



STATUTORY INSTRUMENTS.

S.I. No. 493 of 2008

PHARMACEUTICAL SOCIETY OF IRELAND (EDUCATION AND
TRAINING) RULES 2008

(Prn. A8/1893)

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PHARMACEUTICAL SOCIETY OF IRELAND (EDUCATION AND
TRAINING) RULES 2008

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.

Dated this 28 day of November 2008

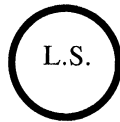
BERNARD LEDDY

President

AMBROSE McLOUGHLIN

Registrar

I consent to the making of these Rules.



GIVEN under my Official Seal,
28 November 2008

MARY HARNEY,
Minister for Health and Children.

S.I. No. 493 of 2008

PHARMACEUTICAL SOCIETY OF IRELAND (EDUCATION AND
TRAINING) RULES 2008

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S.I. No. 493 of 2008

PHARMACEUTICAL SOCIETY OF IRELAND (EDUCATION AND TRAINING) RULES 2008

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) Rules 2008.

Commencement

2. These rules shall come into force on 29 November 2008.

Interpretation

3. (1) 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);

‘Advisory Committee on Pharmaceutical Training’ means the Committee established by virtue of the EU Council Decision 85/434/EEC of 16 September 1985¹;

‘Council’ means the Council established by section 10 of the Act;

‘criteria’ means the criteria for the recognition and approval of programmes of education and training, leading to the award of a degree in pharmacy published under Rule 7 and which are for the time being in force;

‘designated learning and competencies’ in respect of a person pursuing a qualification appropriate for practice, has the meaning assigned to it in Rule 4 and refers to such document which is 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);

‘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;

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

Notice of the making of this Statutory Instrument was published in “Iris Oifigiúil” of 2nd December, 2008.

‘Professional Registration Examination’ means the examination conducted in accordance with Part 5;

‘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;

‘tutor pharmacist’ means a registered pharmacist who has been recognised by the Council under Rule 19;

‘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.

(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.

Designated learning and competencies for persons obtaining qualifications appropriate for practice

4. (1) For the purposes of these Rules, the Council shall prepare, adopt and publish a framework document setting out the designated learning and competencies which must have been acquired by a person who has pursued the programmes of education and training referred to in Rule 5 leading to a qualification appropriate for practice. Such document shall be known as the Designated Learning and Competencies and shall set out the designated learning and competencies including the body of knowledge, the skills, the practical experience, the training and the values which should be acquired by such a person and shall at least include those set out in the Schedule.

(2) The Council shall review and update the designated learning and competencies 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 pharmacy, healthcare practice and higher education.

(3) Where the Council proposes to amend the designated learning and competencies, 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 designated learning and competencies.

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—

- (a) holds a degree in pharmacy that is recognised and approved by the Council in accordance with Part 3,
- (b) has completed an in-service practical training programme in accordance with Part 4, and
- (c) has passed the Professional Registration Examination in accordance with Part 5,

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 DEGREE IN PHARMACY

Recognition and approval of degrees in pharmacy

6. Subject to the provisions of these Rules and for the purposes of Rule 5(a), the Council may recognise a degree in pharmacy if it—

- (a) provides not less than 4 years of full-time theoretical and practical training at a recognised institution, and
- (b) conforms to the designated learning and competencies in so far as they are relevant and appropriate to the training specified in paragraph (a).

Criteria for the recognition and approval of programmes of education and training leading to the award of a 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 programmes of education and training, leading to the award of a degree in pharmacy.

(2) Those criteria shall at least—

- (a) incorporate, in an indicative syllabus, those subjects and branches of knowledge set out in paragraph 2 of the Schedule and designated learning and competencies relevant to such programme, and
- (b) set out minimum requirements relating to the delivery of the programme including long-term commitment, staffing, premises, facilities, funding, policies, procedures and organisational structures.

(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 pharmacy, healthcare practice and higher education.

(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 be subsequently amended under this Rule.

Application for recognition of a programme of education and training leading to the award of a degree in pharmacy

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

- (a) make application in writing to the Registrar in the manner and form as may be prescribed by the Council from time to time, 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, funding and procedures, will conform with—
 - (i) the designated learning and competencies relevant to such programme, and
 - (ii) the criteria for the recognition and approval of programmes of education and training, leading to the award of a degree in pharmacy, published under Rule 7.

(2) The Council on receipt of an application under paragraph (1) and on being satisfied that the proposed programme leading to the award of a degree in pharmacy meets the requirements referred to in paragraph (1)(b), shall grant its recognition and approval for the said degree.

(3) In the grant of its recognition and approval to a recognised institution in respect of a degree in pharmacy offered by it, the Council may attach such conditions as may be relevant and necessary.

