RCSI

GENERAL ISSUES IN THE ADMINISTRATION OF THE PROFESSIONAL REGISTRATION EXAMINATION (PRE) FOR THE October 2015 AND MAY 2016 SITTINGS

ORIGINAL FORMAT

RCSI DEVELOPING HEALTHCARE LEADERS WHO MAKE A DIFFERENCE WORLDWIDE

GENERAL ISSUES IN THE ADMINISTRATION OF THE PROFESSIONAL REGISTRATION EXAMINATION (PRE) ORIGINAL FORMAT FOR THE October 2015 AND MAY 2016 SITTINGS

Document Control

Version	Status	Author	Origin	Reviewer	Approved	Date
1.0	Draft	Siun Ahern, Matthew Lynch	2014/2015	, Michelle Flood, Susan Gray, James Barlow	n/a	
Final				PSI Council		
Final				RCSI Academic Council		
Final				RCSI Medicine and Health Sciences Board		

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1.0 GENERAL ISSUES IN THE ADMINISTRATION OF THE PROFESSIONAL REGISTRATION EXAMINATION

1.1 General Professional Registration Examination Regulations

These are the examination regulations of the Professional Registration Examination (PRE) (Original Format) for the October 2015 and May 2016 sittings (where held)which is provided by the Royal College of Surgeons of Ireland (RCSI) for the Council of the Pharmaceutical Society of Ireland (PSI) and with appendix A constitute for the purposes of the *Pharmaceutical Society of Ireland (Education and Training) Rules 2008* (SI 493/2008; Appendix B) the 'examination procedures and standards to be achieved'. All subsequent references to Professional Registration Examination or PRE hereafter in this document refer to the examination in its original format only. It should be noted that the provisions of this document apply only to the original format of the Professional Registration Examination. The new format Professional Regulation Examination for those undertaking the NPIP from 2014/2015 onwards is the subject of a separate General Issues document.

The PRE may be undertaken by i) interns as part of the National Pharmacy Internship Programme (NPIP); ii) by pharmacists as part (Stage 4) of the recognition process of Third Country Pharmacists Qualifications for the purposes of Section 16(2)(b) of the Pharmacy Act 2007 as amended and iii) by other candidates instructed to do so for defined purposes as determined by the Council of the PSI.

This document is intended to be read in conjunction with the syllabus for the Professional Registration Examination (Appendix A), *the Pharmaceutical Society of Ireland (Education and Training) Rules 2008* (Appendix B), the current version (at the taking of the examination) of the College policy documents: RCSI Examination and Assessments, RCSI Exceptional Circumstances Policy and RCSI Appeals Policy and Procedures. All RCSI Policy documents can be accessed on request from the Programme Co-ordinator (mpharm@rcsi.ie).

1.1.1 PRE

1.1.1.1Candidates will be notified of the PRE dates at least three months in advance of the intended sitting. It is important to note that examination times and venues are subject to change at short notice. It is the responsibility of the student to be available for the duration of the entire assessment period as outlined by the Programme Team.
1.1.1.2 Eligibility for candidates to apply to sit the PRE is in accordance with Rule 20 (1) of

the *Pharmaceutical Society of Ireland (Education and Training) Rules 2008*. In the event that a tutor pharmacist is not in a position to complete the statutory declaration provided for in Rule 18 (1)(b) of the *Pharmaceutical Society of Ireland Education and Training Rules* (2008) ['the Rules'] the candidate may appeal the decision to the PSI appeals process in accordance with the Rules. The details of this Appeal Procedure can be obtained from the PSI (education@thepsi.ie).

1.1.1.3 The PRE (where held) must be taken at the appointed times in each year.
1.1.1.4 All candidates for the PRE are made aware that they must ascertain for themselves the most current dates for the application deadlines for the examination, the actual dates of the examination, and any other relevant dates relating to the examination. Notices concerning this information will be issued by the progamme coordinator and are available from the PSI.

1.1.1.5 It is the responsibility of each candidate to ascertain the specific dates, assigned venues and times of the PRE.

1.1.1.6 Students with a disability as defined in the Equal Status Acts (Ireland) 2000 to 2004 are advised to contact the Disability Support Service (DSS) disability@rcsi.ie on admission to the College, or on subsequent diagnoses, if special arrangements may be required for the completion of examinations. Students are required to apply for alternative examination arrangements (i.e. additional exam supports) at least 6 weeks prior to the date set for examination.

1.1.2 Admission to Examination Areas

1.1.2.1 Admission to examination areas is set out in the Policy document RCSI Examinations and Assessments. This should be accessed directly from the Programme Co-ordinator.

1.1.3 Conduct, absence, illness and breaches of regulations during examinations

1.1.3.1 Conduct, absence, illness and breaches of regulations during examinations is set out in the Policy document RCSI Examinations and Assessments. This should be accessed directly from the Programme Co-ordinator.

1.1.3.2 Candidates must adhere to the rules documented in the *Professional Registration Examination (PRE) Rules of Conduct* document issued to all candidates in advance of the examination taking place.

1.1.4 Professional Registration Examination

1.1.4.1 Candidates are required to apply to the PSI to undertake the PRE in accordance with Rule 20.

1.1.4.2 Every eligible candidate is required to sit the PRE at the first sitting in the Academic Year, unless he/she is absent by permission or through illness. In the event of illness, a candidate who is unable to attend the examination must lodge a medical certificate as soon as possible and always within THREE days of the examination. Further details can be found in the Exceptional Circumstances Policy available on request from the Programme Co-ordinator.

1.1.4.3 An intern (this excludes Recognition of Third Country Pharmacist Qualification as a Qualification as appropriate for practice in Ireland [TCQR applicants] and other candidates referred to in Section 1.1 of this document) who fails in any element of the PRE must, before he/she is re- examined, produce evidence that he/she has pursued the study of the subject in which he/she was referred during the interval before the next sitting of the PRE.

