

Draft Accreditation Standards for the Five-Year Fully Integrated Masters Degree Programmes in Pharmacy

Public Consultation Version

These Accreditation Standards have been developed to assure that the five-year fully integrated Masters degree programmes in pharmacy (MPharm) recognised and approved by the Council of the Pharmaceutical Society of Ireland (PSI) meet the stated requirements below.

1. The purpose of a five-year fully integrated Masters degree programme in pharmacy (the Professional Degree Programme) is to produce pharmacy graduates who have the knowledge, skills, attitudes and behaviours to meet the Core Competency Framework for Pharmacists (CCF) (see Appendix A) to be prepared for patient-centred pharmacy practice in all pharmacy settings and so be entitled to apply to have their names entered in the Register of Pharmacists under the Pharmacy Act 2007 (No. 20 of 2007). This Register is kept by the PSI. Their learning must be based upon and underpinned by appropriate and sufficient understanding of the principles and techniques of the pharmaceutical, biomedical and social sciences and pharmacy practice.
2. The Professional Degree Programme will seek to develop graduates who possess:
 - (a) the necessary scientific and professional knowledge and skills;
 - (b) professional and personal integrity and discipline of mind;
 - (c) 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;
 - (d) the capability to provide pharmacist-delivered patient care, to advance the practice of pharmacy and its contribution to society, to pursue research and other scholarly activities, and to assess and evaluate desired health outcomes;
 - (e) a commitment to life-long learning, in particular an awareness of the need to maintain appropriate experience in the practice of pharmacy, keep abreast of scientific and professional developments in pharmacy and undertake appropriate continuing professional development (CPD) relevant to the practice of pharmacy.
3. By awarding an accredited degree, the Higher Education Institute (HEI) is confirming that a graduate fully demonstrates the competencies necessary to apply to enter the Register of Pharmacists held by the PSI.
4. These standards are intended to underpin and complement the statutory requirements set out in the Pharmacy Act 2007 (as amended) and any related statutory instruments. This includes the requirement that the Higher Education Institutes (HEIs) concerned produce and submit an annual report to the Registrar of the PSI on matters relating to the programme of education and training being provided.

The Professional Degree Programme Provider must engage in a systematic planning process and have a current strategic plan that facilitates achievement of the Professional Degree Programme Provider's mission, goals and objectives.

- 1.1 The mission should include a clear statement of the educational philosophy including how the organisation will foster a culture that:
 - (a) promotes professional behaviour among students, staff and all those contributing to the Professional Degree Programme; and
 - (b) respects and supports the needs of diverse stakeholders, students and staff.
- 1.2 There should be evidence that the mission, goals and objectives have been reviewed and validated by the Higher Education Institution (HEI) and should be demonstrably congruent with the mission of the HEI and are within the context of societal and professional changes occurring and contemplated. The mission statement should set out clearly the primacy of patient safety, care and well-being. This must be demonstrated by the existence of:
 - (i) a chronological log of any concerns raised relating to patient safety and well-being that arise as a consequence of the educational process;
 - (ii) clear and published procedures known to all staff and students to immediately review and address such concerns that may impact upon patient safety;
 - (iii) a Fitness to Practise policy known to all staff and students to assure patient safety and public protection at all times; and
 - (iv) an explicit recognition that by awarding a degree accredited by the Council of the PSI, the HEI is confirming that a graduate is fit to apply to have their names entered in the Register of Pharmacists.
- 1.3 The Professional Degree Programme Provider should have a published statement of its mission and goals and set out its key performance indicators (KPIs) and timescales for their implementation and review. This should include an explanation of how the Professional Degree Programme Provider will monitor and evaluate its performance against the goals and objectives of its strategic plans.
- 1.4 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 Professional Degree Programme Provider including clearly defined learning outcomes to demonstrate that at the end of the Professional Degree Programme, the graduate is competent to practise pharmacy in a patient-centred, professional and ethical manner, and demonstrates a commitment to lifelong learning;
 - (c) A statement of the educational philosophy for the Professional Degree Programme and how it:
 - (i) supports or assures that graduates will be prepared for entry to the profession of pharmacy including patient-centred practice in line with the Core Competency Framework for Pharmacists as established by the PSI Council from time to time;
 - (ii) prepares graduates for practice as pharmacy professionals who will embrace lifelong learning; and

- (iii) provides structured experience of interprofessional working to facilitate team-work in the delivery of patient-centred care.
- (d) A commitment to excellence in teaching and learning methods;
- (e) A vision for leadership in practice, research and other scholarly activity and educational activities.

1.5 For a newly planned and/or recently established programme, the Professional Degree Programme Provider must provide a comprehensive strategy outlining the planning, development and implementation phases of the programme.

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There must be clear management structures for the Professional 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 Professional Degree Programme.

- 2.1 The Professional Degree Programme must be planned and delivered by an identifiable organisational unit preferably a School or Faculty of Pharmacy ('the School'), which has responsibility for the Professional Degree Programme and associated resources. Furthermore the Professional Degree Programme must be planned and maintained through transparent processes and must 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;
 - (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 placed into any part of the programme that involves access to patients, the public or confidential data, if they are considered likely to pose a risk.
- 2.3 The Head of the School must be qualified to provide leadership in pharmacy professional education, including research and scholarly activities, and so 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 registered in Ireland who can provide leadership in the practice and profession of pharmacy and have authority for effective advocacy for pharmacy within the HEI and be held accountable for the oversight of practice-based learning. This person must be at a senior level within the School and be registered in the Register of Pharmacists and thereby be familiar with, and subject to, the PSI statutory Code of Conduct.
- 2.4 The HEI must support the development of suitable relationships between the School and other academic and service units of the HEI for instruction, research and practice-based and interprofessional learning.
- 2.5 External relationships or collaborations with the pharmacy profession must be facilitated to foster the School's teaching, learning and research capabilities. The School should have access to, and arrangements with, HEI affiliated healthcare teaching facilities in support of the practice-based and interprofessional learning needs of the Professional Degree Programme [see also Standard 3.5(c)]. Wherever possible, collaborative approaches to practice-based placements must be used in conjunction with other HEIs in the State offering a pharmacy degree programme.
- 2.6 The Professional 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 required for registration as pharmacists.

