Draft Interim Accreditation Standards for the Bachelor of Science (Pharmacy)/Bachelor of Pharmacy Undergraduate Degree Programmes in Pharmacy

Public Consultation Version of 14.07.2011

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

1. The purpose of undergraduate pharmacy education (the pharmacy degree programme) is to produce pharmacy graduates who have the knowledge, skills and attributes to safely participate in the National Pharmacy Internship Programme (NPIP). Graduates should be prepared for patient-centred pharmacy practice and their learning should be based upon and underpinned by appropriate and sufficient understanding of the principles and techniques of the pharmaceutical sciences.

2. Undergraduate pharmacy education will seek to develop in the student:

    (a) professional and personal integrity and discipline of mind;
    (b) an understanding of and a commitment to the ethos of professionalism, in particular a commitment to the concept of patient centredness and duty of care;
    (c) the capability to adapt to developments in pharmacy and medicine;
    (d) 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 continuing education and professional developments in the profession of pharmacy and undertake appropriate continuing professional development relevant to the practice of pharmacy.

3. To ensure graduates are properly prepared to apply for entry to the NPIP and so ensure patient safety and public protection, the undergraduate pharmacy degree programme (the Degree Programme) must take account of the NPIP competence standards and the core competency framework as approved by the PSI Council from time to time.

4. These standards are intended to underpin and complement the statutory requirements set out in the Pharmacy Act 2007 (as amended) and the Pharmaceutical Society of Ireland (Education and Training) Rules 2008 including the requirement to produce and submit an annual report.

Draft Standard 1	PHARMACY SCHOOL AND MISSION

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

1.1 There should be evidence that the mission, goals and objectives have been reviewed and endorsed by the Higher Education Institution (HEI) and should be demonstrably congruent with the mission of the HEI.

1.2 The School should have a published statement of its mission and goals and set out its key performance indicators (KPIs).

1.3 The strategic plan must include but need not be limited to:

(a) Its mission and goals with associated KPIs;
(b) The underpinning aims and objectives of the School;
(c) A statement of the educational philosophy for the Degree Programme and how it:
  (i) supports or assures that graduates will be prepared for entry to and participation with the NPIP; and
  (ii) prepares graduates for practice as pharmacy professionals who will embrace lifelong learning;
(d) A commitment to excellence in teaching and learning methods.

Draft Standard 2	LEADERSHIP, ORGANISATION AND GOVERNANCE

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

2.1 The Degree Programme must be planned and delivered by an identifiable organisational unit preferably a School or Faculty of Pharmacy, which has responsibility for the Degree Programme and associated resources. Furthermore the Degree Programme must be planned and maintained through transparent processes and clearly identify who is responsible for what at each stage.

2.2 There must be effective systems in place to ensure that students:

(a) do not jeopardise patient safety and only do tasks (under appropriate supervision) for which they are competent;
(b) are monitored and assessed to assure they always work and perform safely;
(c) understand what fitness to practise mechanisms apply to them;
(d) are not awarded an accredited degree or pass into intern training if they are considered likely to pose a risk to patients or the public.

2.3 The Head of the School must be in a position to influence the HEI and 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 the authority for effective advocacy for pharmacy within the HEI. This person must be registered in the Register of Pharmacists held by the PSI and be familiar with and subject to the statutory code of conduct.

2.4 The Degree Programme must comply with the principles of equality, diversity and fairness and meet all the requirements of National and European law as it relates to the education, training and qualification of pharmacists.

2.5 As part of the annual reporting process to the PSI, the School must submit data on student intake, student numbers, student achievement and progression through the Degree Programme with the School's commentary and analysis.

Draft Standard 3	GRADUATES

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

3.1 They must demonstrate the generic and personal qualities expected of a pharmacy graduate: empathy; leadership; effective communication; independent and critical thinking; cultural understanding; a commitment to lifelong learning; professional and ethical conduct; reflective practice; awareness of limitations and risk; information literacy; team work; and problem-solving.

