

DRAFT 11: - 28th January 2014

S.I. No. _____ of 2014

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

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*), hereby makes the following rules:-

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 shall come into force on 1st June 2014.

Application of rules

3. (1) These Rules shall apply to any person who, after the date of coming into force of these Rules, commences or wishes to commence a course of study leading to the award of a qualification appropriate for practice.

(2) The Pharmaceutical Society of Ireland (Education and Training) Rules 2008 (S.I. No. 493 of 2008) shall cease with effect from the 1st June 2014 except for those persons who had commenced before that date, a course of study under those Rules, leading to the award of a qualification appropriate for practice.

Interpretation

4. (1) In these Rules ó

Actø 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 European Communities (Recognition of Professional Qualifications relating to the Profession of Pharmacist) Regulations 2012 (*S.I. No. 235 of 2012*) and by the European Communities (Recognition of Professional Qualifications relating to the Profession of Pharmacist) Regulations 2013 (*S.I. No. 377 of 2013*);

'Advisory Committee on Pharmaceutical Training' means the Committee established by virtue of the EU 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;

'criteria' means the Accreditation Standards for the Five-Year Fully Integrated Masters Degree Programme in Pharmacy published under Rule 8 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 same meaning as 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) of the Irish Medicines Board Act 1995 (*No. 29 of 1995*) as inserted by section 10(c) of the Irish Medicines Board (Miscellaneous Provisions) Act 2006 (*No. 3 of 2006*);

'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;

'Society' means the Pharmaceutical Society of Ireland, established pursuant to section 5(2) of the Act;

'training establishment' means any of the establishments referred to in paragraph (1)(b) of Rule 15 or in paragraph (1) of Rule 16.

¹ Official Journal of the European Communities L 253 , 24/09/1985 P. 0043 - 0044

'tutor pharmacist' means a registered pharmacist who has been recognised as a tutor pharmacist by the recognised institution under Rule 17;

- (2) In these Rules, unless the context otherwise requires, any reference to a Rule or Schedule shall be construed as a reference to a Rule or Schedule contained in these Rules, any reference to a Part shall be construed as a reference to a Part contained in these Rules, and any reference in a Rule or in a Schedule to a paragraph shall be construed as a reference to a paragraph in that Rule or Schedule.

Core Competency Framework for Pharmacists

5. (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. This document shall set out the competencies that include the 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. Such document shall be informed by the body of knowledge, the skills, and the values set out in the Schedule.
- (2) 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.
- (3) Where the Council proposes to amend the Core Competency Framework for Pharmacists, it shall publish its proposals on its website and issue invitations to the relevant stakeholders to comment, within such reasonable period of time as specified by the Council, upon those proposals.
- (4) 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

6. 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

7. Subject to the provisions of these Rules and for the purpose of Rule 6, the Council may recognise a Masters degree in pharmacy as a qualification appropriate for practice if it 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 8.

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

8. (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) Those criteria 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, and
 - (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.
- (3) The Council shall review the criteria 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, it shall publish its proposals on the Society's website and issue invitations to the relevant stakeholders to comment on those proposals.
- (5) The Council shall publish on its website the criteria adopted, or as may subsequently be amended under this Rule.

Application for recognition of a five-year integrated programme of education and training leading to the award of a Masters degree in pharmacy

9. (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 6, 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 8.
- (2) The Council, on receipt of an application under paragraph (1) 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 him or her to provide further information in support of his or her application.
- (3) 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.
- (4) 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.
- (5) 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.
- (6) 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 (4).
- (7) Where the Council has under Rule 8(5) published revised 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 revised 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

10. (1) Where the Council has recognised and granted its approval under Rule 9 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 9(1)(b) and any conditions that the Council may have imposed under Rule 9(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.

Visits to recognised institutions

11. (1) Notwithstanding the review to be conducted under Rule 10, where the Council has recognised and approved a Masters degree in pharmacy under Rule 9, the Council shall be entitled to arrange for the conduct of 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 12 and 13.

Manner of reviews and visits

12. (1) Where the Council carries out a review under Rule 10 or a visit under Rule 11, 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 associated training facilities and training establishments.
- (2) It shall be the duty of visitors having visited the institution, including any of its 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 continues to satisfy the requirements specified under Rule 9.
- (3) 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.
- (4) The visitors in their report to the Council on the institution concerned may recommend that the Council ó
 - (a) continue to grant its recognition and approval for the Masters degree in pharmacy,

- (b) continue to grant its recognition and approval for the Masters degree in pharmacy subject to certain conditions that they shall specify,
- (c) 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, or
- (d) 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

13. (1) The Council, on receipt of the report of the visitors under Rule 12, shall forthwith send a copy of the report to the institution concerned. 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 the report of the visitors as aforesaid and of any comments and observations received from the institution concerned, by resolution ó
- (a) continue to grant its recognition and approval for the Masters degree in pharmacy,
 - (b) continue to grant its recognition and approval for the Masters degree in pharmacy subject to certain conditions that it shall specify,
 - (c) defer a decision on its continued recognition and approval for the Masters degree in pharmacy pending the satisfactory resolution of certain matters of concern touching upon the requirements of these Rules, that it shall specify, or
 - (d) refuse to continue to grant its recognition and approval for the programme of education and training and give its reasons for so doing.
- (3) Where the Council proposes to adopt a resolution that would have the effect of refusing to continue to grant its recognition and approval for what was a Masters degree in pharmacy recognised and approved by the Council for any reason arising from the requirements of these Rules, it shall notify the institution accordingly and any notification given 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,

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

- (4) Where a resolution under paragraph (2)(d) 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 under Rule 9 had been granted, the Council may revoke the resolution to which paragraph (4) applies 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.