- 2.7 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 Professional Degree Programme with the School's commentary and analysis. The School must maintain a reliable, accurate and workable management information system in support of this.
- 2.8 The Head of School has an obligation to report to the PSI:
- (a) on key issues including any changes in resources that are pertinent to the delivery of the Professional Degree Programme; and
 - (b) at the point of graduation, a confirmation that each graduate has met the competencies in the CCF. In order to do this, the School must maintain, in accordance with any policy as approved by the PSI Council from time to time or any legislative provisions, an ongoing record of 'fitness to practise' matters and any other matters that could have a material impact on future fitness to practise when the student/graduate in the future is practising as a pharmacist.

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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 that may arise in order to ensure the effective delivery of a Professional Degree Programme that continues to meet the 'Accreditation Standards of the five-year fully integrated Masters degree programmes in pharmacy' as approved by the PSI Council from time to time.

3.1 Academic Staff

The School must have a sufficient number of core academic staff and other teaching staff including professionally qualified staff such as teacher-practitioners, practice educators and tutor pharmacists, appropriately qualified, experienced and expert in pharmaceutical sciences and pharmacy practice. There must be an appropriate mix of academic staff practising as pharmacists in clinical practice including senior staff who can influence policy within the School. This staff must:

- (a) provide the majority of teaching and learning support for the Professional Degree Programme. Where 'service-teaching' is identified as essential, there shall be a robust means of managing its integration into the Professional Degree Programme and ensuring that the teaching is oriented towards pharmacy;
- (b) individually and collectively, demonstrate a commitment to the mission of the School and to the goals and objectives of the Professional Degree Programme and a continuing commitment to be effective teachers;
- (c) provide the academic direction for all teaching and learning support or assessment provided by individuals from outside the School;
- (d) liaise with any staff from outside the School involved in teaching to support the adaptation of examples used in teaching and learning to contemporary pharmacy context and to ensure that it is patient-centred;
- (e) be provided with the resources, support and academic environment which allows staff members to maintain their knowledge at the leading edge of pharmaceutical, biomedical, and social sciences and clinical pharmacy practice;
- (f) be encouraged and supported to engage in scholarship and research which is disseminated nationally and internationally;
- (g) have access to an organised professional development programme open to all teaching staff members 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 of the HEI and to all those contributing to teaching, learning and assessment. The programme for tutor pharmacists must be amenable to flexible delivery and meet the requirements as approved by the PSI Council from time to time. Evidence of the impact of professional development programmes should be demonstrated.

3.2 Practice Educators

The School must have a sufficient number of Practice Educators, in joint appointment positions with practice placement sites as practicable, who will provide the specialised teaching on the

interface between the learning within the schools and that within the workplace and who will provide support to the students on placement and to their tutors.

3.3 External Experts

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

3.4 Support Staff

The School must have a sufficient number of support staff suitably qualified/trained and experienced to support its operation. This staff must have access to an organised development programme open to all support staff consistent with their respective responsibilities. Evidence of the impact of this programme should be demonstrated.

Technical staff should be proficient in the operation and maintenance of scientific instrumentation and other equipment. Technical staff should take an active role in the preparation and delivery of laboratory practice sessions and projects.

3.5 Tutor pharmacists

Pharmacists acting as tutors for the practice-placement elements of the programme must be of sufficient number, appropriately qualified and experienced and be professional role models with the knowledge, skills, attitudes and behaviours to effectively mentor, monitor and evaluate students.

3.6 Infrastructure and Financial Resources

- (a) The School must have the financial resources necessary to accomplish its mission and goals;
- (b) The School must ensure that accommodation (including teaching rooms and laboratories), equipment, library facilities, IT (including appropriate interactive distance learning technology/VLE), subject specific IT specialist software (for example dispensing software), clinical skills facilities and other resources available to it are sufficient for the effective delivery and assessment of the planned Professional Degree Programme to the numbers of students in each year of the Professional Degree Programme and overall; properly taking account of the other teaching and research commitments of the School;
- (c) There must be policies and procedures to ensure that training establishments for the practice-placement elements of the Professional Degree Programme are appropriate for the delivery of this element of the Professional Degree Programme and meet any requirements as approved by the PSI Council from time to time, including any requirements relating to consistency of approaches to placements
- (d) The School should have contingency plans, developed and documented, to cover any deficiencies in infrastructure, equipment or personnel.

The curriculum must be planned to deliver an integrated learning experience that combines and co-ordinates all components in a logical and cohesive manner with clearly articulated linkages between and across units within years and between years. The Professional Degree Programme must be planned as a whole to deliver graduates who have the knowledge, skills, attitudes and behaviours to meet the Core Competency Framework for Pharmacists necessary for entry to the profession of pharmacy and to assure the accountability of the profession to society.

- 4.1 The curriculum must be progressive in dealing with issues in increasingly complex and inter-related ways so that graduates meet the Core Competency Framework for Pharmacists as established by the PSI Council from time to time and that they can practise safely and effectively according to the statutory Code of Conduct for pharmacists, and any other guidance and requirements as approved by the PSI Council from time to time.
- 4.2 Sufficient time should be allocated over the whole period of the Professional 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. From the beginning, the Professional Degree Programme must be delivered in an environment which places study in a professional and academic context and requires students to conduct themselves professionally. Appropriate assessment of the development of professionalism should take place throughout the Professional Degree Programme.
- 4.3 The curriculum should embrace the scope of contemporary pharmacy practice responsibilities to patient-centred care as well as the emerging roles of the pharmacist within the context of societal and professional changes occurring and contemplated.
- 4.4 The curriculum must be designed, delivered and regularly reviewed to keep abreast of advances arising from research and development in medical and pharmaceutical science and services. The scientific base of the curriculum must be of adequate depth, scope and quality and sequenced appropriately to provide both a foundation and continuing support for the intellectual and clinical objectives of the Professional Degree Programme.
- 4.5 The curriculum must be delivered by interdisciplinary teams in order that the subject matter of the degree is integrated, 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, interactions and use, including the evidence-based use of medicines by patients and including health screening, health promotion, pharmaceutical care and the interprofessional nature of health and social care services.
- 4.6 The curriculum must be designed to ensure that, from the early stages of the Professional Degree Programme through to the advanced practice experiences, students are encouraged to assume and are assisted in assuming, responsibility for their own learning, including assessment of their learning needs. Students should also be encouraged to participate and be assisted in participating in the education of others.