3.2 They must possess the specialist knowledge, skills and attributes to enter the NPIP leading to registration as a pharmacist competent to practise in a patient-centred professional and ethical manner including but not necessarily limited to:

(a) The requisite knowledge of how medicines are developed, manufactured and brought to the market place;
(b) The requisite knowledge of medicines, medical devices and medicines formulation and their preparation and the competence to prepare medicines extemporaneously, as may be necessary;
(c) The competence to supply medicines in accordance with pharmaceutical knowledge, legislative requirements and codes of professional conduct and practice;
(d) The ability to reason through professional dilemmas in a structured manner and justify action options chosen in a manner respectful of pharmacy law, the statutory Code of Conduct and common frameworks for ethical decision-making;
(e) The requisite pharmacological, pharmaceutical and clinical knowledge to safely and effectively interpret and evaluate prescriptions and other orders for medicines;
(f) The requisite knowledge and communication skills to fulfil their role in advising and counselling patients, other healthcare professionals and others about medicines and their usage;
(g) The requisite knowledge and skills to recognise common disease states and make appropriate responses to presented symptoms;
(h) The requisite knowledge and appreciation of the principles of quality and quality assurance mechanisms in all aspects of scientific and professional activities;
(i) An understanding and application of research methodologies relevant to natural, clinical and social sciences;
(j) An understanding of the need for and application of an evidence-based approach to problem solving.

Draft Standard 4	CURRICULUM

The curriculum is planned and delivered as an integrated programme with clearly defined learning outcomes that cover the generic and personal qualities and the specialist knowledge, skills and professional attributes necessary for entry to the NPIP (see Standard 3).

4.1 The curriculum should ideally be delivered by interdisciplinary teams in order that the subject matter of the degree is integrated and the student is provided with the knowledge and experience that will facilitate an understanding of the key aspects of the manufacture, preparation, quality control, distribution, actions and uses of medicines including outcome analysis.

4.2 The Curriculum should be guided by but not limited to the indicative syllabus shown in Appendix A of this document.[1]

4.3 Sufficient time should be allocated over the whole period of the Degree Programme to enable the formation of an appropriate ethical and professional approach to practice and this process should begin early in the first year. Appropriate assessment of this attribute shall also take place throughout the Degree Programme.

4.4 Sufficient time should be allocated over the whole period of the Degree Programme to develop knowledge and understanding of pharmacy law and its interpretation and application to practice.

4.5 The curriculum should provide a thorough training in research methods applicable to scientific and health research. The Degree Programme includes in the final year a significant laboratory-based or practice-based research project that meets the requirements of a level 8 degree programme on the National Framework of Qualifications.

4.6 Where appropriate and possible, the curriculum should be reinforced by practice experience that is designed to integrate the student's experience gained with their study of pharmaceutical science and the disciplines relevant to the practice of pharmacy.

4.7 The curriculum must comply with the various minimum legal requirements at national and European level (see Appendix B).[2] The curriculum must take account of the recommendations of the Advisory Committee on Pharmaceutical Training (European Commission, 1995). In this respect, a curriculum compliant with the European Credit Transfer and Accumulation System (ECTS) meets the total hours requirement of these recommendations.

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

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

Draft Standard 5	TEACHING AND LEARNING STRATEGY

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

5.1 The Teaching and Learning Strategy must:

a) take account of the predicted preferred learning format of the intended audience as well as the most effective methods to demonstrate competency against the required learning outcomes;
b) emphasise the contribution of the pharmacist in the healthcare team and, where appropriate, during the Degree Programme, teaching and learning should take place alongside and together with students of other related healthcare professions. Wherever possible, students should gain first-hand structured experience of practice, including contact with patients.
c) feature a variety of teaching and learning approaches appropriate to stated learning outcomes, which may include but not be limited to: lectures; practical classes; seminars; tutorials and other forms of interactive small-group teaching whether that be face-to-face or in the virtual learning environment.
d) facilitate the development of the student's communication skills and this should be underpinned by the theoretical basis within the social and behavioural science content of the Degree Programme.
e) encourage students to take responsibility for their own learning both within the Degree Programme and as a basis for later continuing professional development.
f) place emphasis upon the development of problem-solving skills and the justification of decisions made both on an individual and team-based basis.
g) ensure that teaching and learning take place alongside and with reference to research and other postgraduate activities.

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

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

5.4 The Teaching and Learning Strategy must incorporate a student code of conduct that is communicated to students and used to promote professional behaviour.

Draft Standard 6	ASSESSMENT STRATEGY

The Assessment Strategy is aligned with the curriculum learning outcomes (see Standard 4) and with the teaching and learning strategy (see Standard 5) and uses effective and validated diagnostic, formative and summative assessment methods within all components of the Degree Programme.