(4) On the recognition and approval of a degree in pharmacy under this Rule, the Council shall publish a notice to that effect in *Iris Oifigiúil* and on the Society's website.

(5) A recognised institution, in respect of which a 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 (3).

(6) Where the Council has under Rule 7(5) published revised criteria, the recognised institutions responsible for the award of the 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

9. (1) Where the Council has recognised and granted its approval under Rule 8 to a 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(3) 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 11 and 12.

Visits to recognised institutions

10. (1) Notwithstanding the review to be conducted under Rule 9, where the Council has recognised and approved a degree in pharmacy under Rule 8, 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 11 and 12.

Manner of reviews and visits

11. (1) Where the Council carries out a review under Rule 9 or a 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.

(2) It shall be the duty of visitors having visited the institution as aforesaid to report in writing to the Council as to whether in their opinion the standard of compliance and delivery of the degree in pharmacy continues to satisfy the requirements specified under Rule 8.

(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—

- (a) continue to grant its recognition and approval for the degree in pharmacy,
- (b) continue to grant its recognition and approval for the degree in pharmacy subject to certain conditions that they shall specify,
- (c) defer its decision on the continued recognition and approval for the 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 requirements of these Rules that they shall specify, or
- (d) refuse to continue to grant its recognition and approval for the 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 the report of the visitors under Rule 11, 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—

- (a) continue to grant its recognition and approval for the degree in pharmacy,
- (b) continue to grant its recognition and approval for the degree in pharmacy subject to certain conditions that it shall specify,
- (c) defer a decision on its continued recognition and approval for the 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 grant its recognition and approval for what was a 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 degree in pharmacy by the institution concerned shall be entitled to present for the Professional Registration Examination, or be entitled to registration as a pharmacist, on the basis of a 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 8 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 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

13. (1) A recognised institution in respect of which a 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 degree in pharmacy has been recognised and approved by the Council under Rule 8, shall notify the Registrar forthwith of any material changes 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 those changes are such as would enable any 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 Council 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) 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 PROGRAMME

Completion of the in-service practical training programme

14. (1) Subject to the provisions of this Part, and for the purposes of Rule 5(b), a person who has been awarded a degree in pharmacy that has been recognised and approved by the Council in accordance with Part 3 shall complete in the State at least twelve months of an in-service practical training programme, under the direct supervision of a tutor pharmacist, in a registered retail pharmacy business or in the pharmaceutical department of a hospital if he or she wishes to apply under Part 5 to present for the Professional Registration Examination. Such in-service practical training programmes shall be subject to the prior approval of the Council.

(2) Notwithstanding the provisions of paragraph (1), and in accordance with Rule 17, such a person may complete in the State a period of not less than 6 months practical training other than in a registered retail pharmacy business or the pharmaceutical department of a hospital with the prior approval of the Council, and always provided that at least 6 months of the required training shall have been conducted in a retail pharmacy business or in the pharmaceutical department of a hospital as provided for in paragraph (1).

Content and standards of the in-service practical training programme (including courses of education and training)

15. (1) The content and standards of the in-service practical training programme shall be designed so as to ensure that it conforms to the designated learning and competencies relevant and appropriate to such in-service practical training programme.

(2) The in-service practical training programme shall be conducted in a manner so as to ensure that the person undertaking the programme, as a minimum, has demonstrated his or her ability to apply competently—

- (a) the body of knowledge and skills acquired during the programme leading to the award of the degree in pharmacy,
- (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.

(3) For the purposes of achieving the outcomes specified in paragraph (2), the Council may require persons undertaking in-service practical training programmes to undertake, during such programmes, courses of education and training of such duration and length as the Council may require.

(4) The Council shall evaluate, including by way of assessment, the performance of such person with the aim of assessing his or her ability—

- (a) to apply those parts of the designated learning and competencies relevant and appropriate to the in-service practical training programme; and
- (b) albeit under the direct supervision of the tutor pharmacist, to competently pursue the profession of pharmacist.

Application to undertake the in-service practical training programme

16. (1) A person who has acquired a degree in pharmacy that has been recognised and approved by the Council, shall make application to the Registrar to undertake the in-service practical training programme referred to in Rule 14 if he or she wishes to apply under Part 5 to present for the Professional Registration Examination.

(2) A person making application to undertake the in-service practical training programme shall submit his or her application to the Registrar on a form available from the Council.