1.1.4.4. Breaches of Examination Regulations and Procedures following the evacuation of a College building during the course of the PRE are set out in RCSI Examinations and Assessments Policy document for the relevant academic year, available on request from the Programme Co-ordinator.

1.2 Exceptional Circumstances

1.2.1 The RCSI Exceptional Circumstances Policy applies to each sitting of the PRE and all eligible candidates should familiarise themselves with the Policy document for the relevant academic year, available on request from the Programme Co-ordinator.

1.3 Feedback on Performance in the Professional Registration Examination

1.3.1 Feedback following Multiple Choice format assessments

The Programme Director of Assessment (or his/her nominee) will provide feedback to candidates on their performance in part 2 of the PRE. Feedback on individual examination performance in multiple choice format assessments (Part 1 of PRE) will not be provided to candidates. Illustrative multiple choice questions will be made available to students electronically on the VLE.

1.3.2 Feedback following Objective Structured Clinical Examination (OSCE)

Candidates who wish to receive individualised feedback on their performance in Part 2 of the PRE must contact the NPIP Programme Coordinator (mpharm@rcsi.ie) within fourteen (14) calendar days of the date of publication of the relevant OSCE results to make an appointment to meet with the Programme Director of Assessment to discuss their request for feedback.

1.4 Procedures for Post Assessment Moderation

1.4.1 RCSI has a system of internal moderation, which takes place after the PRE, and in advance of both the PSI and the joint RCSI and National University of Ireland (NUI) examination boards. All candidates for the PRE should familiarise themselves with this moderation process which is set out in RCSI Policy on Examinations and Assessment for the relevant academic year, available on request from the Programme Co-ordinator. As a consequence of this moderation process examination re-checks are not permitted.

1.5 Appealing the Decision of an Examination Board

1.5.1 Appealing the decision of an examination board for the PRE is set out in the Policy on Appeals for the relevant academic year, available on request from the Programme Co-ordinator.

1.6 Delivery of examination results to candidates

1.6.1 Examination marks and grades are delivered directly to interns' with a registered student number electronically via email as soon as is practicable following the relevant Examination Board meetings.

1.6.2 The marks and grades for TCQR candidates are delivered to them directly by officers of the PSI as soon as is practicable following the relevant Examination Board meetings.

1.6.3. Transcripts can be ordered for interns via the Moodle.

1.7 Time expiry

1.7.1 A candidate shall pass the PRE within 3 years of his or her successful completion of all other required components of the programme they are undergoing. This three (3) year time period shall not include any period of statutory protected leave such as Maternity Leave, Parental Leave, Carer's Leave and/or Adoptive Leave and may not include any period of Sick Leave approved by the PSI.

1.7.2. An intern (not a TCQR or other candidate), as part of the requirement to obtain a M.Pharm. shall be successful in undertaking the PRE within a maximum of four sittings.

2.0 THE ROLE OF NUI AND PSI EXTERNAL EXAMINERS

2.1.NUI External Examiners

The appointment, term and responsibilities of External Examiners appointed by the National University of Ireland to the Masters in Pharmacy programme is in accordance with the NUI Senate Policy Document and the RCSI policy on NUI External Examiners. These policy documents are available on request from the NPIP Programme Director.

2.2 PSI External Examiners

The Council of the PSI will appoint External Examiners as provided for in Rule 21(5) of the Rules. Such appointed examiners are eligible for re-appointment but shall not serve as examiners for more than 6 consecutive sittings of the PRE.

2.3 Function

The External Examiner (this applies to both NUI and PSI appointed individuals to act in that capacity) acts as a reviewer and moderator of the assessment process, which is carried out by the internal examiners. The External Examiner takes an overview of standards, assessment and grading and is not involved ordinarily in the assessment of individual candidates.

The participation of External Examiners in the assessment process of the PRE is in accordance with the following principles:

[a] External Examiners will review assessment strategies and assessment instruments to confirm their appropriateness;

[b] External Examiners may review candidates assessed work to determine that internal assessment and grading practices are appropriate and consistent. External Examiners will have reasonable access to such examples of the candidates assessed work, as they deem necessary;

[c] External Examiners should not normally act as second markers of candidates work;

[d] External Examiners may review the distribution of grades to confirm results and may

recommend adjustments for a cohort of students;

[e] External Examiners will comment on the standards achieved by candidates in relation to the pre-determined academic outcomes set and in comparison with national and international standards for the subject area;

[f] External Examiners may provide advice and guidance on teaching, learning and assessment practices and this advice may also contribute to wider quality processes within the School.

Appendix A

Syllabus for theProfessional Registration Examination (Original Format) for the October 2015 & May 2016 sittings (where held)

NUI & RCSI External Examiner: Professor Derek. Stewart (Robert Gordon University)

PSI External Examiners: Professor Stephen Byrne (University College Cork) & Professor Kevin Mc Guigan (RCSI)

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Preamble:

This document is the syllabus of the Professional Registration Examination which is the summative assessment of the *National Pharmacy Internship Programme* (Section 1) and Stage 4 of the application process of a *Third Country Pharmacist Qualification as a Qualification Appropriate for Practice* (Section 2).

