Accreditation Standards
for the Five Year Master's Degree Programmes in Pharmacy

Approved by PSI Council September 2019

Introduction

These Accreditation Standards have been reviewed and revised to assure that a five-year fully integrated Master's degree programme in pharmacy (MPharm) recognised and approved by the Council of the Pharmaceutical Society of Ireland (PSI) meets the stated requirements below.

1. The purpose of a five-year fully integrated Master's 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) as required to be prepared for patient-centred pharmacy practice in all pharmacy settings and to 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, 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;
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> (b) professional and personal integrity and discipline of mind;
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> (c) an understanding of and a commitment to the ethos of professionalism, in particular a commitment to the concept of patient centeredness and duty of care;
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> (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;
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> (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 Institution (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. Accordingly, these standards have been developed and approved for the purposes of Rule 7 of the Pharmaceutical Society of Ireland (Education and Training) (Integrated Course) 2014 (S.I. No. 377). This includes the requirement that the Higher Education Institution (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.

Standard 1: Strategy

The Professional Degree Programme Provider (or Higher Education Institution (HEI)) must have a current strategy that underpins the programme's objectives.

1) The strategy and the objectives thereunder should:

   a) Promote professional behaviour among students, staff and all those contributing to the Professional Degree Programme.

   b) Be committed to the development of graduates who satisfy the requirements of the Core Competency Framework for Pharmacists.

   c) Respect and support the needs of diverse stakeholders, the public, students, staff and all those contributing to the Professional Degree Programme.

2) There should be evidence that the strategy and its objectives are subject to regular review and validated by the Higher Education Institution.

3) The implementation of the strategy must include but need not be limited to:

   a) The objectives of the Professional Degree Programme Provider in relation to the Professional Degree Programme.

   b) The implementation of the strategy must ensure that it:

      i) Assures that graduates will be prepared for entry to the profession of pharmacy including patient-centred practice in line with the current Core Competency Framework for Pharmacists, as updated by the PSI Council from time to time.

      ii) Prepares graduates for practice as pharmacy professionals who will be equipped with the skills for lifelong learning.

      iii) Provides structured experience of interprofessional learning to facilitate teamwork in enhancing patient care.

   c) A commitment to excellence in teaching and learning methods.

   d) A vision for leadership in practice, research and other scholarly activity and educational activities.

4) 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.

Standard 2: Leadership, Organisation and Governance

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.

1) The Professional Degree Programme must be planned and delivered by an identifiable organisational unit, preferably a School or Faculty of Pharmacy, which has responsibility for the Professional Degree Programme and associated appropriate 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) The Head of the School must demonstrate leadership in pharmacy professional education, research and scholarly activities, and so be able 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. 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.

3) The HEI must support the development of suitable relationships between the School and other academic and service units of the HEI for instruction, research, practice-based and interprofessional learning.

4) 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 and other healthcare facilities in support of the practice-based and interprofessional learning needs of the Professional Degree Programme. Wherever possible, collaborative approaches to practice-based placements must be used in conjunction with other HEIs in the State offering a pharmacy degree programme.

5) The Professional Degree Programme must be based on and promote 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 and must be delivered in such a way that the diverse needs of all students are met.

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 Professional Degree Programme and Fitness to Practise cases. Key issues, including any changes in resources that are pertinent to the delivery of the Professional Degree Programme and any equality and diversity issues which could have an impact on students, should be included with the School's commentary and analysis. The School must maintain a reliable, accurate and workable management information system in support of this.

7) The Head of School has an obligation to report to the PSI:

   a) At the point of graduation, a confirmation that each graduate has met the competencies in the CCF.

   b) Any 'fitness to practise' matters and/or any other matters that could have a material impact on future fitness to practise when the student/graduate is practising as a pharmacist.

Standard 3: Resources

The School must have sufficient academic staff, practice educators, external experts, support staff as well as tutor pharmacists, infrastructure and financial resources in order to ensure the effective delivery of a Professional Degree Programme.

1) Academic Staff

   The School must have a sufficient number of core academic staff and other teaching staff appropriately qualified, experienced and expert in pharmaceutical sciences and pharmacy practice. Policy within the School must be developed to facilitate input from staff and external experts with contemporary experience of practice, to curriculum design and development, assessment design and development, and course management and coordination activities.