- 4.7 The Curriculum should be guided by, but not limited to, the indicative syllabus shown in Appendix B of this document¹ and it should take account of, and be responsive to, developments in pharmaceutical science and services and in pharmacy practice.
- 4.8 The curriculum must provide appropriately comprehensive training in research methods applicable to scientific and health research in order to meet the CCF and it must include practice research. In addition, the Professional Degree Programme must include a significant research component that meets the requirements of a level 9 degree programme on the National Framework of Qualifications.
- 4.9 There must be a continuum of structured and quality assured practice-placement experiences throughout the curriculum from introductory to advanced that are of adequate scope, intensity, structure and duration to support achievement of the CCF. The structure of these practice-placement experiences must meet the PSI Council policy as approved from time to time. These experiences must integrate, apply, reinforce and advance the knowledge, skills, attitudes and behaviours developed through the other components of the curriculum.
- 4.10 The curriculum must comply with the various minimum legal requirements at national and European level (see Appendix C).² The curriculum must take account of the recommendations of the Advisory Committee on Pharmaceutical Training (European Commission, 1995)³.

¹ The indicative syllabus exists as a general guide to an appropriate scope of curriculum content for the Professional Degree Programme. It is not intended to define a contemporary pharmacy programme.

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

³ In this respect, a curriculum compliant with the European Credit Transfer and Accumulation System (ECTS) meets the total hours requirement of these recommendations.

The Teaching and Learning Strategy must be designed to deliver a curriculum that produces graduates that meet the Core Competency Framework for Pharmacists as established by the PSI Council from time to time.

5.1 The Teaching and Learning Strategy must:

- a) be structured to provide an integrated experience of relevant science and pharmacy practice, a balance of theory and practice and the development of independent learning skills;
- 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 and, where appropriate, during the Professional Degree Programme, teaching and learning should be organised so that students can learn with and from students of other related healthcare professions;
- d) include practical experience of working with patients, carers and other health care professionals. The intellectual and professional demands of the practice experience should increase year on year and the teaching and learning strategy must articulate how this will be achieved (for example, off-site placements, learning sessions involving patients, carers and/or health professionals and simulations);
- e) articulate how experiential and practice-based learning and the input of tutor pharmacists is integrated within the Professional Degree Programme and how it contributes to the overall outcomes of the Programme;
- f) correspond to contemporary and potential future requirements of pharmacy practice, featuring a variety of teaching and learning approaches appropriate to stated learning outcomes, and be in step with current healthcare developments and provision, reflective of changing client and service needs and so ensure that graduates meet the CCF to be eligible to apply for registration as pharmacists. Approaches should include a combination of didactic, experiential and direct observational activities, including the development of appropriate clinical skills. Adult education principles should be introduced in the latter stages of the Professional Degree Programme and, in particular, to underpin the practice-placement elements;
- g) facilitate the development of the student's consultation, counselling and communication skills (as referred to in the CCF) and this should be underpinned by the theoretical basis within the social and behavioural science content of the Professional Degree Programme;
- h) encourage students to take responsibility for their own learning both within the Professional Degree Programme and as a basis for later continuing professional development;
- i) place emphasis upon the development of problem-solving skills and the justification of decisions made both on an individual and team-based basis;
- j) ensure that teaching and learning take place alongside and with reference to research and other scholarly activities in order that all students develop critical, analytical skills, an understanding of research methods and to support evidence-based decision-making and practice;
- k) ensure that the students recognise 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 must ensure that pharmacy law, ethics, professionalism and pharmacy practice are taught predominantly by pharmacists with appropriate contemporary experience of practice, drawn preferably from within the School.
- 5.4 The Teaching and Learning Strategy must develop a culture of professionalism, collegiality, civility and respect among students and staff and this must be underpinned by a clear and realistic student code of conduct that is explained, communicated and enforced to assure professional behaviour. This must be supported by Fitness to Practise procedures that address causes for concern raised about students (see Standard 2).

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The Assessment Strategy must ensure that all graduates demonstrate the competencies set out in the Core Competency Framework for Pharmacists as established by the PSI Council from time to time. The strategy must align with the teaching and learning strategy (see Standard 5) and use 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 Professional Degree Programme.

6.1 The Assessment Strategy must:

- (a) be planned at the Professional Degree Programme level to include a range of methods, at each level of study, appropriate to assess the progressive attainment of all competencies set out in the CCF and the process of professionalisation;
- (b) include clearly defined marking criteria and the pass criteria must reflect safe and effective practice. All assessments must take account of patient safety and any evidence of unsafe practice must result in failure. Condonation and compensation should not normally be applied and, if used, the graduate must still demonstrate all competencies as set out in the CCF;
- (c) be framed by Institutional regulations for the Professional Degree Programme that are appropriate for an award that is both academic and professional in nature;
- (d) provide clear guidance to students relating to assessment of stated professional and learning outcomes, with objective reporting on assessments;
- (e) 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 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;
- (f) emphasise the contribution of the pharmacist in the healthcare team and where appropriate, during the Professional Degree Programme, the student is assessed alongside and together with students of other related health professions;
- (g) demonstrate a holistic approach and include, for example, mechanisms which measure cognitive learning, mastery of essential practice skills, ability to communicate effectively, team-working, numeracy and use of data in problem-solving;
- (h) develop students as self-directed learners underpinned, where possible, by participation in peer review and assessment;
- (i) include a formal examination of pharmacy law towards the end of the Professional Degree Programme;
- (j) address pharmaceutical calculations in all years of the Professional Degree Programme;
- (k) include a final formal summative objective structured clinical examination in year five that seeks to assess in an integrated manner the performance of students based on the curriculum delivered over the five years of the Professional Degree Programme.

6.2 The Assessment Strategy must be supported by a robust and transparent appeals process that is fully documented and communicated to students.

- 6.3 There must be rigorous processes for review, monitoring and evaluation of all elements of the assessment strategy that identify and take account of inconsistencies and so ensure fairness and reliability.

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All processes and activities related to the Professional 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. There must be evidence that this process is being used to enhance the quality of the provision.