1.0 National Pharmacy Internship Programme

The qualification at the successful completion of the National Pharmacy Internship Programme (NPIP) is a Master of Pharmacy (National Framework of Qualifications Level 9 Major Award), which will be awarded by the National University of Ireland (NUI). It is a twelve-month, full-time; blended-learning programme conducted over three semesters. Satisfactory completion of six taught modules (including tutor-assessed competency standards), a research dissertation module and a Professional Registration Examination (PRE) is required. Successful completion of each taught module will attract 10 European Credit Transfer and Accumulation System (ECTS) credits. The basis for the curriculum is the identification and definition of learning outcomes that describe the knowledge, skills and behaviours required of a newly registered pharmacist. These outcomes are mapped to the objectives, learning outcomes and syllabus of the appropriate module. Pharmacy intern performance is assessed by tutor appraisals, in-course assessment and formative and summative assessments. Required competencies are consistent with international norms for pharmacy professional education. A substantial dissertation (either an organisational development dissertation or a clinical audit) will be required, attracting 30 ECTS credits. The PRE will be a terminal assessment that will contain multiple-choice questions (MCQs) on pharmaceutical calculations and prescribing science and an Objective Structured Clinical Examination (OSCE). This terminal assessment is accounted for in the assessment strategies of each of the taught modules and is subject to the approval of the Council of the PSI that is the basis of this document. The entire programme carries 90 ECTS credits.

2.0 Third Country Pharmacist Qualification

Sections 16(2)(b) and 16(6) of the Pharmacy Act 2007 (as amended) enables the Council of the Pharmaceutical Society of Ireland (PSI) to recognise formal qualifications as pharmacists obtained in third countries, as qualifications appropriate for practice, provided that the standard of any such qualification is not lower than the standard of those necessary for practice in Ireland. The details of how this process operates are set out in general terms in Part 6 of the Pharmaceutical Society of Ireland (Registration) Rules 2008 (*S.I. No. 494 of 2008*). Broadly, there are 4 stages which, when completed, will result in the issue of a Certificate enabling the applicant to make application for registration as a pharmacist in Ireland. The PRE is contained in Stage 4.

Stage 1 – Assessment of qualification to determine if it meets the minimum training conditions for pharmacists specified in Article 44 of the Professional Qualifications Directive (Directive 2005/36/EC as amended). If it appears that the qualification may conform to these minimum conditions, the Applicant proceeds to Stage 2. If not, the application is rejected.

Stage 2 – Assessment of standard of applicant: The applicant must sit an Equivalence Examination to determine his/her standard of training, education, examinations and qualifications. This examination also takes into account any other relevant training undergone or experience gained by the applicant, evidence of which is provided by the applicant in the form of a portfolio. The Equivalence Examination takes the form of a Multiple Choice Question (MCQ) examination and an Objective Structured Clinical Examination (OSCE) which is conducted by the School of Pharmacy, RSCI, on behalf of the PSI. The standard of questions set in the MCQ and OSCE is set at Level 9 of the National Framework of Qualification (Level 7 of the European Qualifications Framework). The performance of the applicant in the Equivalence Examination, taking into account any evidence in his/her portfolio, is assessed by a panel of independent assessors who make a recommendation to Council as to the standard of the applicant *(see Role of Assessor and Purpose of this Form).*

Stage 3 – Adaptation period: If following completion of the assessment in Stage 2, the Council has any doubt about a matter relating to the standard of training, education, examinations and qualifications of the applicant in acquiring his or her qualification as a pharmacist, he or she will be required to undertake an **adaptation period** (i.e. period of in-service practical training) of not less than 6 months' duration which must be satisfactorily completed before presenting for the PRE.

Stage 4 – Professional Registration Examination: The applicant is required to sit and pass the PRE of which this document outlines the approved syllabus and specimen questions for Part 1.

Upon satisfactory completion of all of the above four Stages, the applicant will be issued with a certificate confirming he/she is regarded as having a **qualification appropriate for practice in Ireland** and he or she may then proceed to make application to the PSI for registration as a pharmacist.

3.0 Approach to assessment

As health care delivery increasingly undergoes major transformation due to a range of factors, so too does the education of pharmacists, who will work in these new environments. An ever increasing knowledge base, new technologies, the exponential increase in the range of medicinal products and devices, the need for cost effectiveness and increasing awareness of the risk and cost to society of medical therapies are some of the changes affecting the delivery of health care.

The traditional artificial divide between didactic teaching of intensive highly discipline-organised basic sciences followed by a period of unstructured clinical activity is increasingly regarded as not preparing interns adequately for their future work. In addition, many educators have long held the view that the pharmacy school experience does not prepare pharmacists adequately to attend to the 'whole' person, to the psychological needs of patients, to the health services within which they will be practising or to the health care needs of communities and of the population.

In response to these concerns there is now much more emphasis on greater integration of basic and clinical sciences, greater emphasis on the grasp of concepts rather than memorising facts as well as greater focus on clinical teaching, which is better aligned to the changes in health care delivery. The most recent approaches to pharmacy education are also best described as a redirection towards an experiential, learner-centred model that will enable pharmacists to be both life-long learners with the knowledge and skills available to value the psychosocial as well as the biological aspects of health care.

Assessment has been at the forefront of RCSI's thinking when developing the NPIP. It has been recognised that meaningful education and training would not occur without significant reform of assessment practice that was part of the old pre-registration year. It is essential that interns are competent to practice safely and in a skilful and compassionate manner. It is only through valid and reliable assessment that RCSI can ensure that graduates have the requisite skills to practice competently and compassionately.

The assessment strategy for the M. Pharm. uses a variety of assessment modalities mindful of the need to balance validity with reliability. Knowledge will be assessed using a mix of multiple-choice questions, extended matching items and constructed response questions. Skills will be evaluated using predominantly Objective Structured Clinical Examinations (OSCEs). Project work, supervisor reports and portfolios will be used for testing knowledge, attitudes and reflective skills.

3.1 Purpose of assessment

When considering an appropriate assessment, the purpose of that assessment needs to be taken in to account for it will influence methods and implementation. The purpose of assessment in the NPIP includes the following aspects:

- Judge mastery of knowledge, skills and attributes;
- Provide feedback (to interns and tutors);
- Motivate interns to learn;
- Direct and drive intern learning.