   This staff, full-time and part-time, must:

   a) provide most of the teaching and learning support for the Professional Degree Programme; however, where 'service-teaching' is identified as required for a small part of the programme, there shall be a robust means of managing its integration into the Professional Degree Programme.

   b) provide the academic direction for all teaching and learning support or assessment provided by individuals from outside the School.

   c) be provided with the resources, support and academic environment which allows staff members to maintain their knowledge at the leading edge of pharmaceutical, biomedical, social sciences, and clinical pharmacy practice.

   d) be encouraged and supported to engage in scholarship and research which is disseminated nationally and internationally.

   e) have access to an organised professional development programme open to all teaching staff members consistent with their respective responsibilities.

   f) ensure that teaching and learning in modules/course units in that area take place in a pharmacy context, in particular where no pharmacist is appointed within an area of academic expertise.

   g) ensure that pharmacy law, ethics, professionalism and pharmacy practice are taught predominantly by pharmacists with appropriate contemporary experience of practice.

2) Practice Educators

The School must have a sufficient number of Practice Educators who will provide the specialised teaching on the interface between the learning within the schools and that within the practice placement and who will provide support to the students on placement and to their tutors.

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.

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 development opportunities.

Technical staff should be suitably qualified and should take an active role in the preparation and delivery of laboratory practice sessions and projects.

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. The orientation, support and enhancement of the tutor pharmacist role should be demonstrated.

6) Infrastructure and Financial Resources

a) The School must have the financial resources necessary for delivery of its strategic objectives.

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.

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 reasonably foreseeable deficiencies in infrastructure, equipment or personnel that may arise in order to ensure the effective delivery of the Professional Degree Programme.

Standard 4 Curriculum: Structure and Evaluation

The curriculum must be planned to deliver an integrated experience that combines and coordinates all teaching, learning and assessment components in a logical and cohesive manner with clearly articulated linkages within years and between years. The Professional Degree Programme must be planned and regularly evaluated 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.

1) 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. The curriculum must be designed, delivered and regularly reviewed to keep abreast of advances arising from policy, and research and development, in medical and pharmaceutical science and practice. The curriculum should be guided by, but not limited to, the indicative syllabus shown in Appendix A of this document.

2) The curriculum must be progressive in dealing with issues in increasingly complex and interrelated 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.

3) The curriculum should enable students to form an appropriate ethical and professional approach to practice. This 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.

4) The curriculum must be designed, delivered and reviewed by interdisciplinary teams in order that the subject matter of the degree is integrated and delivered in a patient-focused manner. The scientific base of the curriculum must be of adequate depth, scope and quality and sequenced appropriately to support the intellectual and clinical aspects of the Professional Degree Programme.

5) 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.

6) The curriculum must provide appropriately comprehensive training in research methods applicable to scientific, health and practice research in order to meet the CCF. 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.

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[1] The indicative syllabus exists as a general guide to the scope of curriculum content for the Professional Degree Programme.

7) There must be a continuum of structured and quality assured practice-placement experiences throughout the curriculum from introductory to advanced, and across the main practice settings of community, hospital and industry, that are of adequate scope, intensity, structure and duration to support achievement of the CCF competencies. 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.

8) There must be rigorous processes for review, monitoring and evaluation of all elements of the curriculum. Such processes should incorporate external scrutiny of student assessments.

9) The curriculum must be supported by Institutional regulations for the Professional Degree Programme that are appropriate for an award that is both academic and professional in nature, including those relating to fitness to practice.

   The regulations must be supported:

   a) by fitness to practice procedures that address causes for concern raised about students

   b) by robust and transparent appeals processes that are fully documented and communicated to students

   c) underpinned by a clear and realistic student code of conduct that is explained, communicated and enforced to assure professional behaviour.

10) 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 recommendations of the Advisory Committee on Pharmaceutical Training (European Commission, 1995)[3].

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[2] To include the Schedule of the Pharmaceutical Society of Ireland (Education and Training) (Integrated Course) Rules 2014 (S.I. No. 377 of 2014)

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

Standard 4 Curriculum: Teaching, Learning and Assessment

The curriculum documentation must be guided by a Teaching and Learning Strategy and an Assessment Strategy. The Teaching and Learning Strategy must enable graduates to meet the Core Competency Framework (CCF) for Pharmacists as established by the PSI Council from time to time and must emphasise the contributions of pharmacists in industry and research as well as within healthcare teams in patient-facing settings. The Assessment Strategy must align with the Teaching and Learning Strategy and ensure that all graduates demonstrate the CCF competencies and behaviours.

