided it is satisfied that the material changes to the institution's programme of education and training satisfy the requirements of these Rules and that a due and proper explanation has been furnished to the Council setting out the reasons for the institution's failure to notify the Council of the proposed changes.

PART 4

IN-SERVICE PRACTICAL TRAINING

Completion of the in-service practical training

14. (1) Subject to the provisions of this Part, and for the purpose of Rule 6(b), a person pursuing a Masters degree in pharmacy, that has been recognised and approved by the Council in accordance with Part 3, shall complete at least twelve months of in-service practical training consisting of—

- (a) at least four months in one of the establishments referred to in Rule 15(1) and which shall be undertaken during the fourth year of the course, and
- (b) not less than eight consecutive months under the direct supervision of a tutor pharmacist, in a registered retail pharmacy business in the State, or in the pharmacy department of a hospital in the State and which shall be undertaken in the fifth year of the course commencing in the Second Semester. This establishment shall not be the same establishment in which the student undertook the in-service practical training for the purposes of subparagraph (a).

(2) A person pursuing a Masters degree in pharmacy shall not undertake his or her in-service practical training in a training establishment, or under the supervision of a tutor pharmacist, if he or she has a connection with either the training establishment or the tutor pharmacist concerned.

(3) For the purposes of paragraph (2), a person shall be regarded as connected if he or she or a connected relative of his or hers is the pharmacy owner or in the case of any other training establishment, if a connected relative is exercising any supervisory or management role in that training establishment, and in the case of a tutor pharmacist, if he or she is a connected relative of that tutor.

(4) In this Rule “connected relative” has the meaning assigned to it in paragraph 9 of Schedule 1 to the Act and also includes a grandparent, uncle, aunt, niece, nephew, brother-in-law, sister-in-law or parent-in-law, of the person.

Establishments in which in-service practical training may be undertaken

15. (1) Subject to the prior approval of the recognised institution, the following are the establishments in which the in-service practical training referred to in Rule 14(1)(a) may be undertaken:

- (a) a pharmacy open to the public or in the pharmacy department of a hospital,
- (b) the pharmaceutical science department in a university or other such higher education institution involved in the education and training of pharmacists,
- (c) a pharmaceutical establishment where one or more of the following activities are undertaken—
 - (i) the manufacture of medicinal products by an authorised manufacturer;
 - (ii) the wholesaling of medicinal products by an authorised wholesaler;
 - (iii) the conduct of tests of strength, quality or purity of medicinal products;

- (iv) the preparation and assembly of documentation in the making of arrangements for the conduct of clinical trials in accordance with the Control of Clinical Trials Acts 1987 and 1990 or the European Communities (Clinical Trials on Medicinal Products for Human Use) Regulations 2004 (S.I. 190 of 2004) (as amended);
- (v) the preparation and assembly of information, documentation, samples and other materials as may be required in the making of applications for marketing authorisations;
- (vi) the manufacture of active drug substances;
- (vii) the conduct of research and development with a view to the discovery of:
 - (I) new active drug substances,
 - (II) new pharmaceutical dosage forms, or
 - (III) new or improved methods of manufacture for existing medicinal products or existing pharmaceutical dosage forms;
- (viii) the provision of a scientific service by a marketing authorisation holder in accordance with the provisions of Regulation 24(1)(a) of the Medicinal Products (Control of Advertising) Regulations 2007 (S.I. No. 541 of 2007), or
- (d) an establishment, organisation or section thereof other than those of the types referred to in subparagraphs (a), (b) and (c), where, in the opinion of the recognised institution such establishment, organisation or section thereof works in or is directly connected with or has significant involvement or participation in the practice, evaluation, regulation, administration or governance of pharmacy, medicinal products, blood products, tissues and cells, medical devices, or the delivery of health services,

provided that the training concerned is conducted under the supervision and guidance of a registered pharmacist in accordance with the criteria as they relate to supervision in such circumstances and any guidelines in that regard that may from time to time be published by the Council.

(2) The recognised institution may require any information which it considers reasonably necessary from any proposed training establishment, for the purpose of giving its approval to the undertaking of in-service practical training at that establishment.