The development and implementation of the new outcomes-based M. Pharm. curriculum at RCSI has represented a major shift from the more traditional discipline-based approach to curriculum delivery. Using this approach assessment is regarded as an integral element and is linked intimately to module outcomes.

3.2 Formative and summative assessment

As part of the curriculum design there has been a move away from the predominantly summative nature of assessment of the past towards a greater emphasis on formative assessment. Like summative assessment, formative assessment measures student mastery of a unit's learning outcomes but it does not provide a barrier to progression through the course. It is intended to give students feedback on their learning progress and opportunities to improve knowledge and refine performance. It is also an opportunity for the teacher to note what students have mastered and which students require remediation. Although the overall strategy will emphasise formative assessment to assist student learning, it is recognised that RCSI has a responsibility to ensure interns enter the register able to practise in a competent manner; i.e. that they are *fit for purpose*. This is achieved by mandating competency in all parts of the competence standard framework (Level 4) before graduation.

The summative assessment strategy is the PRE and the syllabus is set out hereafter.

4.0 Professional Registration Examination (PRE) Original Format

Eligibility to sit and frequency of the PRE will be as per the requirements determined in Rule 20 of the *Pharmaceutical Society of Ireland (Education and Training) Rules 2008*.

The syllabus for the PRE requires approval by the Council of the PSI. The PRE will be in two parts: Part 1 & Part 2. Part 1 comprises Part A: Pharmaceutical Calculations MCQ and Part B: Inter-professional Prescribing Science MCQ. Part 2 consists of a 12 station OSCE. Parts 1 and 2 must be passed independently of one another and compensation between Parts 1 and 2 is not permitted. Within Part 1, Parts A and B must be passed independently of one another and compensation between Parts A and B is not permitted.

4.1 Part 1 of the PRE

Part 1 of the PRE is in multiple choice question (MCQ) format. It will comprise of 80 MCQ questions and candidates will be given 180 minutes for completion of Part 1.

Table 1: Part 1 of the Professional Registration Examination

Part	Subject Area	Aligned Module
A	Pharmaceutical Calculations	MP1
B	Inter-professional Prescribing Science	MP2

Part 1 will be comprised of two parts (Part A and Part B). The examination papers for Part A and Part B will be distributed at the commencement of the examination. Part A will be comprised of 40 MCQs in pharmaceutical calculations. The answer sheets (in the form of completed electronic score sheets) for Part A will be collected 120 minutes after the commencement of the examination and those for Part B after 180 minutes. Part B will be comprised of 40 MCQs in prescribing science. The cut score for Part 1 will be determined using statistical methods as approved by the appointed external examiners.

4.1.1 Syllabus for part 1

Part A: Pharmaceutical Calculations

- Systems of Units
- Concentrations
- Dilutions
- Formulations
- Calculation of doses
- Density, displacement volumes and displacement values
- Calculations involving molecular weights
- Parenteral solutions and isotonicity

Part B: Inter-professional prescribing science

A. Prescribing science

1) Prescribing

2) Prescribing in renal impairment

i) Assessing renal function

ii) Nephrotoxic drugs

iii) Drug dosing in renal disease

iv) Drug choice in renal disease

- (a) Analgesia
- (b) Antibiotics
- (c) Anticoagulation

3) Prescribing in liver impairment

i) Assessing liver function

ii) Drug induced liver disease

iii) Drug choice in liver disease

- (a) Analgesia
- (b) Antibiotics
- (c) Anticoagulation

4) Prescribing in the elderly

i) Drug handling in the elderly

ii) Adverse drug reactions

iii) General principles of prescribing

B. Antibiotic & Anti-infective therapy

1) Antibiotic theory

i) Antimicrobial resistance and stewardship

ii) Choice of therapy – empiric and directed

iii) Allergy and cross-reactivity

iv) Monitoring therapy

2) Hospital acquired infections

i) Vancomycin resistant enterococcus

ii) Clostridium difficile

iii) Methicillin resistant staphylococcus aureus

3) Soft tissue and bone infections
i) Cellulitis
ii) Osteomyelitis

4) Infectious endocarditis
i) Sub-acute bacterial endocarditis
ii) IE in patients with prosthetic valves
iii) IE in intra-venous drug users

5) Respiratory tract infections
i) Community Acquired Pneumonia
ii) Hospital Acquired Pneumonia
iii) Respiratory tract infection in specialised groups, e.g. CF, COPD

6) Genitourinay infections

C. Analgesia

1) Acute pain
i) Pain in surgical patients
ii) Pre-operative analgesia options
iii) Post-operative pain relief
iv) Pain management in Acute Coronary Syndrome

2) Chronic pain
i) Visceral pain, e.g. chronic pancreatitis
ii) Arthritic pain
iii) Bony pain
iv) Neuropathic pain
v) Pain management in cancer patients
vi) Pain management in palliation

D. Anti-coagulation
1) Warfarin therapy

i) Indications for warfarin therapy

ii) Commencing warfarin therapy

iii) Monitoring warfarin therapy

iv) Side-effects

v) Interactions – changing dosage while on antibiotics, etc.

vi) Warfarin in renal impairment, liver impairment, the elderly and perioperatively

2) Heparin therapy

i) Indications for heparin therapy

(a) Treatment of Deep Vein Thrombosis & Pulmonary Embolism

(b) Adjuvant therapy in Acute Coronary Syndrome

(c) Prophylactic usage in surgical patients

(d) Prophylactic usage in medical patients

ii) Monitoring heparin therapy

iii) Side-effects

iv) Heparin in renal impairment, liver impairment, the elderly and perioperatively

4.2 Part 2 of the PRE

Part 2 will consist of 12 OSCE stations (2 aligned to each of the 6 modules undertaken) where each intern will be assessed

Number of stations	Station theme	Aligned Module
2	Patient care-safe dispensing	MP1
2	Interprofessional prescribing science	MP2
2	Clinical practice	MP3
2	Professional practice	MP4
2	Patient safety and risk management	MP5
2	Health and medicine information	MP6

