



Consultation Report: Consultation on the draft Accreditation Standards for the Five-Year Master's Degree Pharmacy Programme

Considered by PSI Council on 19 September 2019

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Introduction

This report summarises the feedback received during the July 2019 public consultation process on the Proposed Accreditation Standards for the Five-Year Integrated Master's Degree Programme of Pharmacy.

Background

Section 7 of the Pharmacy Act 2007 provides that it is a principal function of the Pharmaceutical Society of Ireland (PSI) to, inter alia, 'promote and ensure a high standard of education and training for persons seeking to become pharmacists. [Rule 7 of The Pharmaceutical Society of Ireland \(Education and Training\) \(Integrated Course\) Rules 2014](#), as amended, sets out the criteria for recognition and approval of the five year integrated programme of education and training leading to award of Master's degree in pharmacy. Under Rule 7(3), the Council of the PSI is obliged to review the Accreditation Standards for the programmes at intervals not exceeding five years.

Accreditation Standards for the five-year fully integrated Master's degree programme were first approved by the Council of the PSI on 2 October 2014, with the first year of the programme commencing in September 2015. The five-year fully integrated pharmacy degree is currently entering its fifth year and the PSI is in the process of reviewing the accreditation standards which underpin the programme.

Review Process

The PSI initiated early engagement with nominated stakeholders and like parties internationally and nationally in March 2019. These were contacted by e-mail requesting information on their own accreditation processes and invited to submit input on PSI's accreditation standards. The PSI contacted 24 organisations. The following entities made themselves available for meetings and/or provided information:

- Accreditation Council for Pharmacy Education (ACPE)
- Affiliation for Pharmacy Practice Experiential Learning (APPEL)
- Australian Medical Council (AMC)
- Canadian Council for Accreditation of Pharmacy Programs
- Health Information and Quality Authority (HIQA)
- Irish Pharmaceutical Students Association (IPSA)
- Irish Pharmacy Union (IPU)
- New Zealand Pharmacy Council
- Nursing and Midwifery Board of Ireland (NMBI)
- Royal College of Nursing (RCN)
- Royal College of Surgeons in Ireland (RCSI)
- Trinity College Dublin (TCD)
- University College Cork (UCC)
- Veterinary Council of Ireland (VCI)

Following this, an expression of interest (EOI), focusing on those identified as having the skills, competence, and experience in this area, was issued with a view to constituting an expert group to review PSI's accreditation standards, was issued. A group was established as follows:

- Prof. Jane Portlock, Head of Pharmacy Practice at University of Portsmouth (Chair)
- Dr. Nicola Tyers, Director of the Pharmacy Training Company
- Mark Brennan, Deputy Head of Pharmacy at Aston University
- Dr. Brian Cross, Associate Professor and Vice-Chair in the Department of Pharmacy Practice at the Bill Gatton College of Pharmacy at Eastern Tennessee State University ¹

The Expert Group was provided with the initial information and feedback from the stakeholders as well as the current standards, comparator standards (benchmarking) from other professions and pharmacy bodies, and guidance document². They were given the month of April to discuss and revise the current standards.

The PSI received the revised standards from the Expert Group at the end of April and contacted national stakeholders for further feedback on the proposed new standards (See Section Discussion: Engagement Exercises).

The revised draft Accreditation Standards were presented to the Council of the PSI at their meeting of 20 June 2019. The Council approved the draft Accreditation Standards for public consultation.

This is the report on the outcomes of the consultation process.

About the consultation

The public consultation opened on July 2, 2019 and closed on July 31, 2019.

The consultation was notified to the public on the PSI website, and through social media.

Pharmacists, Pharmaceutical Assistants, and approximately 100 targeted stakeholders were made aware of the consultation through email and via the PSI newsletter (email).

Those stakeholders who had previously participated in earlier engagement exercises were contacted by email inviting additional feedback on 3 July 2019 and a reminder e-mail was issued on 18 July 2019.

¹ Unforeseen circumstances impacted Dr. Cross' ability to participate

² *Pharmaceutical Society of Ireland Guidance for Higher Education Institutions to accompany the Accreditation Standards for the five-year fully integrated Master's Degree Programmes in Pharmacy* – Approved by the Council of the Pharmaceutical Society of Ireland on 2 October 2014

Response to the consultation

In total **n=49** responses were received to the public consultation.

Response to the survey was low, with many respondents failing to answer all questions:

43 responses were received to the online survey with a 46% average completion rate for questions 4-15.

2 responses were received via email from individuals

4 submissions were made by stakeholder organisations by email ([Appendix B](#))

- i) Irish Pharmaceutical Students Association (IPSA)
- ii) Union of Students in Ireland (USI)
- iii) Trinity College Dublin (TCD)
- iv) Royal College of Surgeons in Ireland (RCSI)

The Survey

Prior to completing the survey, respondents were asked to review the proposed accreditation standards ([Appendix C](#)). The online survey comprised of 15 questions ([Appendix D](#)) with questions 14 and 15 allowing for open comment.

Responses to the survey are anonymous.

Responses were also accepted by email to education@psi.ie.

Survey Question 1

Respondents were required to answer this question³ before progressing through the remainder of the survey as it pertained to data protection and freedom of information.

This survey is voluntary. By completing it you are agreeing to allow your responses to be processed and analysed by the PSI for the purpose of seeking feedback on the proposed new PSI (Registration) Rules 2018. A consultation report will be compiled and this report, will be published on the PSI website in due course. The information you provide to this survey will be stored in a secure and confidential manner by the PSI, it will only be used for the purposes outlined above and it will be deleted in line with the PSI's record retention policy. The PSI uses SurveyMonkey to gather feedback to our public consultations. Full details of how your information is processed via SurveyMonkey is documented in this privacy policy. Submissions made to public consultations carried out by the PSI are subject to the provisions of the Freedom of Information Act 2014.

Do you agree to the terms above? By selecting 'Yes' you are confirming you consent to providing your answers to the questions in this survey

³ As all respondents wishing to partake in the survey were required to answer this question (n=43).

Survey Question 2

Respondents were asked to identify the category that best described them.⁴

There were **39** responses to this question⁵. The profile of respondents is indicated in the graph below.

