



OUTLINE ACCREDITATION PROCESS FOR THE LEVEL 8 BACHELOR DEGREE

awarded on the successful completion of the

4 YEAR UNDERGRADUATE PHARMACY DEGREE PROGRAMME

(approved by the Council of the PSI on 24 May 2012)

Introduction

This document was developed by an expert working group following a wide-ranging review of literature relevant to the accreditation of pharmacy courses. The standards themselves (Annex 1) were subject to targeted consultation broadly within the profession (Register of Pharmacists and Register of Retail Pharmacy Businesses), with senior officers and managers in the healthcare sector, regulatory bodies for health and social care, higher education institutions and in general with the public via the PSI website.

Context

The legislative background:

Stemming from the Pharmacy Act 2007 (as amended) and recognised in Directive 2005/36/EC of the European Parliament of the Council on the Recognition of Professional Qualifications, the Pharmaceutical Society of Ireland (PSI, the pharmacy regulator) has responsibility and powers for the approval of the programmes of education and training of pharmacists in Ireland. An important stage and component of such education and training is the National Pharmacy Internship Programme (NPIP). The care of the patient and public protection are paramount considerations for the PSI, its registrants (pharmacists) and students. The PSI's approach to the approval of such programmes is a system of standard setting and accreditation. This document sets out and describes that system and forms a key part of assuring that students are properly prepared for entry to the National Pharmacy Internship Programme.

The PSI wishes to facilitate collaboration and joint working in delivery, quality assurance and quality enhancement of the education, training, learning and development of pharmacists. The PSI views its accreditation system as adding to but not – in its principal focus of assuring fitness for entry to internship training and later practice as a pharmacist – strongly duplicating quality assurance within higher education.

Section 7(2)(a)(iv) of the Pharmacy Act 2007 provides that it is a duty of the PSI to:

determine, approve and keep under review programmes of education and training suitable to enable persons applying for registration to meet those criteria and pharmacists to comply with those codes.

Rule 7 of the Pharmaceutical Society of Ireland (Education and Training) Rules 2008 (the Rules) sets out the criteria for the recognition and approval of programmes of education and training leading to the award of a degree in pharmacy as follows:

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.*

Furthermore, paragraph (3) of the Schedule to the Rules provides that the overall five-year programme of education and training should be such that it can provide an assurance that a person who successfully completes all five years 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.

Overview

The PSI works to support and assure that the Irish schools of pharmacy produce graduates whose contributions to patient care are founded on understanding and application of scientific method, of the principles and techniques of the pharmaceutical sciences and of evidence-based health care. Equally, it works to support and ensure that pharmacy graduates have been enabled to develop the professional patient-centred attributes and attitudes set out in its Standards. The PSI's main means of assuring these outcomes and features of Irish pharmacy degree courses is a system of accreditation.

The PSI's main approach to accreditation is assuring that the 4 year undergraduate pharmacy degree programme ('the Degree Programme') is appropriately resourced in accommodation, equipment and staff, and that either all standards for accreditation are met or that the overwhelming majority of them are met with the remainder being addressed by explicit approaches or means.

The output of the accreditation process in a given case is a report carrying a conclusion and recommendations with regard to accreditation. The hoped for outcome is accreditation by the Council of the PSI for a maximum period of 5 years, possibly subject to a number of conditions.

Accreditation Visit

There will normally be a visit over a maximum of two days. Full use will be made of the time available, within the constraint that normally visiting accreditation team members will make only one over-night stop, between Day 1 and Day 2.

The visit will be designed to focus on issues identified from the visiting accreditation team members' reading of the documentation (and the team leader's own pre-visit, where required). The programme will be decided by the team leader in consultation with the Head of School.

Normally, all relevant pharmacy staff and any other pre-identified staff of the Degree Programme provider ('the Provider') should be available during the visit, and the visiting accreditation team should endeavour to speak to them in relatively small groups at some point in the programme. Also at some point during the visit the team will wish to meet senior management.

It is envisaged that the visit will start at mid-to-late morning on Day 1 with a tour of the school and relevant other facilities of the Provider, such as the library or large groups of computer workstations. The visiting accreditation team will appreciate the opportunity to meet with students during the tour and recent graduates, when available. The tour and the rest of Day 1 will be devoted mainly to gathering and analysing evidence of the standards for accreditation being met, and of adequate resourcing of the course.

Day 2 will be devoted to verifying and triangulating the visiting accreditation team's findings, and on drafting a report in bullet point outline. Key findings will be derived, to be shared verbally with the school by the end of the day.

At the end of the visit, the visiting accreditation team will leave the institution without entering into discussion with members of the school, except in the case of the team leader, accompanied by a member of PSI staff, who can briefly clarify to the Head of School and/or programme leader any points of potential misunderstanding from the feedback session.

This is a transparent process and it is intended that the main findings of the visiting accreditation team, provided as feedback, should come as no surprise to the recipient group. All main issues will have been well-rehearsed during the team leader's pre-visit (if applicable) and during the full visit. The main findings provided as feedback at the end of the visit will be confined to whether or not accreditation is to be recommended to the Council of the PSI, together with the likely conditions of accreditation or the likely next steps in the case of no recommendation of accreditation.

Accreditation report

A main report and a summary of the accreditation visit, the latter to be published on the PSI's web-site, will be prepared shortly after the visit. The full report will normally be organised in the following sections:

- i. Introduction
- ii. Process of review
- iii. General matters
- iv. Meeting the Accreditation Standards:
 - (a) Standard 1 - Pharmacy School and Mission
 - (b) Standard 2 – Leadership, Organisation and Governance
 - (c) Standard 3 – Graduates
 - (d) Standard 4 – Curriculum
 - (e) Standard 5 – Teaching and Learning Strategy
 - (f) Standard 6 – Assessment Strategy
 - (g) Standard 7 – Students
 - (h) Standard 8 – Resources
 - (i) Standard 9 – Quality Assurance
- v. Conclusions and recommendations

The summary report will comprise a brief overview based on strengths and weaknesses of the provision along with the conclusions and recommendations.

A first draft will be sent to the members of the visiting accreditation team for their suggested corrections or improvements within 10 working days. The leader of the visiting accreditation team will decide in consultation with the rapporteur and the PSI staff member responsible which of these amendments are to be made. Second drafts will be sent to the head of school for his/her information and to provide an opportunity to correct any errors of fact in the report. The leader of the visiting accreditation team will decide in consultation with the rapporteur and the PSI staff member responsible any amendments to be made. The reports will then be considered by the PSI's Professional Development and Learning Committee in the first instance and ultimately by Council.

Documentation

The Degree Programme provider must submit to the PSI {xx} hard copies and a text file in Microsoft Word of a document set out in sections and sub-sections strictly as below. The Professional Development and Learning Unit will provide a Word template for as much of the documentation as possible. It will also provide guidance on lengths of sections and sub-sections of submissions.

In order to avoid the accreditation team having to infer how a standard is being met from a supplied set of documents, the Provider should provide a concise commentary that clearly sets out how the standards have been met with due specific reference to the documentation set out in the outline accreditation process and any other documents that the Provider chooses to supply in order to demonstrate compliance with each standard.

STANDARD 1: PHARMACY SCHOOL AND MISSION

In order to demonstrate compliance with this Standard, the Provider will be expected to:

- 1.1 Provide a copy of the strategic plan and a commentary to demonstrate how it aligns with the mission, goals and objectives of the Higher Education Institution (HEI). In addition, provide evidence of periodic review together with a summary of any major changes since the last accreditation visit.
- 1.2 Provide copies of all published, current governance documents, such as bye-laws and key performance indicators (KPIs) together with any policies and procedures which have been generated within the School by academic staff consensus under the leadership of the Head of the School in accordance with the HEI's regulations.
- 1.3 Demonstrate within its strategic plan the educational philosophy for the Degree Programme, how it assures that graduates will be prepared for entry to and participation with the NPIP and a fundamental commitment to the preparation of students who possess the competencies necessary for the provision of pharmacist-delivered patient-care, including medication therapy management services, the advancement of the practice of pharmacy and lifelong learning.