- Standard setting of the interactive stations will be performed using statistical methods as agreed by the appointed external examiners
- Non-interactive stations will have a pre-determined pass mark of 50%

4.2.1 Syllabus for Part 2

- *MP1: Patient care: safe dispensing competencies (CS1)); e-learning resources: dispensing and pharmaceutical calculations and on-line lectures and resources*
- *MP2: Interprofessional prescribing science competencies (CS2)) and interprofessional eCases*
- *MP3: Clinical practice competencies (CS3);* Case-Interact© *e-learning and AED & General First Aid course*
- *MP4: Professional practice competencies (CS4); on-line lectures and resources*
- *MP5: Patient safety and risk management competencies (CS5); on-line lectures, videos and resources and PSRM contact sessions*
- *MP6: Health and medicine information competencies (CS6); on-line lectures and resources*

4.2.2 OSCE station construction

The OSCE is a flexible test format based on a circuit of stations at each of which an intern is required to demonstrate a specific clinical skill. At interactive stations, interns interact with a simulated patient (SP) and are assessed on their display of knowledge, attitudes and skills. Station construction is carried out at the RCSI School of Pharmacy on a modular basis. The content of the OSCE, i.e. clinical tasks chosen for the stations will be determined with reference to the curriculum. This blueprinting will ensure that sampling of all domains and themes of the curriculum occurs and thus ensure validity of the OSCE. The complexity of the station tasks will be commensurate with a Level 9 qualification.

The number of stations in the OSCE for each intern will be 12. One examiner will be present at each interactive station. To improve reliability indices, the minimum number of interactive stations (i.e. where a student is assessed interacting with a patient or performing a practical skill) will not be less than eight. The duration of each station will be 5 minutes. All stations will carry equal weighting. Clear instructions will be made available for students, examiners and simulated patients. Briefing of simulated patients will take place prior to Part 2 of the PRE in conjunction with the assessors in a formal and structured manner. This will ensure predictable and consistent ‘clinical’ performance across a number of station circuits.

4.3 Quality assurance

The RCSI Director of Quality Enhancement and Associate Director of Quality will provide quality assurance for Parts 1 and 2 of the PRE internally.

5.0 Specimen questions

5.1 Specimen questions Part 1A

1. A patient on the ward has been prescribed aminophylline in accordance with the following directions.

RCSI Hospital
York Street
Dublin 2

Date: 18/11/12
Patient: Michael Jones
Ward: Intensive Care Unit
Age: 12 years
Weight: 60kgs

Aminophylline 700micrograms/kg/hr

An intravenous solution has been prepared that contains aminophylline 500mg/250ml.

At what rate should this be infused (in mL/hr) to provide MV with the prescribed maintenance dose?

a) 14mL/hr
b) 21mL/hr
c) 23mL/hr
d) 42mL/hr

e) 84mL/hr

2. A liquid medicine being used for a clinical trial is supplied at a concentration of 100mg/5ml. A patient requires 25mg four times a day for 7 days, 20mg three times a day for 5 days, 15mg twice a day for 3 days and 10mg thereafter.

What volume of liquid medicine is needed to provide enough medication for the first 28 days of treatment?

a) 32mL
b) 61mL
c) 204mL
d) 303mL
e) 605mL

3. You have prepared an extemporaneous preparation and now need to label it with the final concentrations of each ingredient. You have mixed 50g of 0.5% w/w hydrocortisone cream and 25g of 2% w/w sulfur cream (the creams are compatible).

What is the final concentration of each of the two drugs? (all concentrations are in %w/w)

a) 0.5% hydrocortisone and 2% sulfur
b) 0.33% hydrocortisone and 0.67% sulfur
c) 0.22% hydrocortisone and 0.67% sulfur
d) 0.67% hydrocortisone and 0.33% sulfur
e) 0.33% hydrocortisone and 0.33% sulfur

4. You are working in a medicines information department and have been asked about the preparation papavertum.

Papaveretum

General Notices

Action and use

Opioid receptor agonist; analgesic.

Preparation

Papaveretum Injection

DEFINITION

Papaveretum is a mixture of 253 parts of Morphine Hydrochloride ($C_{17}H_{19}NO_3$,HCl,$3H_2O$, 375.9), 23 parts of Papaverine Hydrochloride ($C_{20}H_{21}NO_4$,HCl, 375.9) and 20 parts of Codeine Hydrochloride ($C_{18}H_{21}NO_3$,HCl,$2H_2O$, 371.9)

Supplementary information
Molecular weight of anhydrous morphine: 285g/mol
Molecular weight of morphine hydrochloride trihydrate 375 g/mol

Calculate the amount of anhydrous morphine (% w/v) present in papaveretum injection formulated at a concentration (15.4mg/1mL ampoule)

a) 0.25% w/v
b) 0.5% w/v
c) 1%w/v
d) 1.25% w/v
e) 1.5% w/v

5. A patient has been prescribed Epilim® 800mg (sodium valproate) intravenously. It is to be reconstituted to 10mL with water for injection. The displacement volume is 0.25mL/400mg. The displacement volume was not taken into consideration when reconstituting the injection and 10mL of water for injection was added. 10mL of the resulting solution was administered to the patient.

What dose of Epilim® did the patient actually receive (to the nearest mg)?

a) 727mg
b) 762mg
c) 800mg
d) 827mg
e) 848mg

6. You are a pharmacist working on a ward in a hospital. An intern has asked you to double-check a calculation to make sure it is correct. A patient is to be administered 3 litres of 5% w/v glucose over 4 hours. The giving set that will be used delivers 2 drops/mL.