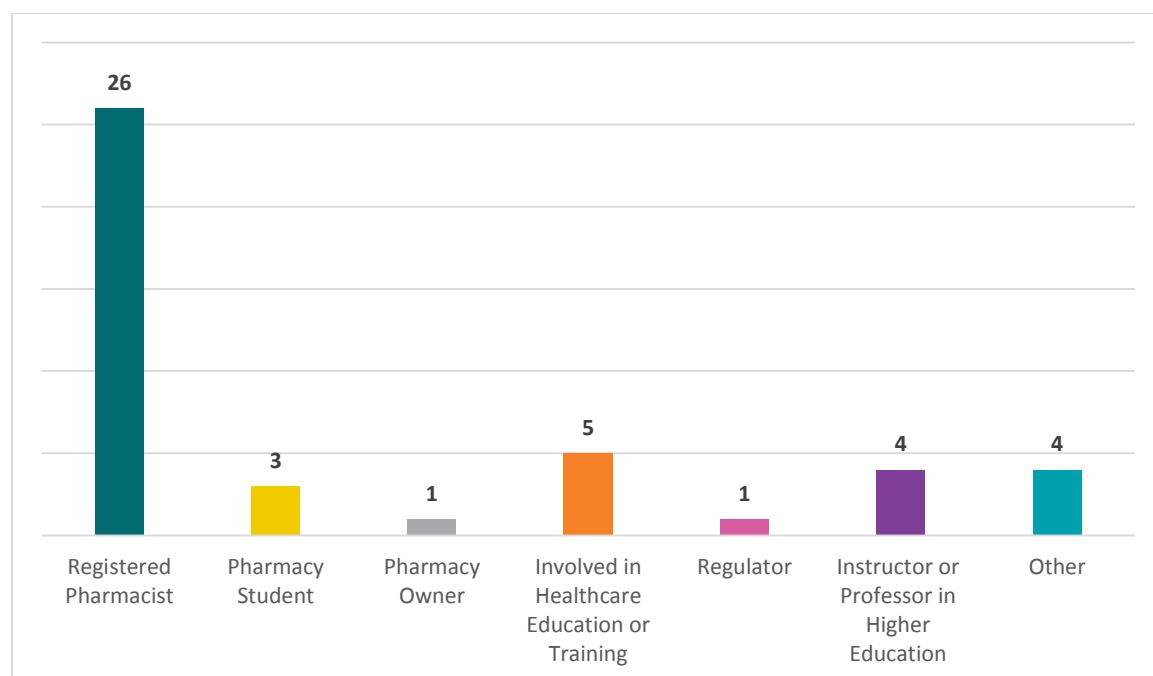


Figure 1: Breakdown of consultation respondents (Survey Question 2).

⁴ Additional categories were provided

⁵ Respondents were permitted to identify with multiple categories

Survey Question 3

Respondents were asked if they were responding on their own behalf or on the behalf of an organisation.

As demonstrated in figure 2, 35 respondents responded on their own behalf, and 4 responded on behalf of an organisation.

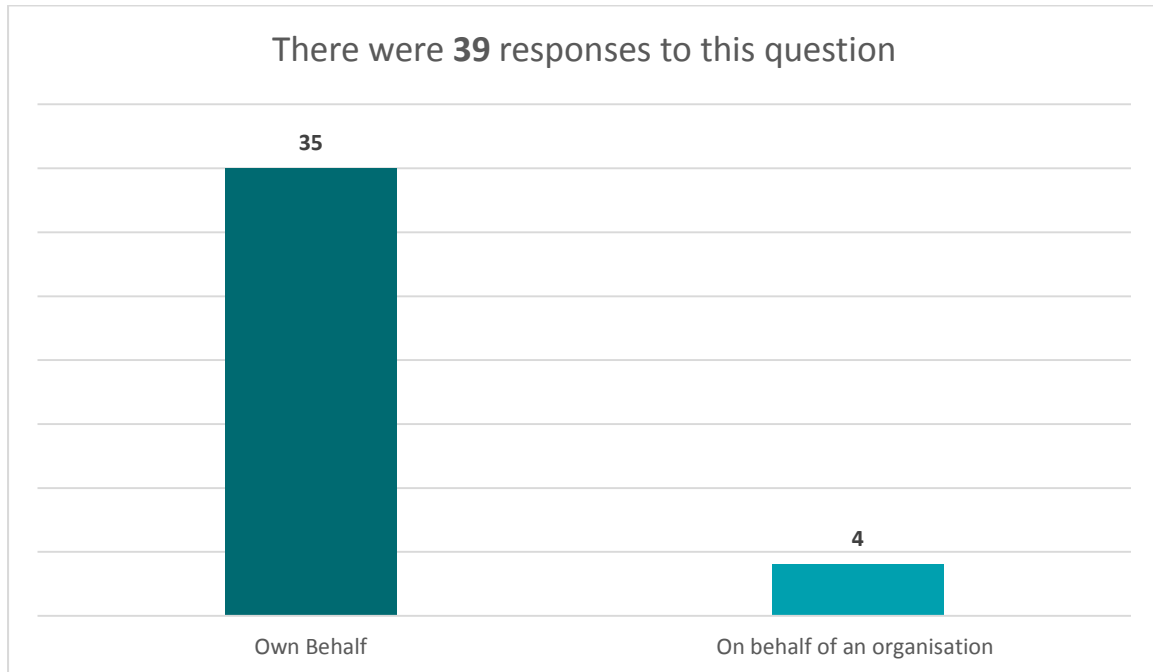


Figure 2: Responding on own behalf/behalf of an organisation

Survey Question 4

The purpose of Standard 1 is to assure that the appropriate strategic planning is in place to deliver a high quality pharmacy training programme.

Do you agree that this is achieved by the proposed Standard 1?

As demonstrated in figure 3, 19 respondents agreed, 6 disagreed and 6 'neither agreed nor disagreed' that this is achieved by Standard 1.

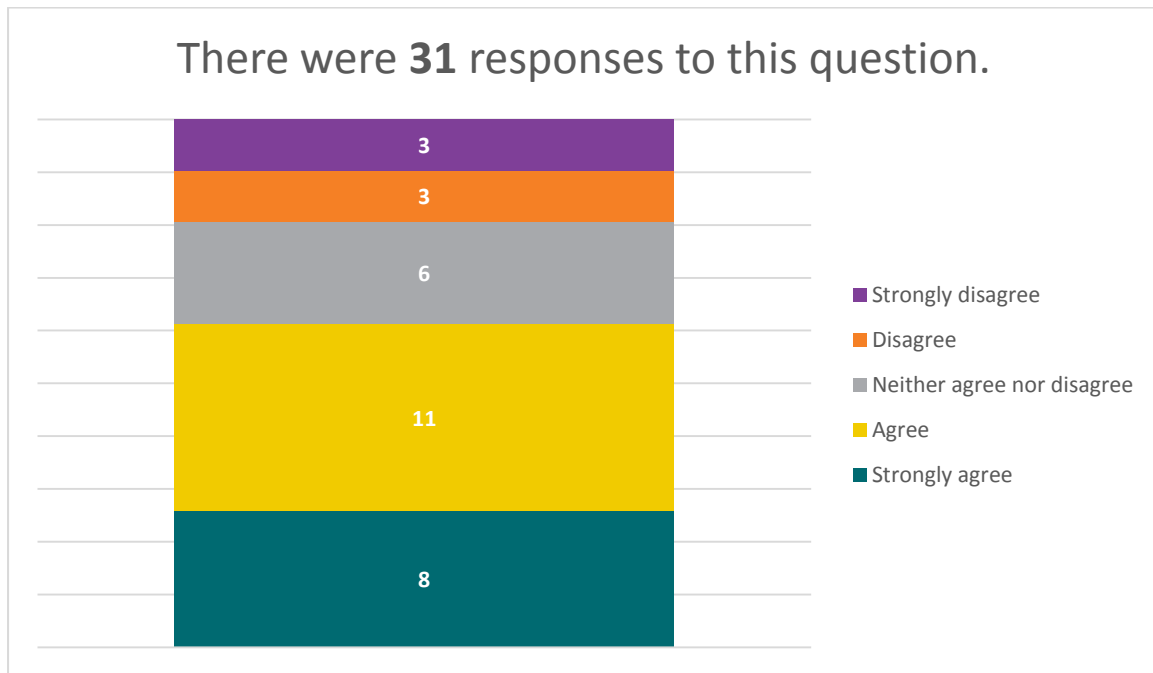


Figure 3: Standard 1 assures appropriate strategic planning is in place for delivery of a high quality pharmacy training programme.