(3) Every such application form shall be signed by the person making the application and shall be accompanied by the following—

- (a) evidence to the satisfaction of the Registrar as to the identity of the person making the application,
- (b) evidence that the person holds a degree in pharmacy that has been recognised and approved by the Council in accordance with Rule 8(2),
- (c) a statutory declaration made by the person making the application that he or she is not aware of any reason on grounds of physical or mental health why he or she might be unable to discharge the responsibilities of a registered pharmacist if so registered,
- (d) a statutory declaration made by the person making the application that there is nothing in his or her past history, conduct or character that, having regard to patient safety and public health, would render it unsafe for that person be permitted to undertake the in-service practical training programme,
- (e) a written statement from the head of the school of pharmacy in the recognised institution from which the person obtained his or her degree in pharmacy, confirming the satisfactory acquisition by the person of the designated learning and competencies relevant to such

programme, which may be issued by the head of school on an individual or collective basis,

- (f) details of the retail pharmacy business or pharmaceutical department of a hospital or such other place where the proposed in-service practical training programme is to be undertaken,
- (g) name and registration number in the Register of Pharmacists of the proposed tutor pharmacist,
- (h) an undertaking from such tutor pharmacist that he or she is willing to directly supervise the said person's proposed in-service practical training programme, and
- (i) any fee that may be payable in connection with that application.

(4) For the purpose of confirming the information given by way of declaration under paragraph (3)(d), the Registrar may seek information from the head of the school of pharmacy in the recognised institution from which the person obtained his or her degree in pharmacy.

- (5) (a) Subject to subparagraph (b), in the event that the Registrar forms the opinion that he or she is not satisfied as to the past history, conduct and character of the person as referred to in paragraph (3)(d), then the person aggrieved by such opinion may request the matter to be reviewed by a panel of 3 persons appointed for that purpose by the Council as soon as is reasonably practicable.
- (b) One of the 3 persons appointed by the Council to the panel shall be a practising barrister or solicitor, with not less than ten years professional practice, or a retired judge.
- (c) The Council shall offer the person a reasonable opportunity to object on substantive grounds to the appointment of any one or more of the persons proposed as members of the said panel.
- (d) The panel shall operate its procedure in a manner laid down by the Council from time to time.
- (e) The panel, having considered such matters as may be put to it by the Registrar and the person concerned, shall then make a recommendation, giving reasons therefor, to the Council.
- (f) The Council shall make a final decision taking into account any such recommendations as may be made by the panel and any representations made by or on behalf of the person concerned.

Establishments in which six months of in-service practical training may be undertaken

17. (1) For the purposes of Rule 14(2), and subject to the prior approval of the Council, six months of an in-service practical training programme may be undertaken at one of the following establishments—

- (a) the pharmaceutical science department in a recognised institution,
- (b) a pharmaceutical establishment where at least two of the following activities are undertaken—
 - (i) the manufacture of medicinal products by an authorised manufacturer;
 - (ii) the conduct of tests of strength, quality or purity of medicinal products;
 - (iii) 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);
 - (iv) the preparation and assembly of information, documentation, samples and other materials as may be required in the making of applications for marketing authorisations;
 - (v) 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;
 - (vi) 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
- (c) an establishment, organisation or section thereof other than those of the types referred to in subparagraphs (a) and (b), where, in the opinion of the Council 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 or of medicinal products.

(2) The Council may require any information which it considers reasonably necessary from any proposed training establishment referred to in paragraph (1)

or Rule 14(1), for the purposes of giving its approval to the undertaking of in-service practical training at that establishment.

(3) Subject to paragraph (4), the Council may, in such exceptional circumstances as it may, in advance, approve on a case by case basis, permit a person to undertake the in-service practical training programme on a part-time basis, provided however that the total amount of such part-time training shall equate in terms of the amount of time devoted to it, to a period of twelve months full-time in-service practical training.

(4) In the circumstances referred to in paragraph (3), the period of in-service practical training concerned shall be completed by a person within a period of 3 years from the date on which the said person commenced the in-service practical training programme.

(5) Save in the circumstances described in paragraph (3) or in circumstances which have been approved in advance by the Council on a case by case basis, no period of in-service practical training of less than 6 consecutive months' duration shall be recognised by the Council.

(6) The practical in-service training programme shall be undertaken in an establishment approved by the Council under the supervision of a tutor pharmacist as his or her sole pupil.

Completion of the in-service practical training programme

18. (1) In order to be deemed by the Council to have satisfactorily completed the in-service practical training programme, the person shall—

- (a) have satisfactorily completed such assessments as the Council may have set down for the purposes of the evaluation of the performance of such person under Rule 15(4), and
- (b) submit a statutory declaration signed by his or her tutor pharmacist or, in a case where there is more than one tutor pharmacist, by both or all of the said tutors, attesting—
 - (i) to the completion of the requisite period of training under the tutor pharmacist's supervision,
 - (ii) to the completion of the designated learning and competencies relevant to such in-service practical training programme, and
 - (iii) subject to paragraph (2), that the tutor pharmacist is not aware of any reason, on grounds of health or character, as to why the person might be unfit to be registered as a pharmacist.