What drop rate should be used?

a) 1.5 drops per minute
b) 6.25 drops per minute
c) 12.5 drops per minute
d) 25 drops per minute
e) 62.5 drops per minute

7. You are working in a busy hospital and the outpatient department has requested glucose powder for glucose tolerance tests. They commonly use Glucose BP, which refers to the monohydrate form. However, due to commercial shortages, you have to supply Anhydrous Glucose BP. The usual dose used in your hospital is 55g Glucose BP.

How much Anhydrous Glucose BP should you package in each single-dose container?

Molecular weight $C_6H_{12}O_6$= 180.16
Molecular weight $C_6H_{12}O_6.H_2O$= 198.17

a) 18g
b) 50g
c) 60.5g

d) 68g

e) 73g

8. A child is prescribed methotrexate once weekly for treatment of leukaemia. The child is 2 feet 5 inches tall and weighs 11kg. In the hospital formulary the dose is 15mg/m^2. You have the formula for body surface area in the dispensary.

$$BSA\ (m^2) = \sqrt{\frac{Height\ (cm)\ X\ Weight\ (kg)}{3600}}$$

Note: 1 foot=12 inches= 304.8mm)

What weekly dose should be prescribed for this patient (correct to one decimal place)?

a) 6.4mg

b) 7.1mg

c) 8.8mg

d) 9.6mg

e) 10.1mg

9. A patient needs to use a 1 in 2500 chlorhexidine gluconate solution for wound washing. In the pharmacy you have a stock of 20% w/v chlorhexidine solution. Using this solution you will need to prepare an intermediate solution such that the patient will then dilute this 20-fold to obtain a solution of the requisite concentration.

What should be the strength of the intermediate solution ?

a) 0.2% w/v
b) 0.4% w/v
c) 0.5% w/v
d) 0.8% w/v
e) 1% w/v

10. It is recommended in guidelines you have read that if the local water supply has a fluoride content of <700 micrograms/L that supplements should be recommended.

People living in which town should take supplements based on their respective water sample resutls?

a) Arklow 0.8ppm
b) Bray 0.6 micrograms/mL
c) Carlingford 0.00013%
d) Durrow 0.00041%
e) Fermoy 1 in 100,000

5.2 Specimen questions Part 1B

1. An 82 year old lady (58kg) has a history of atrial fibrillation. Her drug history is: Aspirin e/c 75mg daily po, Digoxin 125micrograms daily po, Warfarin 3mg daily (monitored and adjusted as per INR). Her general practitioner orders new U&E's and the result of her Serum Creatinine is 134 µmol/L. Estimate her current creatinine clearance using Cockcroft & Gault.

a) 14 ml/min
b) 26 ml/min
c) 31 ml/min
d) 52 ml/min
e) 62 ml/min

2. A 45 year old man (85kg) with chronic liver disease, presents to the emergency department with a 1/52 history of progressively increasing dyspnoea, cough productive of green sputum and intermittent pleuritic chest pain. HR 88bpm, RR 18, Temp. 38.1^{o}C, BP 110/80 Sats 98% on RA. GCS 15/15, WCC 14.2, Neutrophils 11.2. Choose the most appropriate antibiotic regimen taking into consideration his underlying liver impairment.

a) Ciprofloxacin 500mg twice a day po
b) Co-amoxiclav 625mg three times a day po
c) Clarithromycin 500mg twice a day po
d) Flucoxacillin 500mg four times a day po
e) Doxycycline 200mg stat then 100mg daily po

3. A 75 year old lady attends her general practitioner one week after discharge from hospital having been treated for a lower urinary tract infection. She has had 6 episodes of cystitis in the last year and is anxious to avoid future attacks. She is otherwise well with no medical conditions. Which of the following would be an appropriate prophylactic regimen?

a) Trimethoprim 100mg nocte po
b) Ciprofloxacin 250mg daily po
c) Co-amoxiclav 375mg three times a day po
d) Amoxicillin 250mg daily po
e) Metronidazole 200mg daily po

4. A 56 year old man with a history of chronic pancreatitis presents to his general practitioner with an acute exacerbation of chronic abdominal pain. Following assessment, his doctor decides to commence an opioid analgesic and prescribes dihydrocodeine 30mg four times a day po prn for ten days. Which of the following preparations should also be prescribed empirically?

a) Loperamide 4 mg twice a day po
b) Prochlorperazine 10 mg three times a day po
c) Lactulose 15ml twice a day po
d) Pantoprazole 40 mg daily po
e) Cyclizine 50 mg three times a day po

5 – 8. A 58 year old man, presents at the emergency room 2 hours after the onset of severe chest pain radiating to his left arm. He is pale and sweaty. A full history reveals that his father and brother both had myocardial infarctions. He smokes 40 cigarettes per day. He has been prescribed, along with other appropriate medicines, heparin 1000 units per hour adjusted as per the activated partial thromboplastin time (APTT or aPPT). Match each of the aPPT results (in seconds) with the appropriate action. Each option may be used once, more than once, or not at all.

A. Give a bolus dose of 5000 units heparin and increase the rate of infusion by 150 units/hour. Repeat aPTT 6 hours later.
B. Increase the rate of infusion by 100 units/hour. Repeat aPTT 6 hours later.
C. No changes to the rate of infusion. Repeat aPTT 6 hours later.
D. No changes to the rate of infusion. Repeat aPTT the following morning.
E. Stop the infusion for 30 minutes. Restart with a decrease in the rate of infusion by 100 units/hour. Repeat aPTT 6 hours later.