Survey Question 5

The purpose of Standard 2 is to assure that appropriate governance, organisation, and leadership structures are in place to deliver a high quality pharmacy training programme.

Do you agree that this is achieved by the proposed Standard 2?

As demonstrated in figure 4, 12 respondents agreed, 6 disagreed and 8 'neither agreed nor disagreed' that this is achieved by Standard 2.

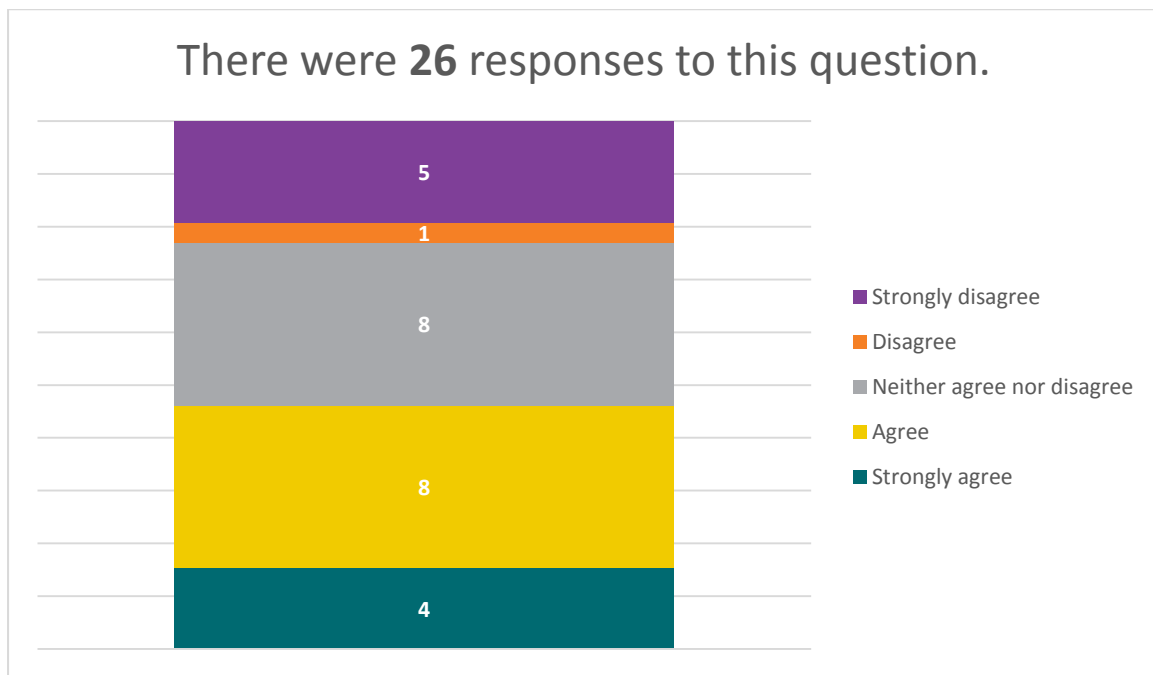


Figure 4: Standard 2 assures appropriate governance, organisation, and leadership structures are in place to deliver a high quality pharmacy training programme.

Survey Question 6

The purpose of Standard 3 is to assure quality of resources and personnel to deliver a high quality pharmacy training programme.

Do you agree that this is achieved by the proposed Standard 3?

As demonstrated in figure 5, 9 respondents agreed, 10 disagreed and 4 'neither agreed nor disagreed' that this is achieved by Standard 3

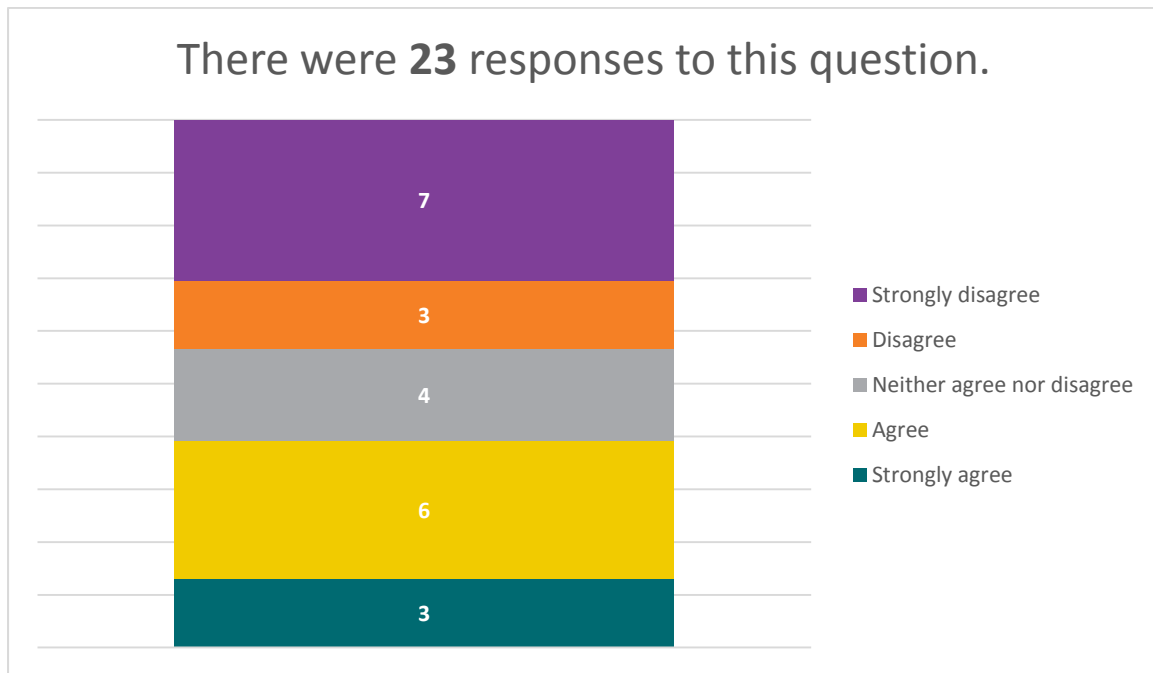


Figure 5: Standard 3 assures the quality of resources and personnel required to deliver a high quality pharmacy training programme.

Survey Question 7

The purpose of Standard 4 is to assure the quality of the curriculum for the pharmacy training programme. This includes that the curriculum is delivered in an integrated way, meets all legal requirements, including that graduates are equipped with the knowledge, skills, attitudes, and behaviours to meet the Core Competency Framework for Pharmacists, and that the curriculum is subject to regular review, monitoring, and evaluation.

Do you agree that this is achieved by the proposed Standard 4?

As demonstrated in figure 6, 10 respondents agreed, 6 disagreed and 6 'neither agreed nor disagreed' that this is achieved by Standard 4.