6.1 The Assessment Strategy must:

(a) provide clear guidance relating to assessment of stated professional and learning outcomes, with objective reporting on assessments and include fair and just complaints and appeals processes;
(b) include assessment of professionalism and the process of professionalization appropriate for application to entry to the NPIP and must take account of the NPIP competence standards and the core competency framework as approved by the PSI Council from time to time;
(c) position knowledge, understanding and competence development in a pharmacy context. Notwithstanding the requirement to ensure a balance of pharmacist input across the programme, should there be no pharmacist appointed within an area of academic expertise there are robust mechanisms in place to ensure that assessment in modules/course units in that area takes place in a pharmacy context;
(d) emphasise the contribution of the pharmacist in the healthcare team and where appropriate, during the Degree Programme, the student is assessed alongside and together with students of other related health professions;
(e) demonstrate a holistic approach and include, for example, mechanisms which measure cognitive learning, mastery of essential practice skills, ability to communicate, team-working, numeracy and use of data in problem solving;
(f) include the demonstration of competence in extemporaneous dispensing and of competence in the dispensing and supply of medicines. In addition, an examination in dispensing procedures must be taken under full examination conditions;
(g) include a formal examination of pharmacy law and a summative assessment of ethics and professionalism in the final year. The award of the degree will be conditional upon success in these assessments;
(h) require achievement of a satisfactorily high standard in assessments of dispensing practice (this may include skills of communication with patients and prescribers), pharmacy law, pharmacy practice (including clinical practice and therapeutics) and ethics and professionalism irrespective of the student's performance in other subjects. Neither compensation or condonement of marks for these subjects is allowed.

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

Draft Standard 7	STUDENTS

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

7.1 Entry to and Progression on the Degree Programme

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

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

7.2 Student Support and Guidance

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

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

Draft Standard 8	RESOURCES

The School must have sufficient allocated resources, financial, physical and staff to ensure effective delivery of a Degree Programme that meets the Accreditation Standards of the BPharm/BSc (Pharm) degree programme as may be approved from time to time by the PSI Council.

8.1 Academic Staff

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

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

8.2 Support Staff

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

8.3 Infrastructure and Financial Resources

The School must ensure that accommodation (including teaching rooms, and laboratories), equipment, library facilities, IT (including appropriate interactive distance learning technology/VLE) and subject specific IT specialist software (for example dispensing software) and other resources available to it are sufficient for the effective delivery of the planned Degree Programme to the numbers of students in each year of the Degree Programme and overall; properly taking account of the other teaching and research commitments of the School.

Draft Standard 9	QUALITY ASSURANCE

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

9.1 Indicators of performance must be established and maintained to monitor compliance with the Accreditation Standards for the Undergraduate Pharmacy Degree Programme set by the PSI Council from time to time.

9.2 There must be robust quality assurance and enhancement systems underpinning the Degree Programme. These must include clear and systematic mechanisms to monitor, review and evaluate all aspects of the education process leading to appropriate action being taken.

9.3 There must be a reliable means of reviewing each student's proficiency over the period of the Degree Programme to provide robust evidence of each student's performance over a sustained period. The award of an accredited degree is conditional on demonstration of sustained achievement of appropriate level of professional performance.

9.4 All changes to the Degree Programme must be documented and approval must be sought in advance from the PSI for curriculum amendments. The programme document management policy must record and retain all changes to the Degree Programme as accredited over time. This is to enable the retrieval of the programme of study undertaken by each student at any time.

9.5 There must be a reliable process to ensure the development of an environment and culture that promotes professional behaviour among students, staff and all those contributing to the Degree Programme.

Appendix A

INDICATIVE SYLLABUS FOR IRISH PHARMACY DEGREE COURSES

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

I. PHARMACY PRACTICE

a. The Practice of Pharmacy

(i) The pharmacist's role in patient-care, industrial and other settings relevant to health or social care.

(ii) Problem-solving in all main aspects of managing medicines (dispensing only being a part of this), clinical pharmacy, responding to symptoms, provision of drug and patient information, recognition and reporting of adverse drug reactions and assessment of drug interactions, drug utilisation evaluation, and measuring outcomes in support of evidence-based practice and achieving maximum clinical effectiveness.

(iii) Principles and methodologies of the social and behavioural sciences relevant to pharmacy.

(iv) Health policy and economics, including particularly pharmacoeconomics and pharmacoepidemiology.

(v) Theory and practice of personal and inter-personal skills, including written and verbal communication skills, and study skills.