STANDARD 2: LEADERSHIP, ORGANISATION AND GOVERNANCE

In order to demonstrate compliance with this Standard, the Provider will be expected to:

- 2.1 Provide a description and explanation of the School and institutional management structures relevant for the Degree Programme including the roles and responsibilities of the key post holders.
- 2.2 Demonstrate the existence, application and effectiveness of systems to assure that students do not jeopardise patient safety, are appropriately supervised, understand what fitness to practise mechanisms apply to them and cannot be awarded an accredited degree or pass into intern training if they are considered likely to pose a risk to patients or the public.
- 2.3 Demonstrate that a clearly identified Head of School:
 - (a) is in a position to influence the HEI and the School policy in relation to pharmacy and to unite and inspire administrators, academic staff, other staff and students to achieve the mission and goals. If the Head of School is not a pharmacist, demonstrate that there is an identified pharmacist in the School who can provide leadership in the practice and profession of pharmacy and have the authority for effective advocacy for pharmacy within the HEI and;
 - (b) has ensured that all accreditation requirements have been met and complied with, including the timely submission of all reports and any plans for substantive change. In the event that remedial action had been required by the PSI to bring the School into compliance, a commentary should be provided on the steps taken by the Head of School to ensure compliance.
- 2.4 Demonstrate that external relationships or collaborations are facilitated with the pharmacy profession to foster the School's teaching, learning and research capabilities.
- 2.5 Demonstrate compliance with the principles of equality, diversity and fairness necessary to meet or surpass National and European legal requirements in relation to the education and training and qualification of pharmacists.
- 2.6 Demonstrate the use and maintenance of a reliable, accurate and workable management information system for recording, retaining and reporting data on student intake, numbers, achievement and progression through the Degree Programme supported by an appropriate and robust system of back-up of critical applications and systems data.

STANDARD 3: GRADUATES

In order to demonstrate compliance with this Standard, the Provider will be expected to:

- 3.1 Provide a description of how the Degree Programme ensures the graduates attain the expected generic and personal qualities eligible for entry to the NPIP (empathy; leadership; effective communication; confidence; independent and critical thinking; cultural understanding; a commitment to lifelong learning; professional and ethical conduct; reflective practice; awareness of limitations and risk; information literacy; team work; and problem-solving).
- 3.2 Provide a description of how the Degree Programme ensures the graduate attains the specialist knowledge, skills and professional attributes to enter the NPIP leading to registration as a pharmacist competent to practise in a patient-centred professional and ethical manner, and meets the requirements of the HEI for the degree (Standard 3.2). Evidence to support the suitability of its graduates could include the experience and performance of former graduates on the programme and evidence from employers of former graduates. In relation to entitlement to entry to the NPIP, the provider would be expected to describe how they seek to:
 - (a) Develop graduates who understand and can demonstrate how to provide patient care in cooperation with patients, prescribers, and other members of an inter-professional health-care team based upon sound therapeutic principles and evidence-based data, taking into account relevant legal, ethical, social, cultural, economic, and professional issues, emerging technologies, and evolving pharmaceutical, biomedical and social sciences that may impact therapeutic outcomes;
 - (b) Develop graduates who understand and can demonstrate how to manage and use resources of the health care system, in cooperation with patients, prescribers, other health care providers, colleagues and administrative and supportive personnel, to promote health; to provide, assess, and coordinate safe, accurate, and time-sensitive medication distribution; and to improve therapeutic outcomes of medication use;
 - (c) Develop graduates who understand and can demonstrate how to promote health improvement, wellness, and disease prevention in cooperation with patients, communities, at-risk populations, and other members of an inter-professional team of health care providers;
 - (d) Promote the development of professional attitudes and behaviour and an understanding of the practice of pharmacy in community, hospital, industrial and academic pharmacy settings.

STANDARD 4: CURRICULUM

In order to demonstrate compliance with this Standard, the Provider will be expected to:

- 4.1 Provide a curriculum map that shows how the subject matter throughout the curriculum and in all programme pathways is integrated and wherever possible delivered by interdisciplinary teams. Reference should be made to how the curriculum:
 - (a) ensures the achievement of the stated outcomes;
 - (b) fosters the development and maturation of critical thinking and problem-solving skills;
 - (c) meets the diverse learning needs of the student cohort;
 - (d) enables students to transition from dependent to active, self-directed, lifelong learners at graduation.
- 4.2 Provide an explanation of how the curriculum has been developed to develop the graduate outcomes in Standard 3 including, where appropriate, reference to the indicative syllabus. It would be expected that the following should be addressed, at a minimum, how the curriculum has been planned to develop in students, knowledge that meets the criteria of good science; professional skills, attitudes and values; and the ability to integrate and apply learning to both the present practice of pharmacy and the advancement of the profession including developments in pharmaceutical science and services and in pharmacy practice.
- 4.3 Demonstrate that in developing specialist knowledge, skills, professional attributes in students, the School ensures that the curriculum fosters the development of professional judgement and a commitment to uphold ethical standards and abide by practice regulations. This should include details of the time allocated over the four years of the Degree Programme.
- 4.4 Demonstrate how the curriculum supports the development of knowledge and understanding of: 1) pharmacy law and its interpretation and application to practice; and 2) the health sector in Ireland. This should include details of the time allocated over the four years of the Degree Programme.
- 4.5 Demonstrate how the curriculum ensures an appropriately comprehensive training in research methods applicable to scientific and health research culminating in the undertaking of a significant final year research project that meets the requirements of a level 8 degree programme on the National Framework of Qualifications.
- 4.6 Provide a description of any practice experience that is integrated within the curriculum and demonstrate how this integrates with the theoretical learning within the School.
- 4.7 Provide a commentary to demonstrate that the curriculum complies with the various minimum legal requirements at national and European level (Standard 4.7) and takes account of the recommendations of the Advisory Committee on Pharmaceutical Training (European Commission, 1995).

STANDARD 5: TEACHING AND LEARNING STRATEGY

In order to demonstrate compliance with this Standard, the Provider will be expected to:

- 5.1 Provide a teaching and learning strategy that is aligned with the curriculum learning outcomes (see Standard 4) and positions knowledge, understanding and competence development in a pharmacy context. It would be expected that the provider demonstrates how the strategy:
 - (a) Takes account of the NPIP competence standards and the core competency framework as approved by the PSI Council from time to time to ensure graduates are properly prepared to apply for entry to the NPIP and so ensure patient safety and public protection;
 - (b) Takes account of the predicted preferred learning format of the intended audience as well as the most effective methods to demonstrate competency against the required learning outcomes;
 - (c) Emphasises the contribution of the pharmacist in the healthcare team including the clinical skills that enable the critical review of patient pharmacotherapies, provides teaching and learning alongside and together with students of other related healthcare professions and where students gain first-hand structured experience of practice, including contact with patients. Where any teaching and learning activity involves patient data, the provider must demonstrate that it has appropriate ethical approval and meets relevant national standards;
 - (d) Provides a variety of teaching and learning approaches appropriate to stated learning outcomes, which may include but not be limited to: lectures; practical classes; seminars; tutorials and other forms of interactive small-group teaching whether that be face-to-face or in the virtual learning environment;
 - (e) Facilitates the development of the student's communication skills and how this is underpinned by the theoretical basis within the social and behavioural science content of the Degree Programme;
 - (f) Encourages students to take responsibility for their own learning both within the Degree Programme and as a basis for later continuing professional development;
 - (g) Emphasises the development of problem-solving skills and the justification of decisions made both on an individual and team-based basis;
 - (h) Ensures that teaching and learning take place alongside and with reference to research and other scholarly activities;
 - (i) Ensures that pharmacy students realise the importance of working as part of a multidisciplinary team.
- 5.2 Provide evidence of the effective mechanisms used to ensure that teaching and learning in all modules/course units take place in a pharmacy context.
- 5.3 Demonstrate that pharmacy law, ethics, professionalism and pharmacy practice are taught predominantly by pharmacists with contemporary experience of practice, drawn preferably from within the School.
- 5.4 Demonstrate that the teaching and learning strategy incorporates a clear and realistic student code of conduct and demonstrate how this has been explained, communicated and enforced to promote professional behaviour.