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

14. (1) A recognised institution in respect of which a Masters degree in pharmacy has been recognised and approved by the Council under Rule 9, 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 9 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 9, 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 9 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 13(2) and, should the Council propose to make such a resolution, it shall follow the procedure for such resolution as set out at Rule 13(3). The adoption of such a resolution shall have the consequences set out at Rule 13(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

15. (1) Subject to the provisions of this Part, and for the purpose of Rule 7(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 16(1) and which shall be undertaken during a period which includes the First Semester in the fourth year of the course, and
 - (b) not less than eight months under the direct supervision of a tutor pharmacist, in a registered retail pharmacy business in the State, or in the pharmaceutical department of a hospital in the State and which shall be undertaken in the fifth year of the course commencing in the Second Semester.
- (2) A person pursuing a Masters degree in pharmacy shall not undertake his or her in-service practical training in an establishment, or under the supervision of a tutor pharmacist, if he or she has a connection with either the establishment or the tutor pharmacist concerned.
- (3) For the purposes of this Rule, a person shall be regarded as connected if he or she or a connected relative of his or her is the pharmacy owner or in the case of any other establishment, if a connected relative is exercising any supervisory or management role in that establishment, and in the case of a tutor pharmacist, if he or she is a connected relative of that tutor.
- (4) In this Rule, the term "connected relative" has the same meaning as in paragraph 9 of Schedule 1 to the Act and includes a grandparent, uncle, aunt, niece or nephew of the person.

Establishments in which in-service practical training may be undertaken

16. (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 the said Rule 15(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 at least two of the following activities are undertaken ó
 - (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 drug substances for use as active pharmaceutical ingredients in medicinal products;
 - (vii) the conduct of research and development with a view to the discovery of:
 - (I) new 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 or medical devices.
- (2) The recognised institution may require any information which it considers reasonably necessary from any proposed training establishment referred to in

paragraph (1) or Rule 15(1)(b), for the purpose of giving its approval to the undertaking of in-service practical training at that establishment.

- (3) The in-service practical training required under Rule 15(1)(a) or 15(1)(b) shall be undertaken in an establishment approved by the recognised institution, provided the owner concerned \acute{o}
 - (i) being a pharmacist or pharmacy owner, is not the subject of any disciplinary sanction referred to in section 48(1)(b) (ii), (iii), (iv) and/or (v) of the Act as may, for the time being, be in force, or 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, and
 - (ii) being a pharmacist, pharmacy owner or other owner, has not, within two years of the date of commencement of the relevant in-service practical training, been convicted of any offence 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 in the case of any other offence, where the offence is one that has been tried on indictment.
- (4) Subject to paragraph (5), the in-service practical training required under Rule 15(1)(b) shall be undertaken under the direct supervision of a tutor pharmacist, as his or her sole pupil, 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 referred to in Rule 15(1)(a) may also be undertaking practical training 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 pharmacists who would be in a position to assist in the supervision of the pupil, the tutor pharmacist concerned may, at the sole discretion of the recognised institution concerned, be entitled to take on up to two further pupils, provided that there is, in the view of the recognised institution, appropriate levels of access to the tutor pharmacist by the pupils at the said premises during the in-service practical training.

Tutor pharmacists

17. (1) A registered pharmacist practising as such who \acute{o}
 - (a) has practised as a pharmacist for a minimum of 3 years with a minimum of 2 years of 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) and/or (v) of the Act as may, for the time being, be in force, or 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 16(3)(ii), and
- (f) in respect of the person pursuing the Masters degree in pharmacy, is not disqualified by virtue of Rule 15(2),

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

- (2) 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.

Holding of professional examination

- 18. (1) The recognised institution shall at the end of the fifth year following completion of the training referred to in Rule 15(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 aforementioned 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. This examination, which shall also include performance-based assessments, 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. The recognised institution shall support the operation of a Code of Conduct for pharmacy students which shall be drawn up in consultation with the Council. This Code shall have regard to the Code of Conduct established for pharmacists under the Act which will be binding on those 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 acquisition by the person of the Core Competency Framework for Pharmacists,
 - (b) that he or she has not become aware of any mental or physical ill-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. 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.

Amendment of Registration Rules

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

- ã(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, 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. XXX of 2014*).

SCHEDULE

Rules 5(1), 8(2)(b), 18(2).

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

1. (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 ó
 - (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,
 - (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 the Professional Qualifications Directive.

- (4) The in-service practical training 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 ó
 - (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),

- (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/EC², and
- (d) the inculcation of the primacy of the patient, and patient safety, above other considerations.

² O.J. No. L.311, 28/11/2001, p.67.

Dated this day of 2014

President

Registrar

I consent to the making of the above Rules.

Given under my Official Seal

this _____ day of _____, _____

Minister for Health

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 2014, 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 programme 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 the 1st June 2014 will not be impacted by the making of these Rules.