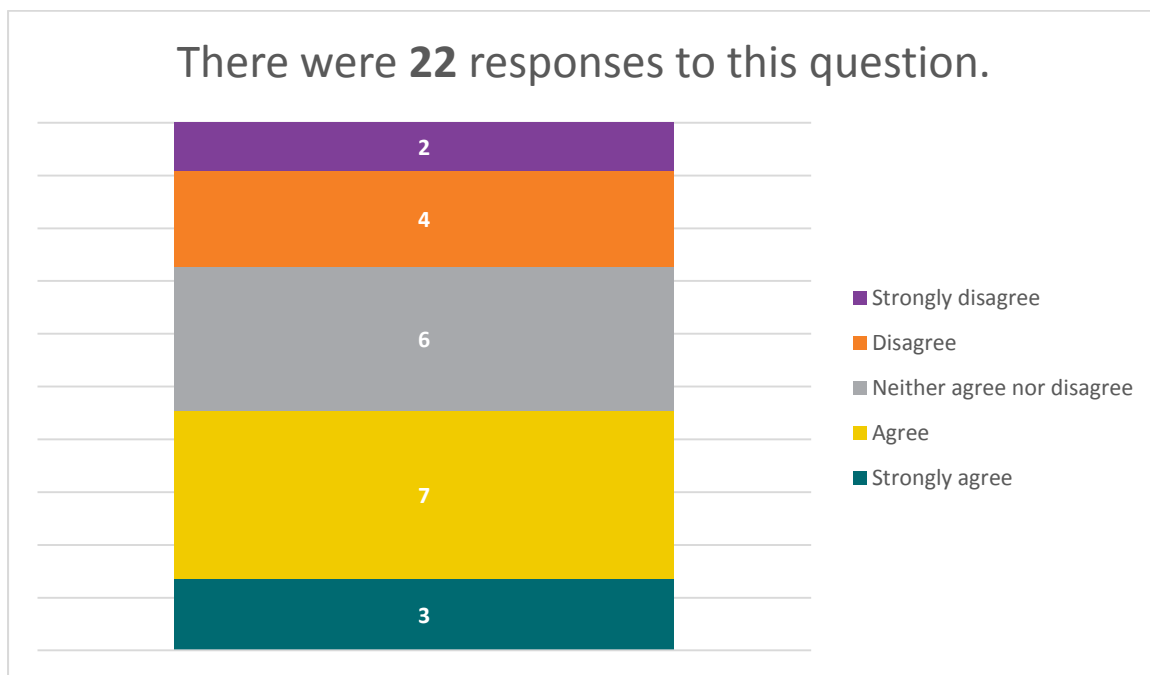


Figure 6: Standard 4 assures the quality of the curriculum for the pharmacy training programme.

Survey Question 8

The purpose of Standard 5 is to quality assure the Teaching, Learning, and Assessment Strategy for the pharmacy training programme.

Do you agree that this is achieved by the proposed Standard 5?

As demonstrated in figure 7, 8 respondents agreed, 5 disagreed and 9 'neither agreed nor disagreed' that this is achieved by Standard 5.

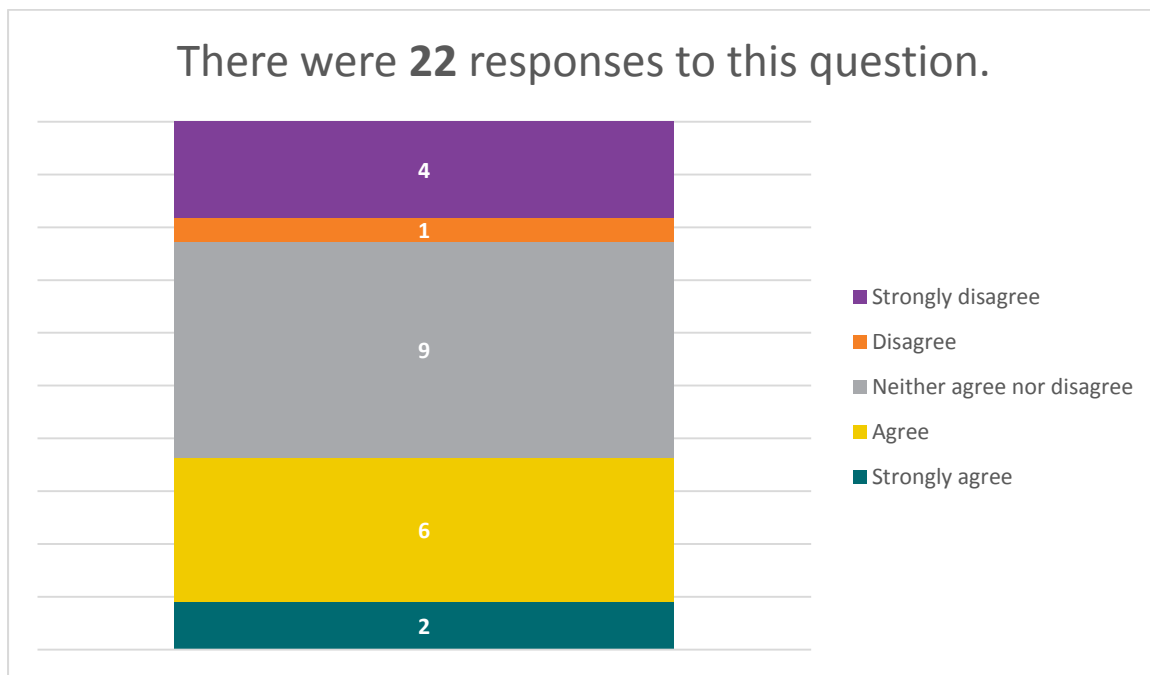


Figure 7: Standard 5 assures the quality of the Teaching, Learning, and Assessment Strategy for the pharmacy training programme.

Survey Question 9

The purpose of Standard 6 is to assure that a demonstrable and continuous quality assurance and enhancement programme is in place for all aspects of the pharmacy training programme.

Do you agree that this is achieved by the proposed Standard 6?

As demonstrated in figure 8, 8 respondents agreed, 6 disagreed and 8 'neither agreed nor disagreed' that this is achieved by Standard 6.

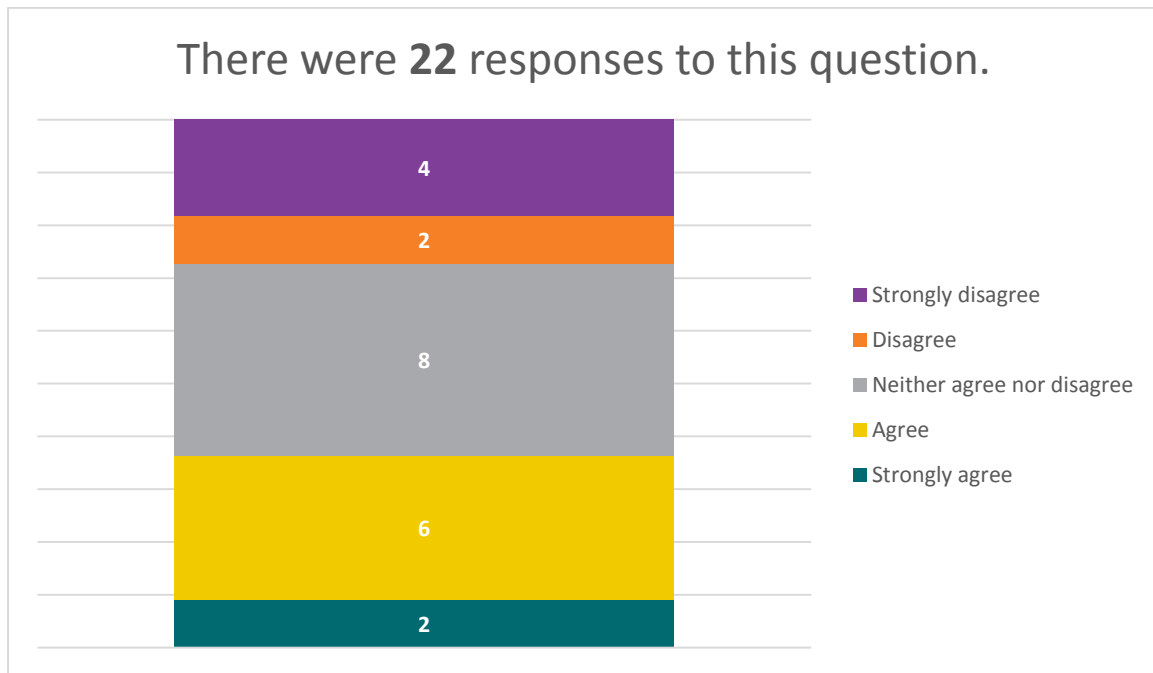


Figure 8: Standard 6 assures a demonstrable and continuous quality assurance and enhancement programme is in place for all aspects of the pharmacy training programme.