STANDARD 6: ASSESSMENT STRATEGY

In order to demonstrate compliance with this Standard, the Provider will be expected to:

- 6.1 Provide a comprehensive assessment strategy and commentary to address its alignment with the curriculum learning outcomes (see Standard 4) and with the teaching and learning strategy (see Standard 5) and developments in pharmacy practice. It would be expected that the strategy and the associated commentary should, at a minimum, demonstrate how it:
 - (a) Provides evidence of clear guidance to students relating to assessment of stated professional and learning outcomes, with objective reporting on assessments and including fair and just complaints and appeals processes;
 - (b) Provides evidence that it includes assessment of professionalism and the process of professionalisation appropriate for application to entry to the NPIP and takes account of the NPIP competence standards and the core competency framework as approved by the PSI Council from time to time;
 - (c) Positions knowledge, understanding and competence development in a pharmacy context;
 - (d) Provides evidence that the contribution of the pharmacist in the healthcare team is emphasised and that, where appropriate, the student is assessed alongside and together with students of other related health professions;
 - (e) Takes a holistic approach and assesses, for example, cognitive learning, mastery of essential practice skills, ability to communicate, team-working, numeracy and use of data in problem solving;
 - (f) Assesses competence in extemporaneous dispensing and of competence in the dispensing and supply of medicines;
 - (g) Includes a formal examination of pharmacy law and a summative assessment of ethics and professionalism in the final year;
 - (h) Assures that specific examination requirements for dispensing practice (this may include skills of communication with patients and prescribers), pharmacy law, pharmacy practice (including clinical practice and therapeutics) and ethics and professionalism are met.
- 6.2 The provider should demonstrate how the assessment strategy:
 - (a) Takes a holistic view of assessment and feedback;
 - (b) Documents student performance and the attainment of desired core knowledge, skills and values;
 - (c) Employs a variety of valid and reliable measures systematically and sequentially throughout the Degree Programme;
 - (d) Uses the analysis of assessment measures with specific attention to any inconsistencies in individual student records, to improve student learning and the achievement of the professional competencies;
 - (e) Includes a robust and transparent and effective appeals process that is fully documented and communicated to students.

STANDARD 7: STUDENTS

In order to demonstrate compliance with this Standard, the Provider will be expected to:

- 7.1 Demonstrate that its criteria, policies and procedures for admission to and progression through the Degree Programme are open and available to prospective applicants and ensure non-discrimination as defined by national laws and regulations. In this respect the provider will be expected to make at least the following available:
- (a) The criteria, policies and procedures for admission to, progression on and successful completion of the Degree Programme made available to students;
 - (b) Recruitment and admissions data since the last accreditation visit;
 - (c) Progression data for all years of the programme since the last accreditation visit together with an analysis of this data and a description of any actions taken to address issues that have arisen from this analysis;
 - (d) Evidence that the Provider produces and makes available to current and prospective students a complete and accurate description of the Degree Programme, including its current accreditation status and full disclosure of any requirements that are to be completed;
 - (e) Evidence of how its admissions criteria and processes are designed to meet the requirements of the Pharmaceutical Society of Ireland (Education and Training) Rules 2008 and to select students who have the potential for success in the Degree Programme and the profession, including Garda vetting;
 - (f) Evidence that the provider produces and makes available to students and prospective students criteria, policies, and procedures for academic progression, academic probation, remediation, missed course work or credit, dismissal, re-admission, rights to due process, and complaints and appeals mechanisms.
- 7.2 Demonstrate the use of appropriate and timely support mechanisms for all students on the Degree Programme. It would be expected that the commentary, at a minimum, should include the following:
- (a) An organisational chart and description of student services available to students and of the principal points of contact;
 - (b) Evidence of how students are informed of student support systems and provide examples of relevant supporting documentation used for student orientation including the student handbook;
 - (c) A description of the methods used to gather student perspectives (e.g. focus groups, meetings with the Head of School or other administrators, involvement in self-study activities, review of student complaints) and an analysis of the outputs and actions arising from them;
 - (d) A copy of the student complaints policy together with a chronological list of any complaints that have been made and a commentary on how they have been dealt with;
 - (e) Evidence that students are encouraged to undertake vocational employment/placement or work experience in a variety of relevant professional settings and where appropriate, a description of the systems in place to support students in securing and maintaining any practice placements that form part of the curriculum;
 - (f) A description of how the provider encourages active engagement with relevant pharmaceutical students' associations, at HEI, national and international level, to develop professional leadership qualities and foster international pharmaceutical links;
 - (g) A description of the counselling services available to students in relation to poor progress, learning difficulties, impairment and disability issues including any health or social problems.

STANDARD 8: RESOURCES

In order to demonstrate compliance with this Standard, the Provider will be expected to:

- 8.1 Demonstrate a sufficient number of academic staff appropriately qualified and experienced and expert in pharmaceutical sciences and pharmacy practice including an appropriate number with contemporary experience of pharmacy practice to meet all of the PSI accreditation standards. It would be expected that the information provided should include but not necessarily be limited to:
 - (a) A full list of all staff that contribute to the delivery of the programme together with details of their individual qualifications, professional registration status and role within the programme;
 - (b) Evidence that the academic staff possesses the required professional and academic expertise, has contemporary knowledge and abilities in current educational philosophy and techniques, and is committed to the advancement of the profession and the pursuit of research and other scholarly activities. Furthermore that all academic staff regardless of their discipline, have or are developing a conceptual understanding of current and proposed future pharmacy practice in a variety of settings and are committed individually and collectively to the programme's missions and goals;
 - (c) Evidence that academic staff members have the capability and continued commitment to be effective teachers. Effective teaching requires knowledge of the discipline, effective communications skills, and an understanding of pedagogy, including construction and delivery of the curriculum;
 - (d) Evidence that the provider reviews the performance of academic staff and other staff on a regular basis;
 - (e) Evidence of an organised professional development programme that is open to all those teaching on the Degree Programme consistent with their respective responsibilities (see Standard 8.1(f));
 - (f) Provide evidence that enrolment is managed in alignment with available academic staff in accordance with sound business practice.
- 8.2 Demonstrate that relevant input from external specialist lecturers is provided to enhance the students' contextual understanding of specific areas. The evidence should include but not necessarily be limited to:
 - (a) A list of all external specialist lecturers engaged by the School together with their qualifications and a description of their contribution to the Programme;
 - (b) Evidence that external specialist lecturers possess the required professional and academic expertise to teach;
 - (c) Evidence that external specialist lecturers who also engage with the formal assessment process possess the required expertise.
- 8.3 Demonstrate a sufficient number of appropriately qualified/trained and experienced support staff to support operation of the School. The evidence should include but not necessarily be limited to:
 - (a) A list of all those support staff engaged by the School together with their qualifications and a description of their contribution to the Programme;
 - (b) A description of central support (e.g. library, student services and IT) provided from outside the School;
 - (c) Provide evidence that enrolment is managed in alignment with available support staff in accordance with sound business practice.

- 8.4 Demonstrate secure and adequate infrastructure and financial resources to meet all of the PSI accreditation requirements. Evidence would include but not necessarily be limited to:
- (a) Details of the physical resources and equipment available to support delivery and examination of the programme and a summary of the annual financial income and expenditure for the programme over the years since the last accreditation;
 - (b) Where placements are formally linked to the curriculum, details of all premises that provide practice together with details of the arrangements in place (including formal and informal agreements) to assure the quality and consistency of the student experience in these placements;
 - (c) Provide evidence that enrolment is managed in alignment with available financial and infrastructure resources in accordance with sound business practice.