- 7.1 There must be clear management structures for the Professional Degree Programme with information about roles and responsibilities, lines of accountability and the authority to act for all those involved in education and training.
- 7.2 The School must describe how it assesses attainment of the educational philosophy of the Professional Degree Programme (see Standard 1.1).
- 7.3 The Professional Degree Programme Provider must be able to demonstrate a rigorous evaluation of the Professional Degree Programme and how outcome data and research into best practice are used to achieve continuous monitoring, risk minimisation, development and enhancement of the Professional Degree Programme. The views and experiences of the students, staff, tutor pharmacists, employers, service users and the PSI on the quality of the Professional Degree Programme must be considered. Wherever appropriate, students, staff, tutor pharmacists, employers and service users should be represented on committees and other groups that have responsibility for the design, implementation and review of the programme.
- 7.4 Key performance indicators (KPIs) must be established and monitored to ensure ongoing compliance with these 'Accreditation Standards for the five-year fully integrated Masters degree programmes in pharmacy' as approved by the PSI Council from time to time, and to meet the standards for the National Framework of Qualifications for a level 9 qualification. Where issues are identified that impact on compliance with the Accreditation Standards, immediate corrective action must be taken and notified to the PSI.
- 7.5 There must be a reliable means of reviewing each student's proficiency over the period of the Professional 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 an appropriate level of professional performance. Fitness to practise mechanisms for students must be in operation and routinely reviewed.
- 7.6 The Professional Degree Programme Provider must establish and operate a rigorous system for the external examination of the Professional Degree Programme. This system must include explicit policies and regulations covering the appointment, terms of office and role of the external examiners.
- 7.7 All proposed material changes to the Professional Degree Programme must be documented and submitted prior to implementation to the PSI for approval in line with the statutory requirements. The Professional Degree Programme document management policy must record and retain all changes to the Professional Degree Programme as accredited over time. This is to enable the retrieval of the programme of study undertaken by each student at any time, including post graduation.

- 7.8 There must be appropriate mechanisms in place to assure and enhance the quality of all practice placements including:
- a) the process to select, assess, accredit and appoint tutors and training establishments;
 - b) tutor development and support structures;
 - c) appropriateness of training establishments;
 - d) organisational support for the tutoring process; and
 - e) the allocation of students to training establishments.

There must be appropriate support for students including processes to monitor, review and take necessary corrective action.

There must also be appropriate levels of collaboration with regard to the quality assurance of practice placements between the School and the other Schools of Pharmacy in the State so as to facilitate and maximise the benefits of practice placements as a critical national resource.

- 7.9 There must be appropriate mechanisms to monitor performance of all staff and the School should provide evidence as to how this is carried out and how this links to the quality enhancement through a development programme (see Standard 3).

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There must be processes at HEI and School level to assist prospective students in their application to the Professional Degree Programme, in securing and maintaining placements for the practice-placement elements of the Professional Degree Programme, and to support students' development as learners and as future practising professionals.

8.1 Entry to and Progression on the Professional Degree Programme

Policies and procedures must be in place and regularly assessed for admission to and successful progression through the Professional 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 including policies on transfer credit and course waivers, progression and successful completion to align with the CCF, alongside any requirements as approved 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 and immunisation requirements appropriate for the practice setting are met.

8.2 Student Support and Guidance

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

- (a) processes to identify and, where appropriate, provide additional educational, cultural and professional support needs as appropriate;
- (b) a system of student support including access to a personal tutor or tutors for academic guidance and pastoral care and evidence of school evaluation;
- (c) support in securing and maintaining placements for the practice-placement elements of the Professional Degree Programme with tutor pharmacists who meet the recognition requirements as approved by the PSI Council from time to time (see also Standard 7.8);
- (d) orientation programmes to both the Professional Degree Programme and the School's expectation of students as members of the professional community. This orientation should include the learning environment, especially where innovative/virtual learning is incorporated into the delivery methods;
- (e) mechanisms to ensure that the views and experiences of students on the quality of the Professional 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 Professional Degree Programme;
- (f) a student complaints policy, including the procedures to be followed and clarity regarding students' rights to 'due process'. The provider must maintain a chronological record of student complaints. There should be an introduction to this policy included in the orientation sessions;

- (g) alongside formal practice placements and those required in line with PSI Council policy on the dispersal of practice placements throughout the five years, students are encouraged 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;
- (h) encouragement of active engagement with relevant pharmaceutical students' representative associations at HEI, national and international level in order to develop individual professional and leadership qualities and foster international pharmaceutical links;
- (i) access to counselling in relation to poor progress, learning difficulties, impairment and disability issues, including any health or social problems and career pathway counselling.

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Appendix A

Core Competency Framework for Pharmacists

DOMAIN 1

PROFESSIONAL PRACTICE

Competency:

1.1 Practises 'patient-centred' care

Behaviours:

- 1.1.1 Demonstrates a 'patient-centred' approach to practice
- 1.1.2 Ensures patient safety and quality are at the centre of the pharmacy practice
- 1.1.3 Educates and empowers the patient to manage their own health and medicines
- 1.1.4 Acts as a patient advocate to ensure that patient care is not jeopardised
- 1.1.5 Monitors the medicines and other healthcare needs of the patient on a regular basis and makes recommendations for improvement to the patient and other healthcare professionals as appropriate
- 1.1.6 Understands patients' rights to receive safe and high quality healthcare including pharmacy care and ensures that patient care delivered reflects evidence-based practice

Competency:

1.2 Practises professionally

Behaviours:

- 1.2.1 Carries out duties as a pharmacist in a professional manner
- 1.2.2 Demonstrates awareness of the position of trust in which the profession is held and practises in a manner that upholds that trust
- 1.2.3 Treats others with sensitivity, empathy, respect and dignity
- 1.2.4 Takes responsibility for their own actions and for patient care
- 1.2.5 Maintains patient confidentiality
- 1.2.6 Obtains patient consent as required
- 1.2.7 Recognises their scope of practice and the extent of their current competency and expertise and works accordingly
- 1.2.8 Maintains a consistently high standard of work

Competency:

1.3 Practises legally

Behaviours:

- 1.3.1 Understands and applies the Pharmacy Act 2007, as amended, and the orders, regulations and rules made thereunder
- 1.3.2 Understands and applies the requirements of both Irish and European pharmacy and medicines law
- 1.3.3 Demonstrates an awareness of other legislation relevant to their practice setting including as appropriate data protection law, health and safety law, employment law, consumer law, equality law and intellectual property rights
- 1.3.4 Demonstrates an understanding of the requirements of the regulatory framework to authorise a medicinal product including the quality, safety and efficacy requirements
- 1.3.5 Demonstrates an awareness of and adheres to professional indemnity requirements

Competency:

1.4 Practises ethically

Behaviours:

- 1.4.1 Understands their obligations under the principles of the statutory Code of Conduct for Pharmacists and acts accordingly
- 1.4.2 Makes and justifies decisions in a manner that reflects the statutory Code of Conduct for pharmacists and pharmacy and medicines law
- 1.4.3 Recognises ethical dilemmas in practice scenarios and reasons through dilemmas in a structured manner

Competency:

1.5 Engages in appropriate continuing professional development (CPD)

Behaviours:

- 1.5.1 Understands and accepts the importance of life-long learning for pharmacists
- 1.5.2 Demonstrates the ability to critically reflect on their own practice and skills, to identify learning and development needs
- 1.5.3 Takes personal responsibility for engaging in CPD and achieving learning and professional development goals
- 1.5.4 Identifies and undertakes appropriate learning activities and programmes that meet identified learning needs
- 1.5.5 Keeps knowledge and skills up to date

DOMAIN 2

PERSONAL SKILLS

Competency:

2.1 Leadership skills

Behaviours:

- 2.1.1 Inspires confidence and applies assertiveness skills as appropriate
- 2.1.2 Leads by example by acting to ensure patient safety and quality within the pharmacy environment
- 2.1.3 Builds credibility and portrays the profession in a positive light by being professional and well informed
- 2.1.4 Contributes to the initiation, development and continuous improvement of services for patients
- 2.1.5 Provides appropriate supervision to non-pharmacist staff and students

Competency:

2.2 Decision-making skills

Behaviours:

- 2.2.1 Demonstrates the ability to make accurate, evidenced based and timely decisions in relation to clinical decision-making and the management of patients
- 2.2.2 Makes decisions and solves problems in a timely manner
- 2.2.3 Gathers information from a number of reliable sources and people to enable them to make well-founded decisions
- 2.2.4 Communicates decisions comprehensively including the rationale behind decisions
- 2.2.5 Ensures that relevant professional, ethical and patient safety factors are fully considered in decisions into which they have an input
- 2.2.6 Distinguishes between important and unimportant issues
- 2.2.7 Demonstrates an attention to detail and accuracy in decision-making
- 2.2.8 Recognises when it is appropriate to seek advice from experienced colleagues, refer decisions to a higher level of authority or to include other colleagues in the decision

Competency:

2.3 Team working skills

Behaviours:

- 2.3.1 Recognises the value and structure of the pharmacy team and of a multiprofessional team
- 2.3.2 Collaborates with other healthcare professionals to

manage the care of a patient

- 2.3.3 Ensures effective handover between team members or to another healthcare professional to ensure continuity of patient care
- 2.3.4 Participates, collaborates and advises on therapeutic decision-making and uses appropriate referral in a multiprofessional team
- 2.3.5 Demonstrates a broad understanding of the services delivered by other healthcare professionals and disciplines

Competency:

Behaviours:

2.4 Communication skills

- 2.4.1 Uses effective verbal, non-verbal, listening and written communication skills to communicate clearly, precisely and appropriately
- 2.4.2 Communicates effectively with patients and their carers, with other healthcare professionals, other support staff, and other relevant third parties
- 2.4.3 Uses appropriate language and checks understanding
- 2.4.4 Demonstrates respect, cultural awareness, sensitivity and empathy when communicating
- 2.4.5 Demonstrates influencing and negotiation skills to resolve conflicts and problems
- 2.4.6 Demonstrates the ability to build positive relationships with patients, carers, colleagues and other healthcare professionals
- 2.4.7 Listens to patients and respects their views about their health and medicines

DOMAIN 3

SUPPLY OF MEDICINES

Competency:

Behaviours:

3.1 Manufactures and compounds medicines

- 3.1.1 Remains up to date with and applies pharmaceutical knowledge on the requirements of formulating and compounding of medicines
- 3.1.2 Demonstrates the ability to perform pharmaceutical calculations accurately
- 3.1.3 Applies pharmaceutical knowledge to select the appropriate route of administration and dosage form for the medicine
- 3.1.4 Applies pharmaceutical knowledge to select appropriate ingredients and excipients of the required quality standard

for the manufacture and compounding of medicines

- 3.1.5 Effectively uses technical skills to prepare pharmaceutical products as appropriate to their practice setting
- 3.1.6 Prepares pharmaceutical products according to the standards required including local standard operating procedures (SOPs), guidelines, or good manufacturing practice (GMP) as appropriate
- 3.1.7 Applies knowledge to ensure the appropriate quality controls and monitoring are in place
- 3.1.8 Maintains appropriate records and documentation
- 3.1.9 Demonstrates an understanding of the legislative framework and requirements that govern the manufacture of medicinal products, including GMP

Competency:

3.2 Manages the medicines supply chain

Behaviours:

- 3.2.1 Demonstrates knowledge of the medicines supply chain and selects reliable and appropriately authorised suppliers of medicinal products
- 3.2.2 Ensures that medicines are stored in appropriate facilities and environmental conditions to ensure stability, quality and safety of the medicinal product over its shelf life
- 3.2.3 Stores medicines in a safe, organised, systematic and secure manner
- 3.2.4 Works with documented policies and procedures to implement an effective stock management and rotation system, including systems for forecasting patient needs and demands and contingency plans for shortages and discontinuations
- 3.2.5 Works with documented policies and procedures to manage the recall of medicines, including the assessment of impact on patient care and required patient follow-up
- 3.2.6 Ensures there is no conflict of interest or inappropriate inducements in the sourcing and supply of medicines
- 3.2.7 Demonstrates an understanding of the legislative framework and requirements that govern the distribution of medicinal products including Good Distribution Practice (GDP)
- 3.2.8 Encourages patients to return any unused, unwanted or expired medicines to the pharmacy for safe disposal