Survey Question 10

The purpose of Standard 7 is to assure quality support and guidance processes are in place for students and prospective students undertaking the pharmacy training programme.

Do you agree that this is achieved by the proposed Standard 7?

As demonstrated in figure 9, 6 respondents agreed, 8 disagreed and 8 'neither agreed nor disagreed' that this is achieved by Standard 7.

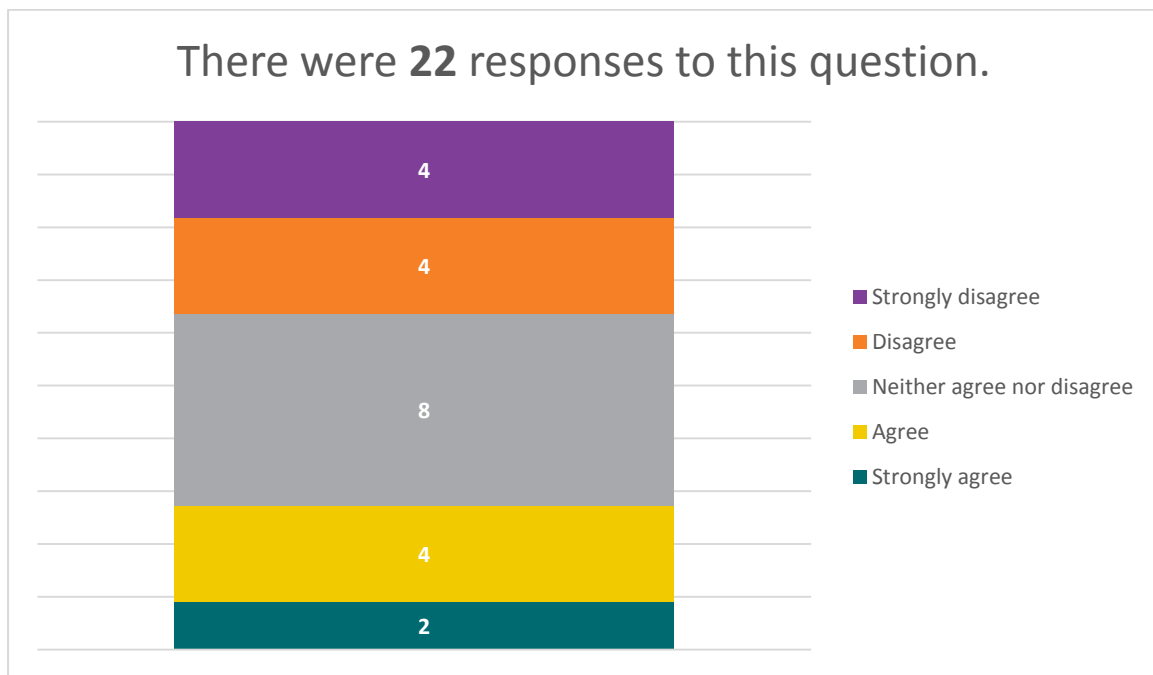


Figure 9: Standard 7 assures quality support and guidance processes are in place for students and prospective students undertaking the pharmacy training programme.

Survey Question 11

Do you agree that the Indicative Syllabus at [Appendix A](#) provides sufficient guidance to the pharmacy programme provider to design and implement a contemporary patient-centred pharmacy programme which is grounded in pharmaceutical science?

As demonstrated in figure 10, 7 respondents agreed, 5 disagreed and 10 'neither agreed nor disagreed' that this is achieved by the Indicative Syllabus.

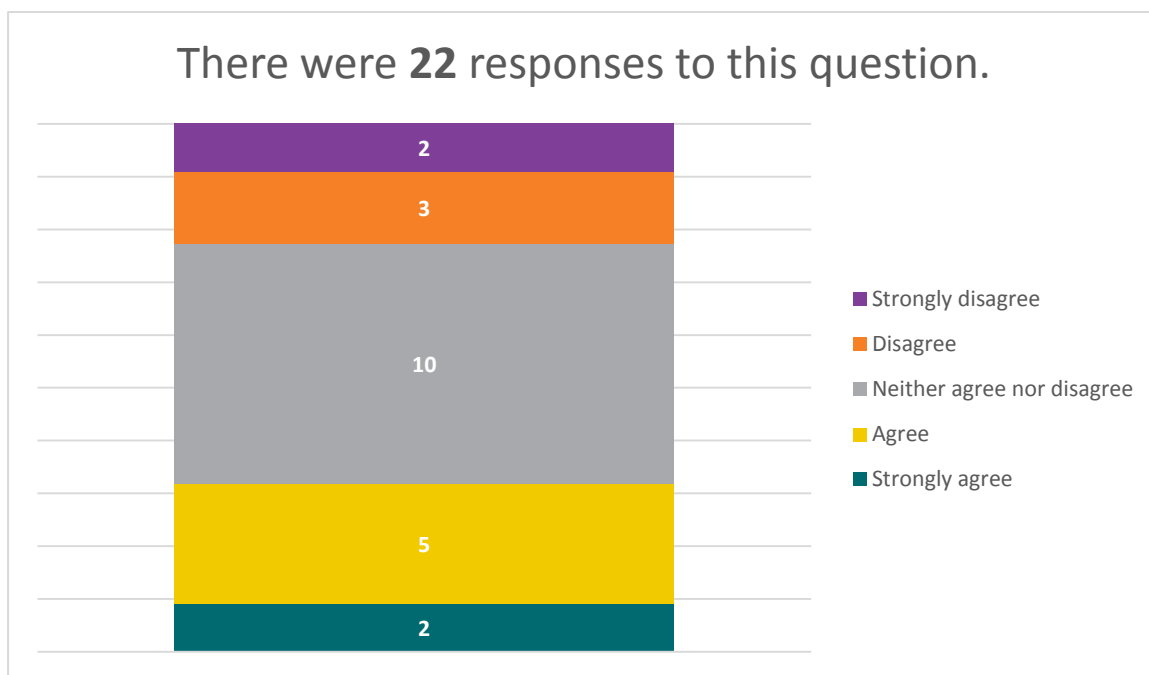


Figure 10: The Indicative Syllabus provides sufficient guidance to the pharmacy programme provider to design and implement a contemporary patient-centred pharmacy programme which is grounded in pharmaceutical science.

Survey Question 12

Would you agree the draft standards are fit for purpose and capture all the elements necessary to support the development of a contemporary and quality pharmacy degree programme?