STANDARD 9: QUALITY ASSURANCE

In order to demonstrate compliance with this Standard, the Provider will be expected to:

- 9.1 Demonstrate how they identify and employ key performance indicators (KPIs) to monitor the extent to which the programme meets the accreditation standards set by the PSI Council from time to time, including how staff and students contribute to quality assurance and enhancement processes.
- 9.2 Demonstrate how the data collected from proactive quality assurance (QA) processes is used to systematically and sequentially monitor, review and evaluate its curricular structure, content, organisation and outcomes to inform continuous improvement of the provision.
- 9.3 Provide evidence of how student proficiency over the period of the Degree Programme is reviewed, recorded and managed and that fitness-to-practise mechanisms are in place for students.
- 9.4 Provide an explanation of the quality assurance system for reviewing and developing the educational system such that it meets the accreditation standards set by the PSI for the Degree Programme and evidence that all proposed changes to the Degree Programme are documented and retained.
- 9.5 Demonstrate how the school provides and develops an environment and culture that promotes professional behaviour and harmonious relationships among students and academic and other staff. Describe the policies applied by the provider to support students, academic staff, administrators and other staff participation, where appropriate, in pharmacy, scientific and other professional organisations to enhance collective awareness of developments in pharmacy.

**Interim Accreditation Standards for the Level 8 Bachelor Degree awarded
on the successful completion of the 4 year undergraduate pharmacy degree
programme**

(approved by the Council of the PSI on 28 March 2012)

INTRODUCTION

These Accreditation Standards have been developed to assure that the undergraduate pharmacy degree programmes recognised and approved by the Council of the Pharmaceutical Society of Ireland (PSI) meet the stated requirements below.

1. The purpose of undergraduate pharmacy education (the pharmacy degree programme) is to produce pharmacy graduates who have the knowledge, skills and attributes to safely participate in the National Pharmacy Internship Programme (NPIP). Graduates should be prepared for patient-centred pharmacy practice, and their learning should be based upon and underpinned by appropriate and sufficient understanding of the principles and techniques of the pharmaceutical, biomedical and social sciences.
2. Undergraduate pharmacy education will seek to develop in the student:
 - (a) professional and personal integrity and discipline of mind;
 - (b) an understanding of and a commitment to the ethos of professionalism, in particular a commitment to the concept of patient centredness and duty of care;
 - (c) the capability to adapt to developments in pharmacy, medicine and healthcare;
 - (d) a commitment to lifelong learning, in particular an awareness of the need to maintain appropriate experience in the practice of pharmacy, keep abreast of continuing education and professional developments in the profession of pharmacy and undertake appropriate continuing professional development relevant to the practice of pharmacy.
3. These standards are intended to underpin and complement the statutory requirements set out in the Pharmacy Act 2007 (as amended) and the Pharmaceutical Society of Ireland (Education and Training) Rules 2008 including the requirement to produce and submit an annual report.

Standard 1	PHARMACY SCHOOL AND MISSION
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The Pharmacy School (the School) must engage in a systematic planning process and have a current strategic plan that facilitates achievement of the School's mission, goals and objectives.

- 1.1 There should be evidence that the mission, goals and objectives have been reviewed and endorsed by the Higher Education Institution (HEI) and should be demonstrably congruent with the mission of the HEI.
- 1.2 The School should have a published statement of its mission and goals and set out its key performance indicators (KPIs) and timescale for their implementation and review. This should include an explanation of how the School will monitor and evaluate its performance against these objectives.
- 1.3 The strategic plan must include but need not be limited to:
 - (a) Its mission and goals with associated KPIs;
 - (b) The underpinning aims and objectives of the School;
 - (c) A statement of the educational philosophy for the undergraduate pharmacy degree programme (the Degree Programme) and how it:
 - (i) supports or assures that graduates will be prepared for entry to and participation with the NPIP; and
 - (ii) prepares graduates for practice as pharmacy professionals who will embrace lifelong learning;
 - (d) A commitment to excellence in teaching and learning methods.

Standard 2	LEADERSHIP, ORGANISATION AND GOVERNANCE
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There must be clear management structures for the Degree Programme with a schedule of roles and responsibilities, and a defined structure and process to show lines of accountability and authority for all those involved in the delivery of the Degree Programme.

- 2.1 The Degree Programme must be planned and delivered by an identifiable organisational unit preferably a School or Faculty of Pharmacy, which has responsibility for the Degree Programme and associated resources. Furthermore the Degree Programme must be planned and maintained through transparent processes and clearly identify who is responsible for what at each stage.
- 2.2 There must be effective systems in place to ensure that students:
 - (a) do not jeopardise patient safety and only do tasks (under appropriate supervision) for which they are competent;
 - (b) are monitored and assessed to assure they always work and perform safely;
 - (c) understand what fitness to practise mechanisms apply to them;
 - (d) are not awarded an accredited degree or pass into intern training if they are considered likely to pose a risk to patients or the public.
- 2.3 The Head of the School must be in a position to influence the HEI and the School policy in relation to pharmacy. In the event that the Head is not a pharmacist registered in Ireland, there must be an identified pharmacist who can provide leadership in the practice and profession of pharmacy and have the authority for effective advocacy for pharmacy within the HEI. This person must be at senior level within the School and be registered in the Register of Pharmacists held by the PSI and thereby be familiar with and subject to the statutory code of conduct.
- 2.4 External relationships or collaborations with the pharmacy profession must be facilitated to foster the School's teaching, learning and research capabilities.
- 2.5 The Degree Programme must comply with the principles of equality, diversity and fairness and meet all the requirements of national and European law as it relates to the education, training and qualification of pharmacists.
- 2.6 As part of the statutory annual reporting process to the PSI, the School must submit data on student intake, student numbers, student achievement and progression through the Degree Programme with the School's commentary and analysis.

Standard 3	GRADUATES
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Graduates must demonstrate the generic and personal qualities and possess the specialist knowledge, skills and professional attributes necessary to apply to enter the NPIP.

- 3.1 They must demonstrate the generic and personal qualities expected of a pharmacy graduate which include: empathy; leadership; effective communication; confidence; independent and critical thinking; cultural understanding; a commitment to lifelong learning; professional and ethical conduct; reflective practice; awareness of limitations and risk; information literacy; team work; and problem-solving.
- 3.2 They must possess the specialist knowledge, skills and professional attributes to enter the NPIP leading to registration as a pharmacist competent to practise in a patient-centred professional and ethical manner, including, but not necessarily limited to:
 - (a) The requisite knowledge of the regulatory framework and the role of pharmacists within it.
 - (b) The requisite knowledge of how medicines are developed, manufactured and brought to the market place;
 - (c) The requisite knowledge of medicines, medical devices and medicines formulation and their preparation and the competence to prepare medicines extemporaneously, as may be necessary;
 - (d) The competence to undertake or advise on all aspects of the medication use process (i.e. procurement, supply, administration, monitoring, prescribing of medicines) in accordance with pharmaceutical knowledge, legislative requirements and codes of professional conduct and practice;
 - (e) The ability to reason through professional dilemmas in a structured manner and justify action options chosen in a manner respectful of pharmacy law, the statutory Code of Conduct and common frameworks for ethical decision-making;
 - (f) The requisite pharmacological, pharmaceutical and clinical knowledge to safely and effectively interpret and evaluate information about medicines and their proper use and to monitor and interpret ongoing therapy and patient progress;
 - (g) The requisite knowledge and communication skills to fulfil their role in advising and counselling patients, other healthcare professionals and others about medicines and their usage;
 - (h) The requisite knowledge and skills to recognise common disease states and make appropriate responses to presented symptoms with appropriate referral to other healthcare professionals as necessary
 - (i) The requisite knowledge and appreciation of the principles of quality and safety and quality assurance mechanisms in all aspects of scientific and professional activities;
 - (j) An understanding of research methodologies relevant to pharmaceutical, biomedical and social sciences;
 - (k) An understanding of the need to identify the evidence and strength of that evidence and its application to problem solving and patient-care;
 - (l) An understanding of the practice of pharmacy in community, hospital, industrial and academic pharmacy settings.