1) The Teaching and Learning Strategy must:

   a) be based upon well-evidenced pedagogic principles.

   b) promote collegiality, civility and respect among students and staff, and underpin a culture of professionalism in which all teaching staff can lead by example.

   c) support the development of:

      i) independent learning skills, both within the Professional Degree Programme and as a basis for later continuing professional development

      ii) consultation, counselling and communication skills, underpinned by social and behavioural science content in the Professional Degree Programme

      iii) leadership skills, problem-solving skills, and rational decision-making skills that promote patient safety and enhance patient well-being

      iv) peer review and assessment skills

      v) critical, analytical skills, and an understanding of research methods to support evidence-based decision-making and practice.

   d) deliver:

      i) a fully integrated and balanced experience of science and practice, and of university-based and practice-based learning

      ii) interprofessional collaboration with students of other healthcare professions in all stages of the Professional Degree Programme,

      iii) meaningful practical experience of working with patients, carers and the public. The intellectual and professional demands of the practice experience should increase as the student progresses through the Professional Degree Programme

      iv) teaching and learning experiences that take place alongside and with reference to research and other scholarly activities.

2) The Assessment Strategy must:

   a) deliver:

      i) a progression through the hierarchy of knowledge and skills development through the five years of the programme, such as the model proposed by Miller[4].

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[4] Miller, G. E. (1990). The assessment of clinical skills/competence/performance. Academic Medicine, 65(9).

ii) a range of methods at each level of study, and appropriate to assess the progressive attainment of all competencies set out in the CCF

iii) clearly defined marking criteria reflecting safe and effective practice. All assessments must take account of patient safety

iv) assessments that are placed in a pharmacy context, reflecting contemporary practice

v) diagnostic and formative assessment opportunities

vi) effective and timely feedback

vii) clear guidance to students relating to assessment of learning outcomes, with objective reporting on assessments.

b) include assessment of:

i) professionalism throughout the Professional Degree Programme

ii) consultation, counselling and communication skills

iii) problem-solving skills, and rational decision-making skills

iv) research and critical analytical skills

v) interprofessional teamworking and leadership skills.

c) include examination of:

i) pharmacy law, including within the statutory professional examination at the end of Year five

ii) pharmaceutical calculations, to include assessment of competency prior to the Year four practice placement

iii) professional competence, via a summative objective structured clinical examination (OSCE), as part of the statutory professional examination at the end of Year five

iv) professional competence, by the tutor pharmacist at the end of Year five.

Standard 6 Quality Assurance and Enhancement

All processes and activities related to the Professional Degree Programme must form part of a demonstrable and continuous quality improvement programme that is responsive to internal and external feedback and review. Assurance is provided through evidence of clearly defined, documented, executed and controlled processes and activities in accordance with a system of Quality Management. The mitigation of risk is also an important part of quality management.

1) The School must describe how it assesses attainment of the strategy of the Professional Degree Programme (Standard 1) and how it seeks to improve the quality of outcomes.

2) The Professional Degree Programme Provider must demonstrate a holistic evaluation of the delivery of the Professional Degree Programme (internal and external) and the professional developed by the programme. This must include examination, feedback, views and experiences from a range of stakeholders including students and the public.

3) Each student's proficiency over the period of the Professional Degree Programme must be tracked. This must include proficiency in practice placements and robust evidence of each student's performance over the whole period. Fitness to practise mechanisms for students must be in operation and routinely reviewed.

4) All proposed material changes to the Professional Degree Programme must be reported to the PSI in accordance with legislative requirements.

5) There must be a quality improvement strategy and quality mechanisms in place for this component to assure and enhance the quality of all practice placements to provide a meaningful learning experience, including but not limited to:

   a) the process to select, assess, accredit, appoint and revoke tutors and training establishments

   b) training, development and support to tutors in delivering the placement objectives

   c) the effectiveness of tutoring mechanisms

   d) the interface between academic study and the in-practice placement

   e) appropriateness of training establishments

   f) organisational support for the tutoring process including when to raise concerns

   g) the allocation of students to training establishments

   h) student support whilst on placement, including clarity around expectations of role and role development

   i) feedback from all stakeholders.