(vi) The pharmacist as a Qualified Person in the pharmaceutical industry.

(vii) Codes of practice and acceptable standards of practice, including the PSI statutory code of conduct for Pharmacists, ~~Practice~~ practice ~~Guidelines~~ guidelines of the Pharmaceutical Society of Ireland and those relating to continuing professional development.

(viii) Approaches to quality assurance and Total Quality Management, including Good ~~Pharmaceutical~~ Manufacturing Practice, Good Distribution Practice, Good Laboratory Practice and Good Clinical Practice (within clinical trials).

(ix) Pharmacy Law and ethics and professionalism, their role and importance within pharmacy.

(x) The use of information technology in pharmacy and more widely in health care.

b. Improvement and Development of Pharmacy

(i) Professional and inter-professional audit of practice with a view to continuous improvement.

(ii) Promotion of good health and disease prevention through health promotion, the pharmacist's contribution (public health role of the pharmacist)

(iii) Health services research and welfare services research:~~;~~ research methods and results relevant to practice.

(iv) New roles for the pharmacist in health care.

c. Pharmacy in Society

(i) The ~~political and~~administrative and ~~-~~legal framework ~~and processes applying~~ in Ireland and in the European Union. ; ~~European Union, the Constitution, the Oireachtas, the Government and the Judiciary: and in the European Union green papers, white papers and legislation; Irish Law; International, European Law.~~

(iii) The duty of care to ~~the~~ patients and to the wider public: concept, scope and application of professional ethics, and the PSI statutory code of conduct for pharmacists~~of the Pharmaceutical Society of Ireland~~.

(iii) Health and illness: definitions and perceptions.

(iv) The p~~P~~hilosophy ~~and~~ behind the provision of health care services in Ireland.

(v) Medicines control (to include the control of ~~V~~veterinary ~~M~~medicines, herbal medicines, homeopathic medicines and other and ~~Alternative Therapies~~other such products): ~~licensing~~ authorisation of medicines: consumer protection, including concepts of product liability ~~and unlicensed medicines~~; legal classification of medicines, including controlled drugs and their sub-~~classes~~categories; the manufacture, packaging, ~~and~~ labelling and distribution of medicines.

(vi) The control of ~~P~~poisons as set out in the Poison Regulations 2008: ~~classes and controls (to include those used in agriculture and horticulture).~~

(vii) Retail pharmacy businesses: the regulations governing the registration management and supervision of ~~a~~ retail pharmacy businesses.~~.~~

(viii) The Pharmacy Act 2007 (as amended by the European Communities (Recognition of Professional Qualifications Relating to the Profession of Pharmacist) (No. 2) Regulations 2008) and the various Regulations and Rules made thereunder. ~~Statutes and regulations pertaining to pharmacy as issued by the Pharmaceutical Society of Ireland, Irish Medicines Board and The Department of Health; Miscellaneous Statutes and Regulations.~~

(ix) ~~Drugs of Abuse and Chemical Dependence: Treatment of Drug Misusers and the Pharmaceutical Society of Ireland Policy on Drug Abuse.~~methadone treatment programme.

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

(i) Sources and purification of substances used in medicine of biotechnological, chemical synthetic, immunological, mineral, animal and plant origin.

(ii) Drug isolation and structural determination from natural and synthetic sources.

(iii) Cell and molecular biology relevant to biotechnology.

(iv) Physico-chemical aspects of drugs and biological systems, including thermodynamics and chemical kinetics.

(v) Analytical methods (including those for biotechnology products): principles, design, development, validation and application.

(vi) Specifications of substances used in medicine, including physical and chemical tests.

(vii) Assessment of chemical and physical stability.

(viii) Good Laboratory Practice.

(ix) Prediction of drug properties, including chemical compatibilities, from molecular structure.

(x) Drug design; principles and future prospects.

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

(i) Properties of materials used in formulations and devices for the delivery of biologically-active molecules; biological, chemical and physical properties.

(ii) Development pharmaceutics, pre-formulation and formulation studies: design and standardisation of medicines for administration to the body by different routes and to specific target sites.

(iii) Functionality of pharmaceutical excipients.

(iv) Environmental control in manufacturing facilities and in the supply chain.

(v) The influence of processing on product quality with respect to biological safety, bio-availability (including bio-equivalence), dosage uniformity and stability.

(vi) Quality assurance of pharmaceutical products and processes.