Standard 4	CURRICULUM
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The curriculum is planned and delivered within a programme that combines and coordinates all components in a cohesive manner with clearly defined learning outcomes that cover the generic and personal qualities and the specialist knowledge, skills and professional attributes necessary for entry to the NPIP (see Standard 3).

- 4.1 The curriculum should ideally be delivered by interdisciplinary teams in order that the subject matter of the degree is integrated (i.e. combining and coordinating all components in a cohesive manner) and delivered in a patient-focussed manner. The student must be provided with the knowledge and experience that will facilitate an understanding of the key regulatory and scientific aspects of the manufacture, preparation, quality control, distribution, actions, application and evidence-based use of medicines by patients, to include health screening, health promotion and pharmaceutical care.
- 4.2 The Curriculum should be guided by but not limited to the indicative syllabus shown in Appendix A of this document.¹ The curriculum should take account of, and be responsive to, developments in pharmaceutical science and services and in pharmacy practice.
- 4.3 Sufficient time should be allocated over the whole period of the Degree Programme to enable the formation of an appropriate ethical and professional approach to practice and this process should begin early in the first year. Appropriate assessment of this attribute shall also take place throughout the Degree Programme.
- 4.4 Sufficient time should be allocated over the whole period of the Degree Programme to develop knowledge and understanding of pharmacy law and its interpretation and application to practice and to develop knowledge and understanding of the health sector in Ireland.
- 4.5 The curriculum should provide appropriately comprehensive training in research methods applicable to scientific and health research. The Degree Programme includes in the final year a significant laboratory-based or practice-based research project that meets the requirements of a level 8 degree programme on the National Framework of Qualifications.
- 4.6 Where appropriate and possible, the curriculum should be reinforced by practice experience that is designed to integrate the student's experience gained with their study of pharmaceutical, biomedical and social sciences and the disciplines relevant to the practice of pharmacy.
- 4.7 The curriculum must comply with the various minimum legal requirements at national and European level (see Appendix B).² The curriculum must take account of the

¹ The indicative syllabus exists as a general guide to an appropriate scope of curriculum content for the undergraduate degree programme in pharmacy but is not intended to define a contemporary pharmacy programme. To ensure continuity with the existing programme provision and the smooth transition to the transitional standards, the indicative syllabus has not been subject to significant review. Minor changes have, however, been made to reflect changes in the law and in the terminology used in pharmacy health provision.

² To include Paragraph (4) of the Schedule of the Pharmaceutical Society of Ireland (Education and Training) Rules 2008.

recommendations of the Advisory Committee on Pharmaceutical Training (European Commission, 1995). In this respect, a curriculum compliant with the European Credit Transfer and Accumulation System (ECTS) meets the total hours requirement of these recommendations.

Standard 5	TEACHING AND LEARNING STRATEGY
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The Teaching and Learning Strategy is aligned with the curriculum learning outcomes (see Standard 4) and positions knowledge, understanding and competence development, in a pharmacy context.

5.1 The Teaching and Learning Strategy must:

- a) take account of the NPIP competence standards and the core competency framework as approved by the PSI Council from time to time to ensure graduates are properly prepared to apply for entry to the NPIP and so assure patient safety and public protection;
- b) take account of the predicted preferred learning format of the intended audience as well as the most effective methods to demonstrate competency against the required learning outcomes;
- c) emphasise the contribution of the pharmacist in the healthcare team including the clinical skills that enable the critical review of patient pharmacotherapies. Where appropriate, during the Degree Programme, teaching and learning should take place alongside and together with students of other related healthcare professions. Wherever possible, students should gain first-hand structured experience of practice, including contact with patients;
- d) feature a variety of teaching and learning approaches appropriate to stated learning outcomes, which may include but not be limited to: lectures; practical classes; seminars; tutorials and other forms of interactive small-group teaching whether that be face-to-face or in the virtual learning environment;
- e) facilitate the development of the student's communication skills and this should be underpinned by the theoretical basis within the social and behavioural science content of the Degree Programme;
- f) encourage students to take responsibility for their own learning both within the Degree Programme and as a basis for later continuing professional development;
- g) place emphasis upon the development of problem-solving skills and the justification of decisions made both on an individual and team-based basis;
- h) ensure that teaching and learning take place alongside and with reference to research and other scholarly activities;
- i) ensure that pharmacy students realise the importance of working as part of a multidisciplinary team.

5.2 Notwithstanding the requirement to ensure a balance of pharmacist input across the programme, the Teaching and Learning Strategy must provide that, where no pharmacist is appointed within an area of academic expertise, there are robust mechanisms in place to ensure that teaching and learning in modules/course units in that area take place in a pharmacy context.

5.3 The Teaching and Learning Strategy should ensure that pharmacy law, ethics, professionalism and pharmacy practice are taught predominantly by pharmacists with contemporary experience of practice, drawn preferably from within the School.

- 5.4 The Teaching and Learning Strategy must incorporate a clear and realistic student code of conduct that is explained, communicated and enforced to promote professional behaviour.

Standard 6	ASSESSMENT STRATEGY
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The Assessment Strategy is aligned with the curriculum learning outcomes (see Standard 4) and with the teaching and learning strategy (see Standard 5) and uses effective and validated diagnostic, formative and summative assessment methods that are reviewed at frequent intervals and take account of developments in pharmacy practice within all components of the Degree Programme.

6.1 The Assessment Strategy must:

- (a) provide clear guidance to students relating to assessment of stated professional and learning outcomes, with objective reporting on assessments and include fair and just complaints and appeals processes;
- (b) include assessment of professionalism and the process of professionalisation appropriate for application to entry to the NPIP and must take account of the NPIP competence standards and the core competency framework as approved by the PSI Council from time to time;
- (c) position knowledge, understanding and competence development in a pharmacy context. Notwithstanding the requirement to ensure a balance of pharmacist input across the programme, should there be no pharmacist appointed within an area of academic expertise there must be robust mechanisms in place to ensure that assessment in modules/course units in that area takes place in a pharmacy context;
- (d) emphasise the contribution of the pharmacist in the healthcare team and where appropriate, during the Degree Programme, the student is assessed alongside and together with students of other related health professions;
- (e) demonstrate a holistic approach and include, for example, mechanisms which measure cognitive learning, mastery of essential practice skills, ability to communicate, team-working, numeracy and use of data in problem solving;
- (f) include the demonstration of competence in extemporaneous dispensing and of competence in the dispensing and supply of medicines. In addition, an examination in dispensing procedures must be taken under full examination conditions;
- (g) include a formal examination of pharmacy law and a summative assessment of ethics and professionalism in the final year. The award of the degree will be conditional upon success in these assessments;
- (h) require achievement of a satisfactorily high standard in assessments of dispensing practice (this may include skills of communication with patients and prescribers), pharmacy law, pharmacy practice (including clinical practice and therapeutics) and ethics and professionalism irrespective of the student's performance in other subjects. Neither compensation nor condonement of marks for these subjects is allowed.

6.2 The Assessment Strategy must take a holistic view of a student's performance and must be supported by a robust and transparent appeals process that is fully documented and communicated to students.

Standard 7	STUDENTS
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There must be processes at HEI and School level to assist prospective students in their application to the Degree Programme and to support students' development as learners and as professionals and their subsequent progression through the Degree Programme.

7.1 Entry to and Progression on the Degree Programme

Policies and procedures must be in place for admission to and successful progression through the Degree Programme and these must:

- (a) be open and available to prospective applicants and ensure non-discrimination as defined by national laws and regulations such as, on the basis of gender, marital status, family status, age, race, religion, disability, sexual orientation, membership of the Traveller community;
- (b) include a clear statement of the requirements for entry, progression and successful completion, in the form of the knowledge, skills and professional attributes needed alongside any requirements that are laid down by the PSI Council from time to time;
- (c) be open, fair, not impose unreasonable requirements on applicants and incorporate a fair and just complaints and appeals process;
- (d) include specific and appropriate criteria relating to the requirements for professional standards and Garda vetting and for how any health requirements appropriate for the practice setting are met.