(3) Subject to subparagraph (6), the in-service practical training required under Rule 14(1)(a) and (b) shall be undertaken in a training establishment approved by the recognised institution, provided the owner of the training establishment concerned—

(a) being a registered pharmacist or pharmacy owner—

- (i) is not the subject of any disciplinary sanction referred to in section 48(1)(b)(ii), (iii), (iv) or (v) of the Act as may, for the time being, be in force,
- (ii) has not been required to provide an undertaking or consent referred to in section 46(1)(b) of the Act as may, for the time being, be in force,
- (iii) has not, within two years of the date of commencement of the relevant in-service practical training, been convicted of any offence, not being an offence tried on indictment, under the Act or under the Misuse of Drugs Acts 1977 to 2006, the Irish Medicines Board Acts 1995 and 2006, the Poisons Acts 1961 and 1977, the Animal Remedies Acts 1993 and 2006 or the European Communities (Animal Remedies) Regulations (No. 2) Regulations 2007 (S.I. No. 786 of 2007), and
- (iv) has not, within four years of the date of commencement of the relevant in-service practical training, been convicted of any offence tried on indictment, or

(b) in any other case—

- (i) has not, within two years of the date of commencement of the relevant in-service practical training, been convicted of any offence, not being an offence tried on indictment, under the Act or under the Misuse of Drugs Acts 1977 to 2006, the Irish Medicines Board Acts 1995 and 2006, the Poisons Acts 1961 and 1977, the Animal Remedies Acts 1993 and 2006 or the European Communities (Animal Remedies) Regulations (No. 2) Regulations 2007 (S.I. No. 786 of 2007), and
- (ii) has not, within four years of the date of commencement of the relevant in-service practical training, been convicted of any offence tried on indictment.

(4) Subject to paragraph (5), the in-service practical training required under Rule 14(1)(b) shall be undertaken under the direct supervision of a tutor pharmacist, as his or her sole student, and who is based at the premises or, in the case of a hospital, at the group of premises where the in-service training is to be undertaken, notwithstanding that a person may also be undertaking in-service practical training under Rule 14(1)(a) with that tutor pharmacist.

(5) Where the tutor pharmacist has available to him or her, at the premises as aforesaid where the in-service training is to be undertaken, other registered pharmacists who would be in a position to assist in the supervision of the student, the tutor pharmacist concerned may, at the sole discretion of the recognised institution concerned, be entitled to take on up to two further students, provided that there are, in the view of the recognised institution, appropriate

levels of access to the tutor pharmacist by the students at the said premises during the in-service practical training.

(6) The approval by the recognised institution of any training establishment referred to in this Rule, and the nature of any in-service practical training that is undertaken therein, and its supervision, shall be in accordance with the requirements of such criteria as may be relevant and in compliance with any guidelines that may from time to time be published by the Council.

Tutor pharmacists

16. (1) A registered pharmacist practising as such who—

- (a) has practised as a pharmacist for a minimum of 3 years with a minimum of 2 years' experience in the field of pharmacy practice in which he or she intends to act as a tutor pharmacist,
- (b) has completed such programmes of education and training as may be set down by the recognised institution from time to time,
- (c) meets the standard of knowledge, skills and experience as may be required by the recognised institution from time to time for such pharmacists,
- (d) is not the subject of any disciplinary sanction referred to in section 48(1)(b)(ii), (iii), (iv) or (v) of the Act as may, for the time being, be in force, and has not been required to provide an undertaking or consent referred to in section 46(1)(b) of the Act as may, for the time being, be in force,
- (e) has not, within two years of the date of commencement of the relevant in-service practical training, been convicted of an offence referred to in Rule 15(3)(a)(iii),
- (f) has not, within four years of the date of commencement of the relevant in-service practical training, been convicted of any offence tried on indictment, and
- (g) in respect of the person pursuing the Masters degree in pharmacy, is not disqualified by virtue of Rule 14(2),

may be recognised by the recognised institution with a view to acting as a tutor pharmacist under these Rules.

(2) Recognition as a tutor pharmacist under this Rule shall, unless previously revoked, be for a period of twelve months and shall be renewable at the discretion of the recognised institution and having regard to the relevant requirements in paragraph (1).

(3) The recognised institution shall, from time to time, following consultation with the Council, specify the requisite standards of knowledge, skills and experience required as a registered pharmacist and the programmes of education and

training to be completed by a registered pharmacist in order that he or she may act as a tutor pharmacist under these Rules.