(vii) Good ~~Pharmaceutical~~ Manufacturing Practice (GMP) and its ~~implications~~requirements.

(viii) Packaging; purpose, design and evaluation.

(ix) Effect of total supply process (supply chain) on product quality including the requirements of Good Distribution Practice (GDP).

(x) Pharmacopoeial and regulatory ~~requirements~~standards.

(xi) ~~Degradation~~ Stability of medicines; their evaluation ~~and control~~in light of their potential biological, chemical and/or physical degradation.

(xii) Sterilisation processes and aseptic procedures in the preparation of ~~pharmaceutical~~ medicinal products and medical devices; monitoring of sterilisation processes and aseptic procedures.

(xiv) Biological methods of measuring drug activity and the principles of biological standardisation~~s~~.

(xv) Drug absorption, disposition, metabolism and excretion; formulation criteria and dosage regimens.

(xvi) Immunological, biotechnological and radiopharmaceutical products.

(xvii) Dressings, medical devices and ~~medical~~ appliances.

IV. THE ACTION AND USES OF ~~DRUGS~~ MEDICINES AND OTHER HEALTHCARE PRODUCTS

(i) Normal and abnormal bodily function: biochemistry, genetics, microbiology, nutrition, immunology, infective processes, pathology, pathophysiology and physiology.

(ii) Actions of ~~drugs~~ medicines within living systems: molecular, cellular, biological, and physical aspects.

(iii) Preventative and therapeutic uses of ~~drugs and~~ medicines, including adverse reactions to and , their ~~i~~nteractions ~~of drugs~~with other medicines, herbal products and foods, and their clinical relevance to treatment.

(iv) Aetiology and epidemiology of major diseases and the principles of their ~~drug~~ treatment.

(v) Recognition of disease states and responding to symptoms of such.

(vi) Zoonoses.

(vii) Clinical evaluation of new ~~drugs and~~ medicines, post-marketing surveillance and knowledge of pharmacovigilance and pharmacoepidemiology.

(viii) Clinical use of medicines, ~~particularly principles which are common to both community and hospital practice;~~ focusing on problem solving.

(ix) Drug and substance misuse, and physiological and psychological dependence.

(x) Alterations in drug absorption, distribution, metabolism and excretion including alterations brought about by~~upon~~ ageing, disease and other ~~changes~~factors.

(xi) Clinical toxicology associated with drug over-dosage, drug or substance misuse or accidental consumption or exposure.

(xii) Medical devices including ~~M~~medicine delivery devices and other ~~medical devices, including equipment~~and appliances ~~for oxygen therapy, equipment for continuous ambulatory peritoneal dialysis, peak-flow meters, syringe-drivers and home care services~~.

(xiii) Dressings and wound management products.

(xiv) ~~Prospects for new~~Potential of novel approaches in therapeutics~~.~~: review and assessment.

Appendix B

Relevant Legislation

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

Article 44 – Training as a pharmacist:

1. Admission to a course of training as a pharmacist shall be contingent upon possession of a diploma or certificate giving access, in a Member State, to the studies in question, at universities or higher institutes of a level recognised as equivalent.

2. Evidence of formal qualifications as a pharmacist shall attest to training of at least five years' duration, including at least:

(a) four years of full-time theoretical and practical training at a university or at a higher institute of a level recognised as equivalent, or under the supervision of a university;

(b) six-month traineeship in a pharmacy which is open to the public or in a hospital, under the supervision of that hospital's pharmaceutical department.

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

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

3. Training for pharmacists shall provide an assurance that the person concerned has acquired the following knowledge and skills:

(a) adequate knowledge of medicines and the substances used in the manufacture of medicines;

(b) adequate knowledge of pharmaceutical technology and the physical, chemical, biological and microbiological testing of medicinal products;

(c) adequate knowledge of the metabolism and the effects of medicinal products and of the action of toxic substances, and of the use of medicinal products;

(d) adequate knowledge to evaluate scientific data concerning medicines in order to be able to supply appropriate information on the basis of this knowledge;

(e) adequate knowledge of the legal and other requirements associated with the pursuit of pharmacy.

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

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

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

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

Article 49:
1. Member States shall ensure that the qualified person referred to in Article 48 fulfils the conditions of qualification set out in paragraphs 2 and 3.