7.2 Student Support and Guidance

Appropriate and timely support mechanisms must be in place for students on the Degree Programme including:

- (a) processes to identify and, where appropriate, provide additional educational, cultural and professional support needs as appropriate;
- (b) access to a personal tutor or tutors for academic guidance and pastoral care;
- (c) mechanisms to ensure that the views and experiences of students on the quality of the Degree Programme are considered. Wherever appropriate students should be represented on committees and other groups that have responsibility for the design, implementation and review of the Degree Programme;
- (d) a student complaints policy, including the procedures to be followed and clarity regarding students' rights to 'due process'. There should be an introduction to this policy included in the orientation sessions;
- (e) encouragement to undertake vocational employment/placement or work experience in a variety of relevant professional settings in order to set learning in the context of pharmacy practice and to inform career choice;
- (f) encouragement of active engagement with relevant pharmaceutical students' associations at HEI, national and international level in order to develop individual professional and leadership qualities and foster international pharmaceutical links;
- (g) access to counselling in relation to poor progress, learning difficulties, impairment and disability issues, including any health or social problems.

Standard 8	RESOURCES
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The School must have sufficient allocated resources, financial, physical and staff and have developed and documented contingency plans to cover deficiencies in order to ensure the effective delivery of a Degree Programme that meets the Accreditation Standards of the BPharm/BSc (Pharm) degree programme as may be approved from time to time by the PSI Council.

8.1 Academic Staff

The School must have a sufficient number of academic staff appropriately qualified and experienced and expert in pharmaceutical sciences and pharmacy practice including an appropriate number with contemporary experience of pharmacy practice. This staff must:

- (a) provide the majority of teaching and learning support for the Degree Programme. (Where 'service teaching' is identified as essential, there shall be a robust means of managing its integration into the Degree Programme);
- (b) provide the academic direction for all teaching and learning support or assessment provided by individuals from outside the School (see also Standard 2);
- (c) liaise with any staff involved in 'service teaching' to support the adaptation of examples used in teaching and learning to contemporary pharmacy context and ensure it is patient-centred;
- (d) be provided with the resources, support and academic environment which allows them to maintain their knowledge at the leading edge of pharmaceutical science and clinical pharmacy practice;
- (e) be encouraged and supported to engage in scholarship and research which is disseminated nationally and internationally;
- (f) have access to an organised professional development programme open to all teaching staff consistent with their respective responsibilities. This programme must provide opportunities to develop teaching, learning and assessment skills and the use of new learning technologies. This requirement applies to both full-time staff and part-time staff including teacher practitioners and all those contributing to teaching, learning and assessment.

8.2 External Experts

The School should ensure that relevant input from external specialist lecturers is provided to enhance the students' contextual understanding of specific areas.

8.3 Support Staff

The School must have a sufficient number of support staff suitably qualified/trained and experienced to support its operation.

8.4 Infrastructure and Financial Resources

The School must ensure that accommodation (including teaching rooms, and laboratories), equipment, library facilities, IT (including appropriate interactive distance learning technology/VLE) and subject specific IT specialist software (for example dispensing software)

and other resources available to it are sufficient for the effective delivery and examination of the planned Degree Programme to the numbers of students in each year of the Degree Programme and overall; properly taking account of the other teaching and research commitments of the School.

Standard 9	QUALITY ASSURANCE
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All processes and activities related to the Degree Programme must be clearly defined, documented, executed and controlled in accordance with a system of Quality Management which assures and demonstrates consistency, reproducibility and transparency of operations.

- 9.1 Indicators of performance must be established and maintained to monitor compliance with the Accreditation Standards for the Undergraduate Pharmacy Degree Programme set by the PSI Council from time to time.
- 9.2 There must be robust quality assurance and enhancement systems underpinning the Degree Programme. These must include clear and systematic mechanisms to monitor, review and evaluate all aspects of the education process leading to appropriate action being taken.
- 9.3 There must be a reliable means of reviewing each student's proficiency over the period of the Degree Programme to provide robust evidence of each student's performance over a sustained period. The award of an accredited degree is conditional on demonstration of sustained achievement of appropriate level of professional performance. Fitness-to-practise mechanisms for student pharmacists must be in operation and routinely reviewed.
- 9.4 All proposed material changes to the Degree Programme must be documented and submitted prior to implementation to the PSI for approval in line with statutory requirements. The programme document management policy must record and retain all changes to the Degree Programme as accredited over time. This is to enable the retrieval of the programme of study undertaken by each student at any time.
- 9.5 There must be a reliable process to ensure the development of an environment and culture that promotes professional behaviour among students, staff and all those contributing to the Degree Programme.

Appendix A

INDICATIVE SYLLABUS FOR IRISH PHARMACY DEGREE COURSES

The indicative syllabus exists as a general guide to an appropriate scope of curriculum content for the undergraduate degree programme in pharmacy but is not intended to define a contemporary pharmacy programme. To ensure continuity with the existing programme provision and the smooth transition to the transitional standards, the indicative syllabus has not been subject to significant review. While a comprehensive review of the indicative syllabus was not appropriate at this point in time (in view of the impending 5-year programme development), minor changes have, however, been made to reflect changes in the law and in the terminology used in pharmacy health provision.

I. PHARMACY PRACTICE

a. The Practice of Pharmacy

- (i) The pharmacist's role in patient-care and patient safety in community, hospital, industrial and academic pharmacy settings.
- (ii) Problem-solving in all main aspects of managing medicines (dispensing only being a part of this), clinical pharmacy practice (including medication safety and medicines information), responding to symptoms, provision of drug and patient information, recognition, management and reporting of adverse drug reactions and quality defects and assessment of drug interactions, drug utilisation evaluation, and measuring outcomes in support of evidence-based practice and achieving maximum clinical effectiveness.
- (iii) Principles and methodologies of the social and behavioural sciences relevant to pharmacy.
- (iv) Health policy and concepts of health economics, including those related to pharmacoeconomics and pharmacoepidemiology.
- (v) Theory and practice of personal and inter-personal skills, including written and verbal communication skills, and study skills.
- (vi) The pharmacist as a Qualified Person in the pharmaceutical industry.
- (vii) Codes of practice and acceptable standards of practice, including the PSI statutory code of conduct for Pharmacists, practice guidelines of the Pharmaceutical Society of Ireland and those relating to continuing professional development.
- (viii) Approaches to quality assurance and Total Quality Management, including Good Manufacturing Practice, Good Distribution Practice, Good Laboratory Practice and Good Clinical Practice (within clinical trials).
- (ix) Pharmacy Law and ethics and professionalism, their role and importance within pharmacy and society.
- (x) The use of information technology in pharmacy and more widely in health care.

b. Improvement and Development of Pharmacy

- (i) Professional and inter-professional audit of pharmacy practice with a view to continuous improvement.
- (ii) Promotion of good health and disease prevention through health promotion, the pharmacist's contribution (public health role of the pharmacist)
- (iii) Health services research and welfare services research: research methods and applying results to support evidence-based practice.
- (iv) New roles for the pharmacist in health care.

c. Pharmacy in Society

- (i) The administrative and legal framework in Ireland and in the European Union. ;
- (ii) The duty of care to patients and to the wider public: concept, scope and application of professional ethics, and the PSI statutory code of conduct for pharmacists.
- (iii) Health and illness: definitions and perceptions.
- (iv) The philosophy behind the provision of health care services in Ireland.
- (v) Medicines control (to include the control of veterinary medicines, blood products, herbal medicines, homeopathic medicines and other alternative medicines): authorisation of medicines: consumer protection, including concepts of product liability; legal classification of medicines, including controlled drugs and their sub-categories; the manufacture, packaging, labelling and distribution of medicines.
- (vi) The control of poisons as set out in the Poison Regulations 2008.
- (vii) Retail pharmacy businesses: the regulations governing the registration management and supervision of retail pharmacy businesses.
- (viii) The Pharmacy Act 2007 (as amended by the European Communities (Recognition of Professional Qualifications Relating to the Profession of Pharmacist) (No. 2) Regulations 2008) and the various Regulations and Rules made thereunder.
- (ix) Drugs of Abuse and Chemical Dependence: Approaches to the treatment of Drug Misusers including the Guidance for Pharmacists on the Safe Supply of Methadone as published by the PSI and which incorporates the document generally referred to as the methadone treatment protocol.