   Where practice placements are delivered through a partnership between a School and other Schools of Pharmacy in the State, there must be information about the collaboration, roles and responsibilities to demonstrate effective governance and quality assurance.

6) There must be appropriate mechanisms to monitor the resources for the development and delivery of the programme, including personnel, IT and organisational structures.

Standard 7 Students

There must be processes at the HEI and School level to assist students in the Professional Degree Programme (both prospective and enrolled), in understanding the expectations of them, as well as the support available to develop as future practising professionals. This includes the practice placement elements of the Professional Degree Programme. Students are expected to actively engage with the Professional Degree Programme recognising the primacy of patient safety and to be supported in developing their role as professionals.

1) Admission to, and progression on the Professional Degree Programme

   Policies and procedures must be in place and regularly assessed and these must:

   a) be open, fair and available to prospective applicants and enrolled students ensuring non-discrimination

   b) include a clear statement of the requirements and student expectations for admission (including policies on transfer credit and course waivers), progression through the programme and successful completion to align with the CCF, alongside any requirements as approved by the PSI Council from time to time

   c) incorporate a fair and just complaints and appeals process with regard to progression on the Professional Degree Programme

   d) specify how professional requirements, including fitness for practise, appropriate for the professional programme are met.

2) Student Support

   Appropriate and timely support must be in place for students in all learning and training environments on the Professional Degree Programme including:

   a) orientation

   b) identification of individual support needs

   c) provision of support for personal, academic, general welfare and careers matters

   d) support for the in-practice placements within the Professional Degree Programme to ensure a good learning experience

   e) access to pharmacy professionals throughout the programme who are able to act as role models

   f) a student complaints policy and procedures.

3) Student Guidance

   Students are expected to actively engage with the Professional Degree Programme recognising the primacy of patient safety whilst also their role in developing as professionals. This includes guidance on:

a) student personal and professional development through support structures that encourage active engagement in relevant or appropriate extra-curricular activities, travel and/or volunteer work/paid work

b) citizenship through encouragement of active engagement with relevant pharmaceutical students' representative associations at HEI, national and international levels, and other groups and committees which may be external to pharmacy.

Appendix A Indicative Syllabus

Introduction

The indicative syllabus set out here is intended to support the delivery of the 5-year fully integrated MPharm programmes in Ireland and should be considered alongside the PSI's Core Competency Framework.

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.

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 advice and care
ii. The ethical obligations of the pharmacist and the duty of care to the patient and the public – placing patients at the centre of what they do.
iii. Health and illness: definitions and perceptions, health psychology and health literacy.
iv. Theory and practice of personal and inter-personal skills, including written and oral communication skills and patient consultation skills.
v. Principles and methodologies of the social sciences and psychology relevant to pharmacy.
vi. The ideas and approaches of concordance and adherence support in healthcare provision, particularly as they apply to medicines optimisation.
vii. The pharmacist's contribution to the promotion of good health and disease prevention.

viii. Normal and abnormal bodily function: anatomy, physiology, genetics, nutrition, biochemistry, immunology, microbiology, pathology, pathophysiology and infective processes.

ix. Aetiology and epidemiology of diseases and the principles of their drug treatment.

x. Symptoms recognition and management, the principles of differential diagnosis, diagnostic methods and tests, and medical terminology.

xi. Disease management and pharmaceutical care planning, including application of clinical guidelines, prescribing guidelines, evidence-based decision making and clinical medication review.

xii. The rationale and evidence–base for complementary therapies.

xiii. Drug and substance misuse, including physiological and psychological dependence.

xiv. Toxicology and adverse effects of medicines and substances of abuse.