Saver in respect of students

17. Where a registered pharmacist, pharmacy owner or other owner of a training establishment becomes restricted by virtue of the provisions of Rule 15(3) and at which time he or she is hosting a student undertaking his or her in-service practical training at the establishment concerned, or where a tutor pharmacist becomes restricted by virtue of the provisions of Rule 16(1)(d),(e) or (f), the consequences of such restriction shall not be considered as impacting on the student concerned, who shall be facilitated by the recognised institution in transferring to another establishment, or to another tutor pharmacist, approved by the recognised institution in order that the student may complete the prescribed period of in-service practical training.

PART 5

GENERAL MATTERS

Holding of professional examination

18. (1) A recognised institution shall at the end of the fifth year following completion of the training referred to in Rule 14(1)(b), hold an examination which shall be known as the Professional Registration Examination and which may be repeated at the discretion of the institution.

(2) The Professional Registration Examination shall be based on the curriculum delivered over the five year course of the integrated degree programme, including the Core Competency Framework and the matters referred to in the Schedule and shall also include performance-based assessments and assessments of patient consultation and counselling skills, and shall place particular emphasis on the legislation and the application of the law pertaining to pharmacy and medicinal products and to the practice of pharmacy in the State, including compliance with the Code of Conduct and the ethics required of a person practising as a pharmacist in the State.

Codes of Conduct for pharmacy students

19. (1) A recognised institution shall support the operation of a code of conduct for pharmacy students which shall be drawn up in consultation with the Council.

(2) The code of conduct referred to in paragraph (1) shall have regard to the Code of Conduct established for pharmacists under the Act which will be binding on the students when they obtain registration in the Register of Pharmacists.

Certification by Head of School

20. No Masters degree in pharmacy shall be awarded to any person by a recognised institution, for the purpose of being recognised under these rules as a qualification appropriate for practice, unless the head or acting head of the school of pharmacy in the said institution has confirmed—

- (a) the satisfactory demonstration of the competencies by the person as set out in the Core Competency Framework for Pharmacists,
- (b) that he or she has not become aware of any health problems that may compromise, in his or her belief, the ability by the person concerned to discharge properly the duties and responsibilities of a registered pharmacist, and
- (c) his or her overall satisfaction that the person concerned is fit to be a registered pharmacist.

Time within which a qualification appropriate for practice may be obtained

21. (1) A person who commences a course under these Rules leading to the award of a qualification appropriate for practice shall, in order to be eligible to obtain such award, complete the said course within eight years of the date on which he or she commenced that course.

(2) Notwithstanding paragraph (1), and where the rules of the recognised institution permit, a recognised institution may, in exceptional circumstances, extend the period prescribed by a period of one year in order that a student be eligible to obtain the award of a qualification appropriate for practice.

Amendment of Registration Rules

22. Schedule 1 to the Pharmaceutical Society of Ireland (Registration) Rules 2008 (S.I. No. 494 of 2008) is amended by substituting paragraph 9(a) by the following:

“(a) in the case of an applicant who has acquired his or her qualification appropriate for practice in the State, evidence to show that he or she—

- (i) has completed the relevant degree in pharmacy and the required period of in-service practical training and has passed the Professional Registration Examination that had been recognised and approved by the Council in accordance with Part 3 of the Pharmaceutical Society of Ireland (Education and Training) Rules 2008 (S.I. No. 493 of 2008), or
- (ii) holds a Masters degree in pharmacy that has been recognised and approved by the Council in accordance with Part 3 of the Pharmaceutical Society of Ireland (Education and Training) (Integrated Course) Rules 2014 (S.I. No. of 2014).”.

Revocation and transitional period

23. (1) Subject to paragraph (2), the Pharmaceutical Society of Ireland (Education and Training) Rules 2008 are revoked.

(2) Notwithstanding the revocation of the Pharmaceutical Society of Ireland (Education and Training) Rules 2008, those Rules shall continue to apply in

respect of persons who commenced, before the coming into operation of these Rules, a course of study under those Rules, leading to the award of a qualification appropriate for practice.

SCHEDULE

Rules 4(3), 7(2)(b), 18(2).