As demonstrated in figure 11, of those who responded, 6 respondents agreed, 5 disagreed and 3 'neither agreed nor disagreed' that the draft standards are fit for purpose.

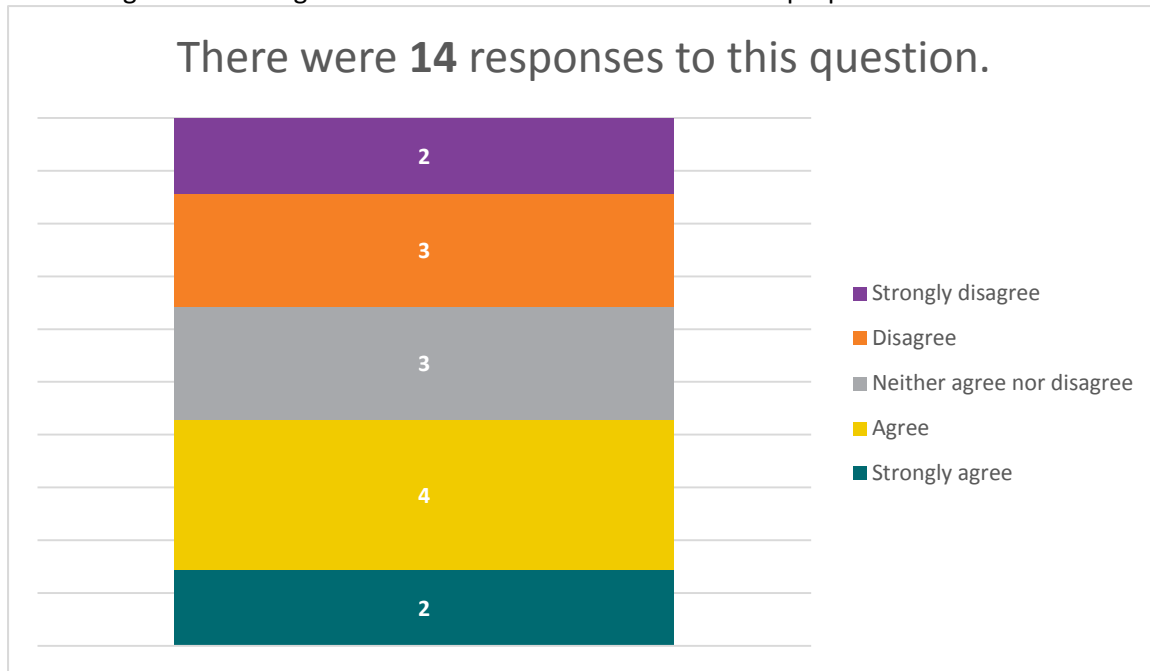


Figure 11: The draft standards are fit for purpose and capture all elements necessary to support the development of a contemporary and quality pharmacy degree programme.

Survey Question 13

Do you agree the proposed standards are easy to read and understand?

As demonstrated in figure 12, of those who responded, 5 respondents agreed, 4 disagreed and 5 'neither agreed nor disagreed.'

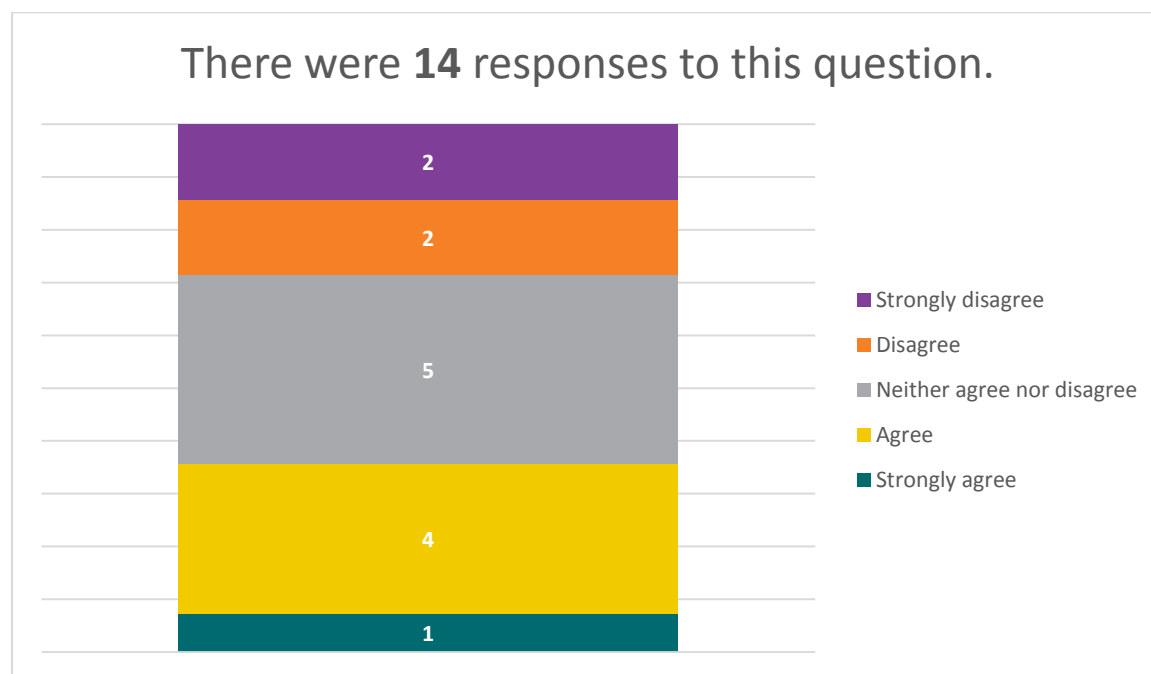


Figure 12: The draft standards are easy to read and understand.

Survey Question 14

What additional areas, if any, do you believe should be included or emphasised in the standards?

There were **11** responses to this question.

	Responses to Survey	PSI Comment
1	It is not possible to offer hospital experience/placement on the new 4+1 programme due to lack of pharmacist resource to adequately supervise the student without taking away from the core work of the pharmacist.	See Discussion Section (Themes: Placement Recruitment, Placement Resourcing)
2	I believe that there should be a greater emphasis on skills and competencies necessary for hospital pharmacy practice. Pharmacy student placements are an essential component of the undergraduate programme. I believe a greater responsibility should be included in the standards to ensure that student placements include all aspects of pharmacy practice with particular emphasis on Hospital Training. The	See Discussion Section (Theme: Placement Recruitment)