Competency:	3.3 Reviews and dispenses medicines accurately
Behaviours:	<p>3.3.1 Validates prescriptions ensuring that prescriptions are authentic, correctly interpreted and in line with legal requirements</p> <p>3.3.2 Manages, organises and prioritises the dispensing of prescriptions according to professional judgement and up to date clinical knowledge</p> <p>3.3.3 Applies knowledge to undertake a therapeutic review of the prescription to ensure pharmaceutical and clinical appropriateness of the treatment for the patient</p> <p>3.3.4 Consults the available patient medical and medicine history or record</p> <p>3.3.5 Screens and manages the prescription or other medicines requisition for any potential clinical problems including therapeutic duplication, interaction with other medicinal products (including interactions with non-prescription medicinal products, herbal products or foods), incorrect dosage or duration of treatment, allergic reactions and clinical abuse and/or misuse</p> <p>3.3.6 Consults with the prescriber or patient for further information and clarification when required</p> <p>3.3.7 Documents and records clinical and professional interventions</p> <p>3.3.8 Selects the correct medicine, strength and pharmaceutical form in accordance with the prescription</p> <p>3.3.9 Accurately dispenses medicines in an organised, safe and systematic way according to procedures and applies sequential accuracy checks</p> <p>3.3.10 Identifies the interchangeability and bioequivalence of different proprietary products where applicable</p> <p>3.3.11 Packages medicines to optimise safety and stability including any appropriate re-packaging and inclusion of patient information</p> <p>3.3.12 Labels medicines with all the relevant required clinical and cautionary or advisory information and in line with legal requirements</p> <p>3.3.13 Uses patient counselling skills to educate the patient and provide all the required information to ensure safe and rational use of the medicines</p> <p>3.3.14 Keeps accurate, up-to-date records on supplies in line with</p>

full legal requirements and to ensure a complete patient medication record

3.3.15 Demonstrates extensive knowledge of dispensary practice software they employ and an appreciation of the potential and limitations of systems

3.3.16 Effectively supervises staff in carrying out tasks in relation to dispensing

DOMAIN 4

SAFE AND RATIONAL USE OF MEDICINES

Competency:

4.1 Patient consultation skills

Behaviours:

4.1.1 Consults with the patient and/or carer to obtain relevant patient medication and disease history

4.1.2 Uses appropriate communication and questioning techniques to gather relevant patient information

4.1.3 Structures consultations against a protocol and uses the patient consultation area appropriately

4.1.4 Assesses symptoms and diagnoses based on objective and subjective measures, if appropriate, using appropriate diagnostic aids and tests

4.1.5 Selects appropriate non-prescription medicines for minor ailments taking into account patients' preferences

4.1.6 Advises patients when and what circumstances in which to seek further medical intervention

4.1.7 Applies first aid when required and acts to arrange follow-up care

4.1.8 Maintains, reviews and updates patient medication history and records in a manner respectful of the confidentiality of patient information and in line with legal requirements

4.1.9 Ensures medicines selection and advice reflects best evidence and guidance in the relevant area

4.1.10 Provides honest, accurate and evidenced-based information on complementary and alternative medicines and therapies

4.1.11 Effectively supervises non-pharmacist staff in relation to non-prescription medicines

4.1.12 Documents interventions and maintains appropriate records

Competency:

4.2 Patient counselling skills

Behaviours:

- 4.2.1 Discusses and agrees with patients the appropriate use of medicines
- 4.2.2 Maximises opportunities for counselling and providing information and advice to patients
- 4.2.3 Counsels patients in a structured and logical manner
- 4.2.4 Counsels patients in a manner respectful of the privacy of the patient including use of the patient consultation area when appropriate
- 4.2.5 Provides the patient with sufficient information to assure the safe and proper use of the medicine
- 4.2.6 Assesses patients' understanding and knowledge of the medicines and provides appropriate information and education
- 4.2.7 Uses language the patient is likely to understand
- 4.2.8 Educates patients in correct use of devices
- 4.2.9 Uses counselling aids to help the patient understand the information
- 4.2.10 Responds appropriately to more challenging or complex scenarios

Competency:

4.3 Reviews and manages patient medicines

Behaviours:

- 4.3.1 Identifies, prioritises and resolves medicines management problems
- 4.3.2 Monitors medicines use and patient adherence, as appropriate, to ensure positive clinical outcomes are achieved and patient needs are met
- 4.3.3 Encourages and facilitates patient adherence
- 4.3.4 Liaises with and provides advice to the prescriber or other healthcare professionals to ensure optimal use of medicines by patients
- 4.3.5 Contributes to the cost-effective use of medicines
- 4.3.6 Recognises and manages adverse drug reactions
- 4.3.7 Recognises and manages inappropriate medicines including dosage problems
- 4.3.8 Recognises and advises on any additional patient monitoring required
- 4.3.9 Contributes to strategies on medication management

including monitoring and improving medicines use

Competency: 4.4 Identifies and manages medication safety issues

- Behaviours:
- 4.4.1 Identifies medication safety as a priority
 - 4.4.2 Takes action to prevent, minimise, resolve and follow up medicines related problems
 - 4.4.3 Maintains and contributes to a reporting system of pharmacovigilance
 - 4.4.4 Reports adverse drug reactions and quality defects to the Irish Medicines Board
 - 4.4.5 Takes steps to improve the safe use of medicines for patients in all practice settings
 - 4.4.6 Encourages patients to be knowledgeable about their medication
 - 4.4.7 Keeps abreast of emerging medication safety information through notifications, alerts, newsletters and other publications; reacts to and implements new safety information including any required patient follow-up and further staff education
 - 4.4.8 Contributes to the implementation, auditing and addressing of risk management to avoid adverse events with medication
 - 4.4.9 Contributes to implementing and maintaining a 'near misses' reporting system and error reporting system
 - 4.4.10 Reviews, learns from and acts upon previous 'near misses' and 'dispensing errors'
 - 4.4.11 Identifies, documents, acts upon and reports errors to include clear and open communication with patients
 - 4.4.12 Discusses medication safety issues with other staff, identifies hazardous practices, contributes to the implementation of new procedures and practices to deal with medication safety risks or issues
 - 4.4.13 Identifies medicines at higher risk of medication errors or with increased safety risks and takes steps to minimise and mitigate risks