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 the skills to operate within health care systems, alongside and together with other health professionals and other scientists.

xv. Healthcare 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 the/a Qualified Person in the pharmaceutical industry.

xvi. The duty of care to the patient and the wider public: concept, scope and application of healthcare ethics.

xvii. Professional standards and guidelines for practice. The principles of Continuing Professional Development (CPD) as a continual process of lifelong learning which is focused on implementing learning within professional practice and improving outcomes for patients.

xviii. Principles of organisation in the workplace, including procedures and policies, resources requirements, management roles and structures within pharmacy settings.

xix. Oversight and development of those working in the pharmacy team.

xx. Communication skills relating to multidisciplinary working and getting the best outcome from medicines for patients.

xxi. The obligations of pharmacists as professionals requiring registration in order to practice including their compliance with statutory codes of conduct.

xxii. Clinical governance: clinical audit and risk management. Quality assurance and improvement. Safety science, including organisation and safety culture, implementation science, managing and learning from errors.

xxiii. Evidence-based policy and practice: use of evidence-based knowledge to develop policy and translate into practice.

xxiv. Use of information technology in pharmacy and more widely in health care.

xxv. Medicines safety – reporting of errors/critical incidents and systems-based risk minimisation (including root cause analysis).

3. The wider context

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

   xxvi. The political and legal framework, requirements and processes relevant to pharmacy in Ireland and within the EU.

  xxvii. The role of public health, health promotion, and health economics, particularly pharmaco-economics.

 xxviii. Scientific, clinical, health services and social services research relevant to pharmacy, translation of evidence into policy and practice.

  xxix. Occupational and environmental health and safety and the related legal requirements.

4. Human and Veterinary Medicines: drug action

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

  xxx. Molecular basis of drug action and the actions of drugs within living systems; molecular, cellular, pharmacogenomics, biological and physical aspects.

  xxxi. Clinical therapeutic uses of drugs and medicines in people including contraindications for, adverse reactions to, and interactions of drugs and their relevance to treatment.

  xxxii. Drug absorption, distribution, metabolism and excretion and influences thereon, including formulation, route of administration, dosage regimen, age and disease.

 xxxiii. Clinical evaluation of new and existing drugs and medicines, and post-marketing surveillance. Good clinical practice (within clinical trials). Pharmacovigilance.

 xxxiv. 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.

  xxxv. Sources and purification of substances of biotechnological, chemical synthetic, immunological, mineral and plant origin used in medicine.

  xxxvi. Physico-chemical aspects of drugs and biological systems, including thermodynamics and chemical kinetics.

  xxxvii. Specifications of substances used in medicine, including physical and chemical tests.

 xxxviii. Analytical methods: principles, design, development, validation and application.

  xxxix. Prediction of drug properties, including chemical compatibilities, from molecular

structure.

xl. Drug design and discovery: principles, approaches and future prospects.

xli. Cell and molecular biology, including genomics, proteomics and gene therapy, relevant to pharmacy.

xlii. Biological methods of measuring drug activity and biological standards.

xliii. Biotechnology and biotechnological processes, personalised medicines and pharmacogenomics.

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.

xliv. Sale, supply, administration and monitoring of medicines,

xlv. Medicines: schedules of medicines and controlled substances; consumer protection, including product liability and professional negligence.

xlvi. Materials used in formulations and devices for the delivery of drugs, their biological, chemical and physical properties, and the development and application of standards.

xlvii. Biopharmaceutics, developmental pharmaceutics, pre-formulation and formulation studies; design and standardisation of medicines for administration by different routes and for delivery to specific target sites.

xlviii. The influence of manufacture and distribution on product quality with respect to biological safety, bioavailability (including bioequivalence), dosage uniformity and stability.

xlix. Packaging and labelling: purpose, design and evaluation.

l. Quality assurance of pharmaceutical products and processes, including Good Laboratory Practice and Good Manufacturing Practice.

li. Microbiological contamination: sources, determination, consequences and control.

lii. Sterilisation procedures and aseptic procedures in the preparation of pharmaceutical products and medical devices; monitoring of sterilisation processes.

liii. Environmental control in manufacturing facilities and in the supply chain.

liv. Degradation of medicines: evaluation and control of biological, chemical and physical degradation.

lv. Immunological, biotechnological and radiopharmaceutical products.

lvi. Dressings and other wound management products.

lvii. Medical devices: their types, regulation and, particularly, their use for the measurement and maintenance of physiological function or medicine delivery.

lviii. Statutes and regulations related to medicines, poisons and controlled substances.

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)

Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community Code relating to veterinary medicinal products (Article 53)

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 as amended

7. **European Communities (Recognition of Professional Qualifications Relating to the Profession of Pharmacist) (No. 2) Regulations 2008, S.I. N0. 489 of 2008**

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'

S.I. No. 377/2014 - Pharmaceutical Society of Ireland (Education and Training) (Integrated Course) Rules 2014