	experience from other European countries, notably Spain, is that Hospital Pharmacist training is supported and encouraged to provide trainees with a very high standard of pharmacy practice suitable for a highly functioning health service.	
3	The onus appears to be with the HEI/School to provide standards for the practise placement elements. I believe the society should lead in setting standards for these placements and identify the competencies and responsibilities of practice based pharmacist/educators. It is in practice that pharmacists interact most intimately with patients (your protectees, if you will) so it behoves the society provide detailed standards in this area. A failure to recognise and define the educator role (hospital/community/industry/other) is to fail patients and pharmacy students.	<p>The standards and quality assurance of experiential learning placements is currently monitored and reviewed through PSI accreditation processes. Draft Standard 6 sets out the requirements in relation to the quality assurance for experiential learning placements.</p> <p>Rule 15(6) of The PSI (Education and Training) (Integrated Course) Rules 2014 provides for the PSI Council to set criteria for the approval of training establishments, the nature of training and its supervision, in guidelines. Your response is noted, however, this matter is outside the scope of the Accreditation Standards consultation.</p>
4	There is insufficient emphasis on the structured placements and engagement with large employers in both the public and private sectors to facilitate same. There is no attempt to link the placements with key deliverables in the workplace, as happens with nursing and medical students. There is no protection for the workload linked with the placements as happens with medical and nursing students. There is no method other than disengagement to ensure tutor competency or location suitability with no link proposed at the employer level as happens with nursing or medical placements. Accommodation at the practice sites as described in 6b are set out for medical students – should these also be specified for pharmacy students?	See Discussion Section (Theme: Placement Resourcing)
5	A greater emphasis on pharmacy economics and understanding how to manage budgets and procurement in a way that protects and benefits patients and government	<p>Noted.</p> <p>Competency 6.4 of the Core Competency Framework (CCF) for Pharmacists relates to Financial Management Skills. All pharmacy programmes are required under the legislation to ensure that graduates can demonstrate the competencies set out in the CCF.</p> <p>The indicative syllabus of these Draft Standards has been updated to include</p>

		reference to “the role of public health, health promotion, and health economics, particularly pharmacoeconomics” under the heading ‘The Wider Context’
6	Emphasis on the availability of sufficient resource in Standard 3 e.g. sufficient Practice Educators and Tutor Pharmacists esp, in Hospital Pharmacy. In my own experience there is not sufficient resources at present to allow Hospitals to engage with the New 5-year degree course.	See Discussion Section (Themes: Placement Recruitment, Placement Resourcing)
7	Each student should know their Core Values	<p>This comment is not clearly understood.</p> <p>The PSI (Education and Training) (Integrated Course) Rules 2014 require institutions to support the operation of a Code of Conduct for pharmacy students, which has regard to the Code of Conduct for Pharmacists under the Act. These Codes of Conducts are introduced to students upon commencement of a pharmacy programme. Fitness to Practice mechanisms must also be put in place at the institution and routinely reviewed (Draft Standard 6)</p>
8	Practical Skills	<p>This comment is not clearly understood. Practical Skills are addressed through curriculum and practical training aspects of the programmes. (Draft Standard 5, Draft Standard 6)</p> <p>The PSI (Education and Training) (Integrated Course) Rules 2014 and Draft Standards 1 and 4 require that graduates of pharmacy programmes can demonstrate the competencies set out in the Core Competency Framework for Pharmacists.</p>
9	Hospital pharmacy	This comment is not clearly understood. Hospital based experiential learning placements are provided for under Draft Standard 4.8.
10	Mandatory payment from placement providers, students now expected to pay 7,500 in fees huge barrier to the profession.	Noted. Fees and payment matters are outside the scope of the Accreditation Standards consultation.
11	5 years?	<p>This comment is not clearly understood.</p> <p>The PSI (Education and Training) (Integrated Course) Rules 2014, in accordance with the requirements of Article 44 EU Directive 2005/36, requires that the pharmacy degree programme is of at least 5 years duration, comprising not less than 4 years full time theoretical and practical training at a</p>

		recognised institution and not less than 12 months of in-service practical training.
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Survey Question 15

Are there any requirements which should be removed or are overly demanding?

There were **6** responses to this question.

	Response to Survey	PSI Comment
1	No	Noted
2	No	Noted
3	Demands on current staffing without additional resources	This comment is not clearly understood. See also Discussion Section (Theme: Placement Resourcing)
4	No	Noted
5	Most of them	Noted
6	It should be done in a year tops. The rest is all a scheme to get more money out of pharmacists.	This comment is not clearly understood. The PSI (Education and Training) (Integrated Course) Rules 2014, in accordance with the requirements of Article 44 EU Directive 2005/36, requires require that the pharmacy degree programme is of at least 5 years duration, comprising not less than 4 years full time theoretical and practical training at a recognised institution and not less than 12 months of in-service practical training.

Email Responses to the Consultation

6 responses were provided by email to the consultation:

Themes emerging from the responses included:

Masters Fee and impact on equality of access	2
Recruitment of Placements (including hospital placements)	3
Schools Reporting Obligations and GDPR	1
Human Rights Awareness and Teaching	1
Development of Teacher Practitioner Roles	1
Resourcing of MPharm Programme	1

Some specific smaller amendments to the Accreditation Standards were proposed in the email responses to the survey and these shall be included in the revised Accreditation Standards which will be presented to Council for consideration and approval.

Discussion

Engagement Exercises

The PSI invited the following stakeholders to engagement meetings immediately before and after a draft of the revised accreditation standards were created.

- Affiliation for Pharmacy Practice Experiential Learning (APPEL)
- Pharmacists in Industry, Education, and Regulatory (PIER)
- Hospital Pharmacists Association of Ireland (HPAI)
- Quality and Qualifications Ireland (QQI)
- Higher Education Institutions (UCC, RCSI, TCD)
- Irish Pharmacy Union (IPU)

Outputs from these engagement exercises were valuable and comprehensive. Stakeholders actively engaged in face to face and teleconference meetings. The PSI welcomed this engagement and are grateful to those who contributed.

The majority of matters raised in the engagement exercises were addressed in the revised draft of the Accreditation Standards, which was subsequently approved by Council at its meeting on 20 June 2019 or public consultation.

Two matters raised in the engagement exercises which were not addressed in the draft Accreditation Standards approved for public consultation are set out in the table below. Stakeholders were informed that while these concerns were noted, the draft wording was left unchanged in the consultation draft to allow for wider opinion on the matter to be gleaned through the consultation process, and all opinions would then be considered by Council in September 2019.

These matters relate to Draft Standards 2.6/2.7 and 4.8:

Draft Standard 2.6/2.7	<p>Concern was voiced over the requirement for reporting of student fitness to practice issues, as set out at draft Standard 2.6/2.7.</p> <p>It was proposed that it is the school's responsibility in legislation to ensure competence and fitness to practice of its graduates and therefore issues should be managed and monitored by the school while the students are under the care of the HEI. The school's fitness to practice policies and procedures may be made available for review.</p> <p>Additionally, the point was raised that many perceived fitness to practice issues could happen early in a student's career and could be resolved before any placements or final sign-off on competencies occurred. It was held that it would be inappropriate to share information on students for problems they may have faced years before being eligible to go on the register.</p> <p>It was requested that guidance be provided on the nature of data required to be reported e.g. statistical or more detailed data.</p>
Draft Standard 4.8	<p>Concern was expressed about the obligation under draft Standard 4.8 to provide hospital placement opportunities, given the current employment and resourcing concerns in the sector.</p>

Public Consultation

Despite contact to over 100 stakeholders, and to all registered pharmacists and pharmaceutical assistants, social media and website notifications, there was a very low level of engagement to the public consultation.

The survey was completed by 43 respondents, however, few completed the survey in full, with response rates to the questions relating to the draft Accreditation Standards ranging from 6 responses to 31 responses. Where dissatisfaction was expressed with particular draft Standards, few respondents chose to provide specific information or feedback in the comment sections provided.

Themes Arising

Key themes arising from the public consultation and engagement exercises are set out below. Please note that these are a summary of some of the themes arising. All responses collected are available for review in the Appendices to this document.