II. THE SOURCES, ISOLATION, CHARACTERISATION, ANALYSIS AND PROPERTIES OF HUMAN AND VETERINARY MEDICINES

- (i) Sources and purification of substances used in medicine of biotechnological, chemical synthetic, immunological, mineral, animal and plant origin.
- (ii) Drug isolation and structural determination from natural and synthetic sources.
- (iii) Cell and molecular biology relevant to biotechnology.
- (iv) Physico-chemical aspects of drugs and biological systems, including thermodynamics and chemical kinetics.
- (v) Analytical methods (including those for biotechnology products): principles, design, development, validation and application.
- (vi) Specifications of substances used in medicine, including physical, chemical and microbiological tests.

- (vii) Assessment of chemical and physical stability.
- (viii) Good Laboratory Practice.
- (ix) Prediction of drug properties, including chemical compatibilities, from molecular structure.
- (x) Drug design; principles and future prospects.

III. DESIGN AND MANUFACTURE OF HUMAN AND VETERINARY MEDICINES: MATERIALS, METHODS AND QUALITY STANDARDS

- (i) Properties of materials used in formulations and devices for the delivery of biologically-active molecules; biological, chemical and physical properties.
- (ii) Development pharmaceuticals, pre-formulation and formulation studies: design and standardisation of medicines for administration to the body by different routes and to specific target sites.
- (iii) Functionality of pharmaceutical excipients.
- (iv) Environmental control in manufacturing facilities and in the supply chain.
- (v) The influence of processing on product quality with respect to biological safety, bio-availability (including bio-equivalence), dosage uniformity and stability.
- (vi) Quality assurance of pharmaceutical products and processes.
- (vii) Good Manufacturing Practice (GMP) and its requirements.
- (viii) Packaging; purpose, design and evaluation.
- (ix) Effect of total supply process (supply chain) on product quality including the requirements of Good Distribution Practice (GDP).
- (x) Pharmacopoeial and regulatory standards.
- (xi) Stability of medicines; their evaluation in light of their potential biological, chemical and/or physical degradation.
- (xii) Sterilisation processes and aseptic procedures in the preparation of medicinal products and medical devices; monitoring of sterilisation processes and aseptic procedures.
- (xiii) Biological methods of measuring drug activity and the principles of biological standardisation.
- (xiv) Drug absorption, disposition, metabolism and excretion; formulation criteria and dosage regimens.
- (xv) Immunological, biotechnological and radiopharmaceutical products.

- (xvi) Dressings, medical devices and appliances.

IV. THE ACTION AND USES OF HUMAN AND VETERINARY MEDICINES AND OTHER HEALTHCARE PRODUCTS

- (i) Normal and abnormal bodily function: biochemistry, genetics, microbiology, nutrition, immunology, infective processes, pathology, pathophysiology and physiology.
- (ii) Actions of medicines within living systems: molecular, cellular, biological, and physical aspects.
- (iii) Preventative and therapeutic uses of medicines, including adverse reactions to and, their interactions with other medicines, herbal products and foods, and their clinical relevance to treatment.
- (iv) Aetiology and epidemiology of major diseases and the principles of their treatment.
- (v) Recognition of disease states and responding to symptoms of such.
- (vi) Zoonoses.
- (vii) Clinical evaluation of new medicines, post-marketing surveillance and knowledge of pharmacovigilance and pharmacoepidemiology.
- (viii) Clinical use of medicines, focusing on problem solving.
- (ix) Drug and substance misuse, and physiological and psychological dependence.
- (x) Alterations in drug absorption, distribution, metabolism and excretion including alterations brought about by ageing, disease and other factors.
- (xi) Clinical toxicology associated with drug over-dosage, drug or substance misuse or accidental consumption or exposure.
- (xii) Medical devices including medicine delivery devices and other appliances.
- (xiii) Dressings and wound management products.
- (xiv) Potential of novel approaches in therapeutics: review and assessment.

Appendix B

Relevant Legislation

- **Directive 2005/36/EC of the European Parliament and of the Council on the recognition of professional qualifications - Article 44 and Annex V.6. – section 5.6.1 (see extracts below)**

Article 44 – Training as a pharmacist:

1. *Admission to a course of training as a pharmacist shall be contingent upon possession of a diploma or certificate giving access, in a Member State, to the studies in question, at universities or higher institutes of a level recognised as equivalent.*
2. *Evidence of formal qualifications as a pharmacist shall attest to training of at least five years' duration, including at least:*
 - (a) *four years of full-time theoretical and practical training at a university or at a higher institute of a level recognised as equivalent, or under the supervision of a university;*
 - (b) *six-month traineeship in a pharmacy which is open to the public or in a hospital, under the supervision of that hospital's pharmaceutical department.*

That training cycle shall include at least the programme described in Annex V, point 5.6.1. The contents listed in Annex V, point 5.6.1 may be amended in accordance with the procedure referred to in Article 58(2) with a view to adapting them to scientific and technical progress.

Such updates must not entail, for any Member State, any amendment of existing legislative principles relating to the structure of professions as regards training and the conditions of access by natural persons.

3. *Training for pharmacists shall provide an assurance that the person concerned has acquired the following knowledge and skills:*
 - (a) *adequate knowledge of medicines and the substances used in the manufacture of medicines;*
 - (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 medicines 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.*

Annex V.6 – Section 5.6.1 Course of training for pharmacists:

- Plant and animal biology
- Physics
- General and inorganic chemistry
- Organic chemistry
- Analytical chemistry
- Pharmaceutical chemistry, including analysis of medicinal products
- General and applied biochemistry (medical)
- Anatomy and physiology; medical terminology
- Microbiology
- Pharmacology and pharmacotherapy
- Pharmaceutical technology
- Toxicology
- Pharmacognosy
- Legislation and, where appropriate, professional ethics.

The balance between theoretical and practical training shall, in respect of each subject, give sufficient importance to theory to maintain the university character of the training.

- **Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community Code relating to Medicinal Products for Human Use – Article 49 (see extract below):**

Article 49:

1. *Member States shall ensure that the qualified person referred to in Article 48 fulfils the conditions of qualification set out in paragraphs 2 and 3.*
2. *A qualified person shall be in possession of a diploma, certificate or other evidence of formal qualifications awarded on completion of a university course of study, or a course recognized as equivalent by the Member State concerned, extending over a period of at least four years of theoretical and practical study in one of the following scientific disciplines: pharmacy, medicine, veterinary medicine, chemistry, pharmaceutical chemistry and technology, biology.*

However, the minimum duration of the university course may be three and a half years where the course is followed by a period of theoretical and practical training of a minimum duration of one year and including a training period of at least six months in a pharmacy open to the public, corroborated by an examination at university level.

Where two university courses or two courses recognized by the State as equivalent co-exist in a Member State and where one of these extends over four years and the other over three years, the three-year course leading to a diploma, certificate or other evidence of formal qualifications awarded on completion of a university course or its recognized equivalent shall be considered to fulfil the condition of duration referred to in the second subparagraph in so far as the diplomas, certificates or other evidence of formal qualifications awarded on completion of both courses are recognized as equivalent by the State in question.

The course shall include theoretical and practical study bearing upon at least the following basic subjects:

- Experimental physics
- General and inorganic chemistry
- Organic chemistry
- Analytical chemistry
- Pharmaceutical chemistry, including analysis of medicinal products
- General and applied biochemistry (medical)
- Physiology
- Microbiology
- Pharmacology
- Pharmaceutical technology
- Toxicology
- Pharmacognosy (study of the composition and effects of the natural active substances of plant and animal origin).