CERTAIN MINIMUM COMPETENCIES TO BE ACQUIRED IN A PROGRAMME LEADING TO OBTAINING QUALIFICATION AS A PHARMACIST

1. The five-year integrated programme of education and training in the course of the qualification appropriate for practice shall at least cover the following subjects—
 - (a) Plant and animal biology,
 - (b) Physics,
 - (c) General and inorganic chemistry,
 - (d) Organic chemistry,
 - (e) Analytical chemistry,
 - (f) Pharmaceutical chemistry including analysis of medicinal products,
 - (g) General and applied biochemistry (medical),
 - (h) Anatomy and Physiology,
 - (i) Medical terminology,
 - (j) Microbiology,
 - (k) Pharmacology,
 - (l) Pharmacotherapy,
 - (m) Pharmaceutical technology,
 - (n) Toxicology,
 - (o) Pharmacognosy,
 - (p) Legislation and the law generally pertaining to pharmacy and medicinal products and to the practice of pharmacy in the State, and
 - (q) Professional conduct and ethics for a person practising as a pharmacist in the State.
2. The balance between theoretical and practical training shall, in respect of each subject, give sufficient importance to theory in order to maintain the university character of the training.

3. The said programme of education and training shall be such that on successful completion it will provide an assurance that the person concerned has acquired the following knowledge and skills—

- (a) adequate knowledge of medicinal products and the substances used in their manufacture,
- (b) adequate knowledge of pharmaceutical technology and the physical, chemical, biological and microbiological testing of medicinal products,
- (c) adequate knowledge of the metabolism and the effects of medicinal products and of the action of toxic substances and of the use of medicinal products,
- (d) adequate knowledge to evaluate scientific data concerning medicinal products in order to be able to supply appropriate information on the basis of this knowledge, and
- (e) adequate knowledge of the legal and other requirements associated with the pursuit of pharmacy,

and such knowledge and skills shall be such as to enable that person to competently practise as a pharmacist and thereby be entitled to gain access to and to at least pursue the professional activities of a pharmacist as set out in Article 45(2) of Directive 2005/36/EC of the European Parliament and of the Council of 7 September 2005².

4. The in-service practical training undertaken in the fifth year of the Masters degree in pharmacy shall be conducted in a manner so as to ensure that the person who has undertaken the training has, as a minimum, demonstrated his or her ability, albeit under the direct supervision of the tutor pharmacist, to competently pursue the profession of pharmacist and in that respect to apply competently—

- (a) the body of knowledge and skills acquired during the training,
- (b) the legislation and the law generally pertaining to pharmacy and medicinal products and to the practice of pharmacy in the State, and
- (c) the standards of professional conduct and ethics for a person practising as a pharmacist in the State.

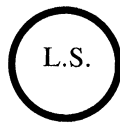
5. The said programme of education and training shall, where appropriate, also have regard to—

- (a) the report and recommendations on the in-service training of pharmacists as adopted by the Advisory Committee on Pharmaceutical Training of the 3rd and 4th of May 1993 (Report III/F/5289/8/90-EN),

²OJ No. L 255, 30.9.2005, p. 22.

- (b) the report and recommendations on pharmaceutical education undergone at higher-education institutions as adopted by the Advisory Committee on Pharmaceutical Training of the 3rd and 4th of May 1994 (Report XV/E/8341/6/93-EN),
- (c) the minimum conditions of qualification specified in paragraph (2) of Article 49 of Directive 2001/83/EC³, and
- (d) the inculcation of the primacy of the patient, and patient safety, above other considerations.

I, LEO VARADKAR, Minister for Health, 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)), consent to the making of the foregoing Rules.



GIVEN under my official seal,
5 August 2014.

LEO VARADKAR,
Minister for Health.

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), hereby makes the foregoing Rules:

Dated this 6th day of August 2014

L. CLARKE,

President.

M. KINSELLA,

Registrar.

³O.J. No. L. 311, 28.11.2001, p.67.

EXPLANATORY NOTE

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

These Rules set out the qualifications appropriate for practice as a pharmacist in the State for the purposes of section 16(1) of the Pharmacy Act 2007.

These Rules also set out the education and training requirement for those persons who, from 1st June 2015, wish to pursue a course in the State leading to registration in the Register of Pharmacists on the basis of a qualification appropriate for practice as a pharmacist that is recognised for that purpose under section 16(1) of the Pharmacy Act 2007.

The Rules also set out the procedures and requirements which apply to the recognition and approval of programmes of education and training leading to the award of a Masters degree in pharmacy in the State and which now become the qualifications appropriate for practice as a pharmacist in the State

In addition, the procedures and requirements which apply to the in-service practical training that are now to be undertaken as an integral part of the five-year course leading to the award of a Masters degree in Pharmacy, are set out in these Rules.

Persons who have commenced their courses before 1 June 2015 will not be impacted by the making of these Rules.

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