Competency:	4.5 Provides medicines information and education
Behaviours:	<p>4.5.1 Provides accurate, quality and safe information and advice to patients, the public and other healthcare professionals regarding medicines</p> <p>4.5.2 Advises patients, the public and other healthcare professionals on the safe and rational use of medicines and devices including the use, contraindications, storage, and side effects of non-prescription and prescription medicines</p> <p>4.5.3 Identifies and utilises appropriate evidenced based sources of information on medicines</p> <p>4.5.4 Provides medicines information in response to queries in a manner appropriate to the recipient</p> <p>4.5.5 Manages information appropriately including documentation</p> <p>4.5.6 Accesses reliable information to ensure cost effective use of medicines</p> <p>4.5.7 Provides education to patients, the public, students and other healthcare professionals on medicines</p>

DOMAIN 5 PUBLIC HEALTH

Competency:	5.1 Population health
Behaviours:	<p>5.1.1 Identifies the primary healthcare needs of patients taking into account the cultural and social setting of the patient</p> <p>5.1.2 Engages with and implements national health and medicines policies and guidelines</p> <p>5.1.3 Identifies the need for, plans and implements new services according to patients needs</p> <p>5.1.4 Demonstrates an awareness of the public health resources available to patients and aids patients in availing of or contacting these services</p>

Competency:	5.2 Health promotion
Behaviours:	<p>5.2.1 Provides information, advice and education for patients and the public on health awareness, disease prevention and control, and healthy lifestyle and wellness</p> <p>5.2.2 Identifies opportunities to engage in health promotion</p> <p>5.2.3 Demonstrates support for initiatives in relation to health promotion</p> <p>5.2.4 Identifies and utilises evidenced based sources of</p>

information on health

Competency:

5.3 Research skills

Behaviours:

- 5.3.1 Applies principles of scientific enquiry to investigate a medicine or practice related issue
- 5.3.2 Possesses the skills to initiate research and practice development activities
- 5.3.3 Understands and adheres to ethical research principles
- 5.3.4 Communicates and applies research findings

DOMAIN 6

ORGANISATION AND MANAGEMENT SKILLS

Competency:

6.1 Self-management skills

Behaviours:

- 6.1.1 Demonstrates organisation and efficiency in carrying out their work
- 6.1.2 Ensures their work time and processes are appropriately planned and managed
- 6.1.3 Demonstrates the ability to prioritise work appropriately
- 6.1.4 Takes responsibility as appropriate in the workplace
- 6.1.5 Demonstrates awareness of the responsibility of their position
- 6.1.6 Ensures punctuality and reliability
- 6.1.7 Reflects on and demonstrates learning from critical incidents

Competency:

6.2 Workplace management skills

Behaviours:

- 6.2.1 Demonstrates an understanding of the principles of organisation and management
- 6.2.2 Works effectively with the documented procedures and policies within the workplace
- 6.2.3 Understands their role in the organisational structure and works effectively within the management structure of the organisation
- 6.2.4 Works effectively with their supervising and superintendent pharmacist(s)
- 6.2.5 Addresses and manages day to day management issues as required in their position of responsibility
- 6.2.6 Identifies pharmacy resource requirements and manages those resources effectively as appropriate to their level of responsibility

6.2.7 Contributes to the management of the workplace in relation to medicines

Competency:

6.3 Human resources management skills

Behaviours:

6.3.1 Identifies and manages human resources and staffing issues as required in their position of responsibility

6.3.2 Recognises and understands their supervision role in relation to non-pharmacist staff and medicines

6.3.3 Engages with systems and procedures for performance management

6.3.4 Supports and contributes to staff training and continuing professional development

Competency:

6.4 Financial management skills

Behaviours:

6.4.1 Demonstrates the ability to effectively analyse and manage financial data and budgetary information

6.4.2 Demonstrates awareness of the health service reimbursement schemes through which patients are entitled to receive medication

6.4.3 Submits appropriate and accurate claims for reimbursement

6.4.4 Ensures appropriate reference sources are used to support applications for service reimbursement

6.4.5 Understands the principles of pharmacoeconomic assessment and medicines cost benefits analysis

Competency:

6.5 Quality assurance

Behaviours:

6.5.1 Recognises quality as a core principle of medicines management and healthcare provision

6.5.2 Understands the role of policies and procedures in the organisational structure and in the provision of healthcare

6.5.3 Contributes to the development, implementation, maintenance and training of staff on standard operating procedures, as appropriate to their level of responsibility

6.5.4 Contributes to regular audit activities and reports and acts upon findings

6.5.5 Identifies and evaluates the evidence-base to improve the use of medicines and services, including risk management

6.5.6 Uses feedback from complaints and audit to improve and develop services in conjunction with their manager

6.5.7 Implements a system for documentation and record keeping

Appendix B

Indicative Syllabus

Introduction

The indicative syllabus set out here is styled on international standards particularly those of Australia and Great Britain with variations to reflect systems and concerns specific to Ireland.

The syllabus items are grouped to give prominence to the patient and avoid traditional pharmacy categorisations, this format is not intended to be imposed on the Professional Degree Programme Providers nor to define a contemporary pharmacy programme or to inhibit innovation. It is intended to be considered alongside the PSI's Core Competency Framework for Pharmacists (CCF) and is intended to be helpful during the transition to the fully integrated five-year Masters degree programmes in pharmacy.

1. The Patient

The patient and patient centredness is the main focus in the programme. The items grouped under this heading address the biological, environmental, psychological and some of the social foundations of treatment with medicines. The syllabus should address specific patient needs in Ireland.

- i. The unique role of the pharmacist in ensuring that the patient benefits from pharmaceutical intervention.
- ii. The ethical obligations of the pharmacist and the duty of care to the patient and the public.
- iii. Principles and methodologies of the social sciences relevant to pharmacy.
- iv. Health and illness: definitions and perceptions.
- v. Theory and practice of personal and inter-personal skills, including written and oral communication skills, and study skills.
- vi. The ideas and approaches of compliance or concordance in health care provision, particularly as they apply to medicines administration.
- vii. The pharmacist's contribution to the promotion of good health and disease prevention.
- viii. Normal and abnormal bodily function: biochemistry, genetics, microbiology, nutrition, immunology, physiology, pathology, pathophysiology and infective processes.
- ix. Aetiology and epidemiology of major diseases and the principles of their drug treatment.
- x. Symptoms recognition and management, the principles of differential diagnosis, important diagnostic methods and tests, and medical terminology.
- xi. Disease management and care planning, including application of clinical guidelines, prescribing guidelines and medication review.
- xii. Complementary therapies.
- xiii. Drug and substance misuse, and physiological and psychological dependence. Clinical toxicology associated with drug over-dosage, drug or substance misuse or accidental exposure.