(2) In the event that a tutor pharmacist is not in a position to complete the statutory declaration provided for in paragraph (1)(b) by reason of his or her death or incapacity, any other pharmacist who was working in the establishment during the period of the placement may, subject to the prior approval of the Registrar, complete the statutory declaration provided for in paragraph (1)(b).

(3) In the event that a tutor pharmacist does not agree to complete the statutory declaration provided for in paragraph (1)(b), the person may request that the matter be reviewed by a panel which shall be constituted for the purpose in the manner provided for in Rule 16(5).

(4) The Council shall offer the person a reasonable opportunity to object on substantive grounds to the appointment of any one or more of the persons proposed as members of the said panel.

(5) The panel shall operate its procedure in a manner laid down by the Council from time to time.

(6) The panel, having considered the matter as may be put to it by the tutor pharmacist and the person concerned, shall make a recommendation, giving reasons therefor, to the Council.

(7) The Council shall make a final decision, taking into account any such recommendations as may be made by the panel and any representations made by or on behalf of the person concerned, and which may include requiring the person to undertake further education and training or in-service practical training.

Tutor pharmacists

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

- (a) has practised as a pharmacist for a minimum of 3 years with a minimum of 1 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 Council from time to time, and
- (c) meets the standard of knowledge, skills and experience as may be required by the Council from time to time for such pharmacists,

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

(2) The Council shall from time to time specify the requisite standards of knowledge, skills, experience required of a registered pharmacist and the programmes of education and training to be completed by a registered pharmacist from time to time in order that he or she may act as a tutor pharmacist under these Rules.

PART 5

PROFESSIONAL REGISTRATION EXAMINATION

Eligibility to apply to present for the Professional Registration Examination

20. For the purposes of Rule 5(c), a person who has obtained a degree in pharmacy recognised and approved by the Council in accordance with Rule 8(2)

and who has successfully completed the in-service practical training programme in accordance with Part 4 shall, upon making application to the Registrar and upon payment of the prescribed fee, be eligible to present for the Professional Registration Examination.

Holding of the Professional Registration Examination

21. (1) The Professional Registration Examination shall be held by or on behalf of the Council twice annually.

(2) The Council shall from time to time establish and publish the syllabus for the Professional Registration Examination, which shall be based on the designated learning and competencies, and shall have particular emphasis on the legislation and the law pertaining to pharmacy and medicinal products and to the practice of pharmacy in the State and the professional conduct and ethics of a person practising as a pharmacist in the State.

(3) A person shall pass the Professional Registration Examination within 3 years of his or her successful completion of the in-service practical training programme.

(4) In respect of the Professional Registration Examination, the Council shall establish and publish examination procedures and the standards to be achieved. The said procedures shall be reviewed and, if necessary, updated at intervals not exceeding five years and all persons undertaking the examination, shall be required to abide by the said examination procedures.

(5) The Council shall have the power to appoint examiners, external examiners and appeals examiners and such examiners shall be eligible for re-appointment but shall not serve as examiners for more than 6 consecutive sittings of the Professional Registration Examination.

PART 6

TRANSITIONAL PROVISIONS

Transitional provisions

22. (1) A person who, on the coming into force of these Rules, is undertaking a course of studies leading to the award of a degree in pharmacy recognised and approved under the Pharmacy Acts 1875 to 1977, or who is undertaking under such Acts a period of in-service practical training leading to registration as a pharmaceutical chemist under those Acts, shall be considered as if such course of studies, or such period of in-service practical training, were being undertaken under these Rules.

(2) Degrees in pharmacy that had been recognised and approved by the Council, under the Regulations of the Pharmaceutical Society of Ireland (Amendment) Regulations 2002 (S.I. No. 212 of 2002) and in force immediately before the coming into operation of these Rules, shall continue to be recognised and approved as if such recognition and approval had been granted under these Rules.

SCHEDULE

Rule 4

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

1. The period of time to be devoted by a person in acquiring the designated learning and competencies as required of a pharmacist shall consist of a programme of education and training of at least five years duration including at least—

- (a) four years of fulltime theoretical and practical training at a recognised institution, and
- (b) twelve months of in-service practical training in accordance with Part 4 of these Rules.

2. (1) The aforementioned programme of education and training in the course of training for pharmacists 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,
- (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 said programme of education and training shall, where appropriate, also have regard to—

- (a) the report on 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 15/E/84341/6/93), and
- (b) the minimum conditions of qualification specified in paragraph (2) of Article 49 of Directive 2001/83/EC².

² O.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.

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 degree in pharmacy in the State.

In addition, the procedures and requirements which apply to the in-service practical training programme and the Professional Registration Examination leading to obtaining a qualification appropriate for practice are set out in these Rules.

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