5 99 seconds
6 32 seconds
7 62 seconds
8 70 seconds

9. A 78 year old woman with a history of chronic cancer pain has been admitted from a nursing home where she has been receiving palliative care. She has presented with poor pain control including a stinging sensation in her limbs. Her drug history is: Morphine sulphate modified release (MST®) 70mg twice daily, Morphine sulphate (Sevredol®)10mg 6 hourly prn (4 doses administered in the past 24 hours) Lactulose 15ml twice daily. What is the most suitable regimen to manage her pain.

a) MST® 70mg twice a day po, Sevredol® 10mg 6 hourly po prn, Lactulose 15ml twice a day po
b) MST® 70mg twice a day po, Sevredol® 20mg 6 hourly po prn, Lactulose 15ml twice a day po,
Diclofenac 50mg three times a day po
c) MST® 90mg twice a day po, Sevredol® 30mg 6 hourly po prn, Lactulose 15ml twice a day po
d) MST® 90mg twice a day po, Sevredol® 30mg 6 hourly po prn, Lactulose 15ml twice a day po, Senna tablets 7.5mg at night po, Pregabalin 50mg three times a day po
e) MST® 90mg twice a day po, Sevredol® 30mg 6 hourly po prn, Lactulose 15ml twice a day po, Senna tablets 7.5mg at night po, Gabapentin 300mg three times a day po.

10. A 64 year old oncology patient, has been transferred to a hospice. He is complaining of pain and nausea. His drug history is: Morphine sulphate modified release po 90mg twice a day Morphine sulphate immediate release po 30mg every 4 hours prn (has required 2 doses in the last 24hrs). The team is considering initiating a subcutaneous infusion pump with an appropriate dose of morphine. What dose would you recommend?

a) Morphine sulphate 105mg over 24 hours
b) Morphine sulphate 120mg over 24 hours
c) Morphine sulphate 135mg over 24 hours
d) Morphine sulphate 285mg over 24 hours
e) Morphine sulphate 360mg over 24 hours

Appendix B

STATUTORY INSTRUMENTS.

S.I. No. 493 of 2008

———————

PHARMACEUTICAL SOCIETY OF IRELAND (EDUCATION AND TRAINING) RULES 2008

(Prn. A8/1893)

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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.

Dated this 28 day of November 2008

I consent to the making of these Rules.

GIVEN under my Official Seal, 28 November 2008

BERNARD LEDDY President

AMBROSE McLOUGHLIN Registrar

MARY HARNEY, Minister for Health and Children.

S.I. No. 493 of 2008

PHARMACEUTICAL SOCIETY OF IRELAND (EDUCATION AND TRAINING) RULES 2008

ARRANGEMENT OF RULES

8. Application for recognition of a programme of education and training lead- ing to the award of a degree in pharmacy.
9. Duty of Council to review approved degrees. 10. Visits to recognised institutions. 11. Manner of reviews and visits. 12. Responses and resolutions following reporting of visits.
13. Obligation on recognised institutions to provide an annual report and to notify material changes.
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PART 4
IN-SERVICE PRACTICAL TRAINING PROGRAMME
14. Completion of the in-service practical training programme.
15. Content and standards of the in-service practical training programme (including courses of education and training).
16. Application to undertake the in-service practical training programme.
17. Establishments in which six months of in-service practical training may be undertaken.
18. Completion of the in-service practical training programme. 19. Tutor pharmacists.
PART 5
PROFESSIONAL REGISTRATION EXAMINATION
20. Eligibility to apply to present for the Professional Registration Examination.
21. Holding of the Professional Registration Examination.
PART 6
TRANSITIONAL PROVISIONS
22. Transitional provisions.
SCHEDULE
Certain minimum designated learning and competencies to be acquired in a programme leading to obtaining qualification as a pharmacist.
Citation
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 func- tions 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
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 Euro- pean 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 estab- lished by virtue of the EU Council Decision 85/434/EEC of 16 September 1985[1];

‘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 qualifi- cation 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 mean- ing 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;

[1]Official 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 Oifigiu´il” of 2nd December, 2008.

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6 [493] ‘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 con- tained 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 appro- priate 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 qualifi- cation appropriate for practice. Such document shall be known as the Desig- nated Learning and Competencies and shall set out the designated learning and competencies including the body of knowledge, the skills, the practical experi- ence, 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 accord- ance 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 train- ing 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—
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(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 prog- ramme 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 scien- tific 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 stake- holders 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 edu- cation 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 assess- ment, including staffing, premises, facilities, funding and procedures, will conform with—
(i) the designated learning and competencies relevant to such prog- ramme, and
(ii) the criteria for the recognition and approval of programmes of education and training, leading to the award of a degree in phar- macy, 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 Oifigiu´il 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 pro- vided continues to conform with the requirements of Rule 8(1)(b) and any con- ditions 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 com- pliance 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.
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10 [493] (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 phar- macy 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 consul- tation, 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 phar- macy 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 prog- ramme 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 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,
[493] 11 (b) a statement setting out in detail the reasons on which the said pro-
posals 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 Examin- ation, 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 resol- ution 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 prog- ramme 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 deliv- ery 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
12 [493]
propose to make such a resolution, it shall follow the procedure for such resol- ution 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 recog- nised 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 phar- macy 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 Exam-ination. 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 prog- ramme 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 man- ner 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 lead- ing to the award of the degree in pharmacy,

(b) the legislation and the law generally pertaining to pharmacy and med- icinal 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 prog- rammes to undertake, during such programmes, courses of education and train- ing of such duration and length as the Council may require.

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

(a) to apply those parts of the designated learning and competencies rel- evant and appropriate to the in-service practical training prog- ramme; and

(b) albeit under the direct supervision of the tutor pharmacist, to com- petently 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 recog- nised 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 Regis- tration 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 avail- able 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
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programme, which may be issued by the head of school on an individ- ual 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 practi- cal 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 train- ing 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 pro- fessional 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 recommend- ation, 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 represen- tations 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 manu- facturer;
(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 dis- covery of:
(I) new drug substances, (II) new pharmaceutical dosage forms, or
(III) new or improved methods of manufacture for existing med- icinal 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)
[493] 15
16 [493] 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 circum- stances 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' dur- ation 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 pharma- cist 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 statu- tory 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 mini- mum 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 prog- rammes 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)
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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 desig- nated 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 exam- iners and appeals examiners and such examiners shall be eligible for re-appoint- ment 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 prog- ramme 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 med- icinal products and to the practice of pharmacy in the State, and
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20 [493] (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 uni- versity character of the training.
(3) The said programme of education and training shall be such that on suc- cessful 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 med- icinal 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 com- petently 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 under- gone 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/EC[2].