2. Health care systems and the roles of professionals

For pharmacy graduates to be able to practice effectively, efficiently and confidently they need to know about, understand and have some of the skills to operate within health care systems, alongside and together with other health professionals and other scientists.

- i. Health care systems in Ireland including roles of pharmacists and other health care professionals in primary, secondary and tertiary health care including the role of pharmacists as Qualified Person in the pharmaceutical industry.
- ii. The duty of care to the patient and the wider public: concept, scope and application of professional ethics.
- iii. Professional standards and guidelines for practice. Self-audit, continuing professional development and maintenance of competency.
- iv. Clinical governance: clinical audit and risk management. Quality assurance and improvement. Managing and learning from errors.
- v. Use of information technology in pharmacy and more widely in health care.

3. The wider context

The pharmacy graduate needs a realistic and well-informed view of how healthcare and pharmacy fits within and operates in the wider world.

- i. The political and legal framework, requirements and processes relevant to pharmacy in Ireland and within the EU.
- ii. Public health promotion/policy and economics, particularly pharmacoeconomics.
- iii. Scientific, clinical, health services and social services research; methods and results relevant to pharmacy.
- iv. Occupational and environmental health and safety.

4. Human and Veterinary Medicines: drug action

The pharmacy graduate must have a detailed appreciation and understanding of how drugs work and behave.

- i. Molecular basis of drug action and the actions of drugs within living systems; molecular, cellular, biological and physical aspects.
- ii. Clinical therapeutic uses of drugs and medicines in man, including contraindications for, adverse reactions to, and interactions of drugs and their relevance to treatment.
- iii. Drug absorption, distribution, metabolism and excretion and influences thereon, including formulation, route of administration, dosage regimen, ageing and disease.
- iv. Clinical evaluation of new and existing drugs and medicines, and post-marketing

- surveillance. Good clinical practice (within clinical trials). Pharmacovigilance.
- v. Prospects for new approaches in therapeutics.

5. Human and Veterinary Medicines: the drug substance

For patient safety and often for the quality and efficacy of treatment, it is important that the pharmacy graduate, uniquely among the team of health professionals, has an appreciation and understanding of the sources and properties of drugs which form the biologically active and therapeutic components of medicines.

- i. Sources and purification of substances of biotechnological, chemical synthetic, immunological, mineral and plant origin used in medicine.
- ii. Physico-chemical aspects of drugs and biological systems, including thermodynamics and chemical kinetics.
- iii. Specifications of substances used in medicine, including physical and chemical tests.
- iv. Analytical methods: principles, design, development, validation and application.
- v. Prediction of drug properties, including chemical compatibilities, from molecular structure.
- vi. Drug design and discovery: principles, approaches and future prospects.
- vii. Cell and molecular biology, including genomics, proteomics and gene therapy, relevant to pharmacy.
- viii. Biological methods of measuring drug activity and biological standards.
- ix. Biotechnology and biotechnological processes.

6. Human and Veterinary Medicines: the medicinal product

The formulation and compounding of medicines, taking the pure drug substance and producing a dosage form for administration to the patient, are at the heart of pharmaceutical science. For the safety, quality, efficacy and economy of treatment with medicines, all pharmacy graduates need knowledge, understanding and capability in this area.

- i. Sale and supply of medicines, including evaluation and management of risk and provision of advice.
- ii. Medicines: schedules of medicines and controlled substances; consumer protection, including product liability.
- iii. Materials used in formulations and devices for the delivery of drugs, their biological, chemical and physical properties, and the development and application of standards.
- iv. Biopharmaceutics, developmental pharmaceutics, pre-formulation and formulation studies; design and standardization of medicines for administration to the body by different routes and for delivery to specific target sites.
- v. The influence of manufacture and distribution on product quality with respect to biological safety, bioavailability (including bioequivalence), dosage uniformity and stability.
- vi. Packaging and labeling: purpose, design and evaluation.

- vii. Quality assurance of pharmaceutical products and processes, including Good Laboratory Practice and Good Manufacturing Practice.
- viii. Microbiological contamination: sources, determination, consequences and control.
- ix. Sterilisation procedures and aseptic procedures in the preparation of pharmaceutical products and medical devices; monitoring of sterilisation processes.
- x. Environmental control in manufacturing facilities and in the supply chain.
- xi. Degradation of medicines: evaluation and control of biological, chemical and physical degradation.
- xii. Immunological, biotechnological and radiopharmaceutical products.
- xiii. Dressings and other wound management products.
- xiv. Medical devices: their types, regulation and, particularly, their use for the measurement and maintenance of physiological function or medicine delivery.
- xv. Statutes and regulations related to medicines, poisons and controlled substances.

DRAFT

Appendix C

Relevant Legislation⁴

- 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)
- 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)
- Pharmacy Act 2007. No. 20 of 2007
- European Communities (Recognition of Professional Qualifications Relating to the Profession of Pharmacist) (No. 2) Regulations 2008, S.I. NO. 489 of 2008
- Pharmaceutical Society of Ireland (Education and Training) Rules 2008 (S.I. No. 493 of 2008)

⁴ This list will be updated as necessary to reflect the most up-to-date legislative requirements that pertain in Ireland

REFERENCES

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

- Accreditation Council for Pharmacy Education (ACPE) (2007) (Revised 2011). *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.*
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- Canadian Council for Accreditation of Pharmacy Programs (2006). *Accreditation Standards and Guidelines for the Baccalaureate Degree Programme in Pharmacy.*
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- General Pharmaceutical Council (2011). *Future Pharmacists – Standards for the initial education and training of pharmacists.*
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- World Health Organisation (WHO) (1997). *The Role of the Pharmacist in the Health Care System. Preparing the Future Pharmacist: Curriculum Development. Report of a Third WHO Consultation Group on the Role of the Pharmacist. ('The Seven-Star Pharmacist')*