Studies in these subjects should be so balanced as to enable the person concerned to fulfil the obligations specified in Article 51.

In so far as certain diplomas, certificates or other evidence of formal qualifications mentioned in the first subparagraph do not fulfil the criteria laid down in this paragraph, the competent authority of the Member State shall ensure that the person concerned provides evidence of adequate knowledge of the subjects involved.

3. *The qualified person shall have acquired practical experience over at least two years, in one or more undertakings which are authorized to manufacture medicinal products, in the activities of qualitative analysis of medicinal products, of quantitative analysis of active substances and of the testing and checking necessary to ensure the quality of medicinal products.*

The duration of practical experience may be reduced by one year where a university course lasts for at least five years and by a year and a half where the course lasts for at least six years.

- **Pharmacy Act 2007, Section 7 (1) (b) and (c) and 7 (2) (a)(iv)**
- **Pharmaceutical Society of Ireland (Education and Training) Rules 2008 (S.I. No. 493 of 2008), Part 3, Rule 7(1) and (2) and Schedule (extract of Schedule reproduced below):**

SCHEDULE

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/EC.

- **European Commission. Advisory Committee on Pharmaceutical Training (1995) Report and Recommendations on pharmaceutical education undergone at higher education institutions (adopted by the Committee at its meeting on 3 and 4 May 1994) (Ref. XV/E/8341/6/93-EN) – see section 4 – ‘Recommendations on the organisation and structure of training at higher education institutions’ (see extract below):**

Firstly, the Advisory Committee on Pharmaceutical Training points out that

The length of pharmaceutical training and the minimum range of subjects in which theoretical and practical training must be undergone are laid down in Directive 85/432/EEC, which also explicitly states that the balance between theoretical and practical training must, in respect of each subject, give sufficient importance to theory to maintain the university character of the training.

Future developments in pharmacy and medicine will lead to constant revisions of syllabus as has been seen with the introduction of new subjects such as molecular biology and biotechnology in recent years. This is essential if pharmacists are to be equipped properly by their course of education and training for practice in various fields.

The Committee makes the recommendations set out below without, however, excluding individual national provisions which are not contrary to the principles in the Directive.

- *A thorough grounding in the basics sciences of chemistry, physics and biology plus mathematics should be accepted as a prerequisite for admission to studies of the pharmaceutical sciences.*
- *In view of the minimum period of four years’ training at a higher education institution laid down in Article 2(3) of Directive 85/432/EEC, the number of hours of such training should total at least 3000 directed and supervised by the academic staff of the higher educational institution concerned.*
- *At least half the higher education course identical for every student should consist of theoretical instruction, and at least 35% of that course should take the form of practical training.*

- *During the training period, pharmacy students must be provided with a sound and balanced grounding in the physical, chemical and biological sciences that represent the basis for their main training in:*
 - *biological systems, the chemistry of drugs and other constituents of medicines, and the interaction between medicines and biological systems.*
 - *medicines design and manufacture.*
 - *the actions and uses of drugs, medicines and other products.*
 - *an introduction to the practice of pharmacy in hospital, industrial, academic and community pharmacy settings, including an introduction to the relevant aspects of the social and behavioural sciences.*
- *At least one third of the whole course should be occupied by the components which collectively deal with the actions, uses and manufacture of drugs and medicines, and a broad balance should be maintained between the other sectors of the course.*
- *Intermediate examinations should be held during the course.*
- *In addition to the core course, which all students must take, individual students should be able to select one or more optional pharmaceutical subjects from a list provided by the academic institution, to reflect their special interests.*
- *Each student should carry out a personally directed research project covering about three to six months under the supervision of the academic staff and present a paper or dissertation on the project.*

REFERENCES

The following have all been considered in drawing up these interim accreditation standards:

- Accreditation Council for Pharmacy Education (ACPE) (2007). *Accreditation Standards and Guidelines for the Professional Program in Pharmacy leading to the Doctor of Pharmacy Degree*.
- Association of Faculties of Pharmacy of Canada (AFPC) (2010). *Educational Outcomes for First Professional Degree Programs in Pharmacy (Entry-to-Practice Pharmacy Programs) in Canada*.
- Australian Pharmacy Council (2009). *Accreditation Standards*.
- Australian Pharmacy Council (2009). *Guidelines and Procedures for Accreditation*.
- Canadian Council for Accreditation of Pharmacy Programs (2006). *Accreditation Standards and Guidelines for the Baccalaureate Degree Programme in Pharmacy*.
- General Pharmaceutical Council (2010). *Future Pharmacists – Standards for the initial education and training of pharmacists*.
- Pharmaceutical Society of Ireland (2010). *Interim Accreditation Standards for the Level 9 Masters Degree awarded on the successful completion of the National Pharmacy Internship Programme*.

Annex 2 – Process Timetable

Timetable for Degree Programme accreditation process

1. Professional Development and Learning Unit identifies team leader and sets date for accreditation visit. Normally this will be within 5 years after the previous visit.
2. Professional Development and Learning Unit requests self-assessment documentation from the Degree Programme Provider.
3. Selection of visiting accreditation team by Professional Development and Learning Unit.
4. Visiting accreditation team finalised.
5. Receipt of documentation, from the Degree Programme Provider, by Professional Development and Learning Unit.
6. Papers sent to visiting accreditation team including rapporteur.
7. Documentation rejected if not in accordance with the PSI specifications.
8. Identification of potential issues jointly by team leader and Professional Development and Learning Unit.
9. Team leader considers need to appoint additional expert to team.
10. Degree Programme Provider pre-visit by team leader, if required.
11. Specification to Provider of any need for additional documentation and of any particular focus of the visit.
12. Feedback from team leader to accreditation team members and Professional Development and Learning Unit on collated responses and pre-visit.
13. Team members to provide their comments and/or potential questions on pre-defined template provided.
14. School visit by full team. Two-day visit.
15. Draft report and summary submitted by team leader and rapporteur to Professional Development and Learning Unit.
16. Draft report and summary provided to Head of School for notification of errors of fact within 25 working days.
17. Finalised reports considered by Professional Development and Learning Committee and ultimately by Council. Visiting team leader in attendance to inform consideration, as required.
18. Main report and accreditation letter sent to Degree Programme provider, and published on PSI's web-site.

Annex 3 – Accreditation Panel

Roles and other remarks

- A team leader – person experienced in degree accreditation responsible for the direction, facilitation and focus of an accreditation event (the Chair), and the content of the report of the visit, although the report writing may be performed by the rapporteur/secretary. Overall, they are responsible and accountable for assuring that the accreditation standards of PSI are being met.
- A non-pharmacist – person expected to make a valuable contribution to the process of assuring that the accreditation standards of the PSI are met, especially where their expertise or experience includes the education of other health care professionals. However, the main reason for their involvement is to see that accreditation is appropriately patient-focused and not primarily self-serving of the provider and the profession.
- A pharmacy academic – person involved in degree accreditation and is expected to bring expertise, based on seniority and experience.

The Accreditation Panel will normally comprise of: team leader, non-pharmacist, pharmacy academic, pharmacy practitioner(s), PSI staff member(s) (in a non-decision-making capacity) and rapporteur/secretary (also non-decision-making).

Panel Training

For the effective and efficient working of accreditation it is essential that all panel members be well acquainted with its purpose and process before undertaking visits. This is also essential for the perception of the course provider that the procedure is robust. Part of that robustness lies in the quality and preparedness of Panel members. Consequently, all Panel members must have recent previous experience of accreditation or have participated in a recent training workshop before serving on a visiting team.

A proportion of recruits to the Panel will have little knowledge, at least initially, of present day higher education and some or all of the non-pharmacist members may have little knowledge of pharmacy. Accordingly, training should address the workings both of higher education and of the profession.