2. A qualified person shall be in possession of a diploma, certificate or other evidence of formal qualifications awarded on completion of a university course of study, or a course recognized as equivalent by the Member State concerned, extending over a period of at least four years of theoretical and practical study in one of the following scientific disciplines: pharmacy, medicine, veterinary medicine, chemistry, pharmaceutical chemistry and technology, biology.

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

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

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

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

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

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

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

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

- **Pharmacy Act 2007, Section 7 (1) (b) and (c) and 7 (2) (a)(iv)**

- **Pharmaceutical Society of Ireland (Education and Training) Rules 2008 (S.I. No. 493 of 2008), Part 3, Rule 7(1) and (2) and Schedule (extract of Schedule reproduced below):**

SCHEDULE

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

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

(a) four years of fulltime theoretical and practical training at a recognised institution, and

(b) twelve months of in-service practical training in accordance with Part 4 of these Rules.

2. (1) The aforementioned programme of education and training in the course of training for pharmacists shall at least cover the following subjects—

(a) Plant and animal biology,
(b) Physics,
(c) General and inorganic chemistry,
(d) Organic chemistry,
(e) Analytical chemistry,
(f) Pharmaceutical chemistry including analysis of medicinal products,
(g) General and applied biochemistry (medical),
(h) Anatomy and Physiology,
(i) Medical terminology,
(j) Microbiology,
(k) Pharmacology,
(l) Pharmacotherapy,
(m) Pharmaceutical technology,
(n) Toxicology,
(o) Pharmacognosy,
(p) Legislation and the law generally pertaining to pharmacy and medicinal products and to the practice of pharmacy in the State, and
(q) Professional conduct and ethics for a person practising as a pharmacist in the State.

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

(3) The said programme of education and training shall be such that on successful completion it will provide an assurance that the person concerned has acquired the following knowledge and skills—

(a) adequate knowledge of medicinal products and the substances used in their manufacture,

(b) adequate knowledge of pharmaceutical technology and the physical, chemical, biological and microbiological testing of medicinal products,

(c) adequate knowledge of the metabolism and the effects of medicinal products and of the action of toxic substances and of the use of medicinal products,

(d) adequate knowledge to evaluate scientific data concerning medicinal products in order to be able to supply appropriate information on the basis of this knowledge,

(e) adequate knowledge of the legal and other requirements associated with the pursuit of pharmacy,

and such knowledge and skills shall be such as to enable that person to competently practise as a pharmacist and thereby be entitled to gain access to and to at least pursue the professional activities of a pharmacist as set out in Article 45(2) of the Professional Qualifications Directive.

(4) The said programme of education and training shall, where appropriate, also have regard to—

(a) the report on recommendations on pharmaceutical education undergone at higher education institutions as adopted by the Advisory Committee on Pharmaceutical Training of the 3rd and 4th of May 1994 (Report 15/E/84341/6/93), and

(b) the minimum conditions of qualification specified in paragraph (2) of Article 49 of Directive 2001/83/EC.

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

Firstly, the Advisory Committee on Pharmaceutical Training points out that

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

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

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

- *A thorough grounding in the basics sciences of chemistry, physics and biology plus mathematics should be accepted as a prerequisite for admission to studies of the pharmaceutical sciences.*

- *In view of the minimum period of four years' training at a higher education institution laid down in Article 2(3) of Directive 85/432/EEC, the number of hours of such training should total at least 3000 directed and supervised by the academic staff of the higher educational institution concerned.*

- *At least half the higher education course identical for every student should consist of theoretical instruction, and at least 35% of that course should take the form of practical training.*

- *During the training period, pharmacy students must be provided with a sound and balanced grounding in the physical, chemical and biological sciences that represent the basis for their main training in:*

- *biological systems, the chemistry of drugs and other constituents of medicines, and the interaction between medicines and biological systems.*
- *medicines design and manufacture.*
- *the actions and uses of drugs, medicines and other products.*
- *an introduction to the practice of pharmacy in hospital, industrial, academic and community pharmacy settings, including an introduction to the relevant aspects of the social and behavioural sciences.*

- *At least one third of the whole course should be occupied by the components which collectively deal with the actions, uses and manufacture of drugs and medicines, and a broad balance should be maintained between the other sectors of the course.*

- *Intermediate examinations should be held during the course.*

- *In addition to the core course, which all students must take, individual students should be able to select one or more optional pharmaceutical subjects from a list provided by the academic institution, to reflect their special interests.*

- *Each student should carry out a personally directed research project covering about three to six months under the supervision of the academic staff and present a paper or dissertation on the project.*