[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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Appendix C

RCSI

Professional Registration Exam (PRE) Rules of Conduct Template

1. PRE Schedule

These are the Rules of Conduct of the Professional Registration Examination (PRE) for the **xxxx** sitting which is provided by the Royal College of Surgeons of Ireland (RCSI) for the Council of the Pharmaceutical Society of Ireland (PSI) (see General Issues in the Administration of the PRE, henceforth GI(PRE) for the purposes of this document only)**.** For the purposes of the PRE, students are randomly assigned into one of three groups (A, B and C) (Appendix 1). The running order for the OSCE segment and the written exam will be determined by the group that you are assigned to and informed to you in advance of the examination).. **All candidates are required to report to their designated registration venue at xxxx** (GI(PRE) 1.1.2). Please note that you will not be able to register anywhere other than your designated registration venue. If you arrive late for registration you will not be permitted to sit the exam.

2. Admission and Registration

Your RCSI Identification Card/Form of Identification **must** be brought to the examination and presented for admission to the Registration Room. At that time you will receive both a **colour-coded OSCE circuit label** to be worn throughout the OSCE, and also a **roll of labels** containing your examination number, to be used at each OSCE station.

3. Personal belongings

All personal belongings brought to the Registration Room including books, wallets, purses, passports, personal identification, hand-bags or briefcases, paper items, coats and outerwear, all pocket contents and **any** digital or electronic items such as watches/timepieces, personal data assistants, mobile telephones or any other devices must be left in the care of the Invigilator in the Registration Room while you are attending the MCQ or your OSCE rotation. You are strongly advised not to bring any electronic items on the day of the exam, with the sole exception of a non-programmable calculator, which may be used for Part 1 of the PRE only. Calculators, if required for the OSCE, will be supplied. Avoid bringing valuables to the examination, as RCSI will **NOT** assume responsibility for loss or damage.

If you must take any medication while at the examination site, bring it with you and show it to the examination staff at registration. Any packaging, inserts or related written material must be left at home or handed in to examination staff.

Appropriate dress code

Interns are expected to dress in a professional manner. Please **do not wear strongly scented cosmetics/perfumes/aftershaves** as some individuals are very allergic to such substances.

4. Examination Process

4.1 Before Starting the Examination

• You will receive a brief orientation to the examination procedures and schedule. Questions regarding possible examination content or appropriateness of responses will **NOT** be answered at this time.

• It is inevitable given the OSCE format that some cohorts of candidates will have to wait longer than others before starting the examination and those in this position will be required to remain in a designated venue to ensure integrity of the examination. Please do not contact/e-mail us with complaints in this regard as we will not, regrettably, be in a position to respond.

4.2 During the Examination (GI(PRE) 1.1.3).

• From the time you enter an Examination Area until you leave, you and other candidates **MUST NOT** converse or communicate with one another in any manner, or speak or read out loud except when interacting with Standardized Patients or examination personnel. Violation of this rule may result in not being permitted to finish the examination and the cancellation of your standing in the session. You may converse with examination personnel as required, in a discrete and confidential manner.

• As the duration of the OSCE segment of the PRE is 90 minutes, there will be two rest stations. During this time you may request permission to use the washroom facilities, accompanied/supervised by an examination staff member. Water will be provided in the rest stations.

• Each OSCE station lasts for 5 minutes. Stations are electronically timed and a 30-second signal warning is given prior to the end of each station. Students must start at the appropriate station as defined by their **colour-coded OSCE circuit label** and follow the numerical sequence.

4.2.1 Candidate Materials

Part 1 (MCQ)

• During the MCQ component of the PRE, approved models of calculator are allowed in the Examination Area. Electronic score sheets for Part 1 of the PRE must be filled in using the pencils supplied.

Part 2 (OSCE)

• All materials essential for the OSCE component of the PRE will be supplied to you in the OSCE stations.

• You may **only** use the references and examination materials which are provided in the OSCE stations.

• No other materials may be used at any time while in the OSCE Examination Area.

• Do **NOT** mark or deface any of the references or examination materials. Candidates who mark or deface the references or examination materials in any manner will be charged for the cost of replacement.

• You may write only on supplied answer sheets which may be provided in some stations.

Note:
Any materials that may compromise the administration or security of the examination, that were not left in the Registration Room, will be confiscated and the candidate in possession of such may not be permitted to begin the examination, or to continue it if it has already begun. Confiscated items will be sent to the Examination Office for inspection, together with a report of the incident, and will be kept until any inspection or investigation is completed. (GI(PRE) 1.1.6).

4.3 Consumption of food and break time between PRE components:

- Interns are encouraged to eat well before arriving for the PRE.

- Water will be available during the examination if required.
- Food will **NOT** be supplied and will **NOT** be available for purchase on the day of the PRE.
- Therefore, students must bring their own food and beverages with them to the Registration Room.
- Food may be consumed while in the Registration Room during the designated break (held also within the Registration Room), but cannot be taken into Examination Areas. (GI(PRE) 1.1.3.1).
- Please note that during the designated break time it is ABSOLUTELY FORBIDDEN to use any electronic device.

5. At the End of the Examination

You must:

- Retrieve any personal belongings
- Leave only when you are officially instructed to leave by the Chief Administrator or registration staff
- Continue to observe all procedures and Rules of Conduct until you leave the examination site.

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