I. Placement Recruitment:

A number of responses commented on the onus on the MPharm programme providers to offer and provide experiential learning placements to students, across the main practice settings and in particular, in the hospital setting, as set out under Standard 4.8. While some responses supported this provision, others noted that external factors may compromise the ability of programme providers to meet the expectations and cited the current difficulties of recruiting hospital pharmacy experiential learning placements. Another response noted that at all times, the programme providers are reliant on the goodwill of personnel and individual practice settings, in order to offer a range of experiential learning placements.

Suggestions were made to amend the wording of Standard 4.8 to take into account that placements can only be provided 'subject to availability' across practice settings.

PSI Response

While these concerns are noted, the availability of placements has always been reliant on the goodwill of individual pharmacists and placement settings throughout the BPharm/National Pharmacy Internship Programme (NPIP) and MPharm programmes. The ethos in the development of the integrated programme was that students would ideally have opportunities for immersion in the three main pharmacy practice settings during their training, to enhance students' experiences and broaden their horizons. Integration of the theoretical and practice learning opportunities enhances the preparation of pharmacists to contribute to patient care and understanding of the needs of the health system by having a more rounded 'whole system' understanding of pharmacy practice across the diversity of settings in which pharmacy is practised.

PSI, as the pharmacy regulator, seeks to assure through the modality of its accreditation processes and standards that graduates from the national pharmacy programme are equipped with the necessary competencies and prepared for roles across the main pharmacy settings, and the conservation of the requirement to have the broad experience is important to conserve.

II. Placement Resourcing

Respondents expressed concern at the lack of structured resources and supports for pharmacists and practice settings to offer students experiential learning placements. One respondent noted that the pharmacy programme differed from nursing and medical training programmes in this regard. These concerns appeared to be expressed in the context of hospital pharmacy placement settings in particular.

PSI Response

The model for the recruitment of experiential learning placements for the BPharm/NPIP and MPharm programmes is based on 'good will' of pharmacists and training establishments. The PSI is committed to assuring the successful implementation of the programme and is happy to engage in any issues arising with the model, as relevant to its role.

In the context of this consultation, however, the matter of resourcing of experiential learning placements rests outside the scope of the Accreditation Standards.

III. Higher Education Institutions Reporting Obligations: Fitness to Practice

At the engagement exercises, concern was expressed from two pharmacy programme providers regarding the reporting requirements, as set out in draft Standard 2.6 and 2.7(b). Issues of concern related to the level and detail of reporting which would be required under the draft standards with respect to students and fitness to practice matters.

It was proposed that it is the school's responsibility in legislation to ensure competence and fitness to practice of its graduates and therefore issues should be managed and monitored by the school while the students are under their care. The school's fitness to practice policies and procedures may be made available for review.

Additionally, the point was raised that many perceived fitness to practice issues could happen early in a student's career and could be resolved before any placements or final sign-off on competencies occurred. It was held that it would be inappropriate to share information on students for problems they may have faced years before being eligible to apply for registration.

It was requested that guidance be provided on the nature of data required to be reported e.g. statistical or more detailed data.

PSI Response

These concerns are noted.

The PSI, as the pharmacy regulator, seeks to protect patient health, safety and welfare through its functions, including its registration functions. The decision to register an individual pharmacist and to thereby allow the practitioner to provide direct patient care remains the responsibility of the regulator. Information on fitness to practice matters may be of relevance to the regulator in this context.

IV. Equality and Diversity

Two stakeholders, while cognisant of the HEIs obligations to comply with legislative requirements on equality, diversity and disability, wished to clarify that while every attempt can be made to accommodate the diverse needs of students, there are occasions where the HEI may be unable to meet all needs. These stakeholders requested that ‘in so far as practicable’ would be included at the relevant standards in acknowledgement of such limited circumstances.

PSI Response

The draft Accreditation Standards seek to support the legislative requirements relating to equality, diversity and disability.

V. Masters Fee: Impact on Equality of Access

Student stakeholder organisations impressed how the current fees required for the fifth year of the programme, place considerable pressures on students. Students believe that the current fees in place go against the provisions of Accreditation Standard 7 for fair, open and non-discriminatory admission and progression procedures for students, and also in the context of Standard 2, which calls for pharmacy programmes to be based on and promote the principles of equality, diversity and fairness.

PSI Response

Fees and payment matters are outside the scope of the Accreditation Standards.

The matter of fees charged in respect of Masters programmes of education rests with the Higher Education Authority. Since January 2019, the PSI have met with students in April 2019 and look forward to meeting with students again in October 2019, operating within the context of the PSIs role as public interest body.

Conclusion

We have noted all responses with thanks. The feedback and comments will be provided to the Council of the PSI for their consideration.

In line with the PSI values and corporate strategy, the PSI is committed to continue working with the academic institutions and sector in relation to the quality of the MPharm programme to ensure the highest standards in education and training for the qualification to practice as a pharmacist.

Appendices

- A Indicative Syllabus
- B E-mail Responses to the Consultation
- C Proposed Accreditation Standards for the Five-Year Integrated Master’s Degree Programme
- D Public Consultation Survey

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.

- i. 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.
- ii. The duty of care to the patient and the wider public: concept, scope and application of healthcare ethics.
- iii. 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.
- iv. Principles of organisation in the workplace, including procedures and policies, resources requirements, management roles and structures within pharmacy settings.
- v. Oversight and development of those working in the pharmacy team.
- vi. Communication skills relating to multidisciplinary working and getting the best outcome from medicines for patients.
- vii. The obligations of pharmacists as professionals requiring registration in order to practice including their compliance with statutory codes of conduct.
- viii. 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.
- ix. Evidence-based policy and practice: use of evidence-based knowledge to develop policy and translate into practice.
- x. Use of information technology in pharmacy and more widely in health care.
- xi. 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 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. The role of public health, health promotion, and health economics, particularly pharmaco-economics.
- iii. Scientific, clinical, health services and social services research relevant to pharmacy, translation of evidence into policy and practice.
- iv. 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.

- i. Molecular basis of drug action and the actions of drugs within living systems; molecular, cellular, pharmacogenomics, biological and physical aspects.
- ii. Clinical therapeutic uses of drugs and medicines in people 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, age 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, 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.

- i. Sale, supply, administration and monitoring of medicines,
- ii. Medicines: schedules of medicines and controlled substances; consumer protection, including product liability and professional negligence.
- 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 standardisation of medicines for administration 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 labelling: 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.

From: [REDACTED]
Sent: 05 July 2019 11:45
To: Education
Subject: Feedback : Integrated Pharmacy Master's

PSI draft accreditation standards integrated five-year Master's degree programmes: Personal Feedback on consultation.

Hello,

Please see below some thoughts in relation to the new integrated five-year Pharmacy Master's degree programmes.

My comments relate to the need to ensure that pharmacy students and staff in academic institutions are aware of their human rights.

Best wishes



Human Rights and Pharmacy Students.

In order to achieve a just society, in which the rights of each person (pharmacist /pharmacy student) are valued and respected,
pharmacists and pharmacy students need to aware of our rights and responsibilities.

Schools and universities, as public institutions of the Irish State, have certain obligations under human rights and equality legislation, both in regard to how education is provided and to what is taught. Human rights and equality are integral to education.

Pharmacy students need to understand equality and know their rights, to understand both how they should be treated, and how they should treat others.

To reap the full benefits of equality and human rights education, it is essential to teach the topics in an environment which respects the rights and differences of both pharmacy students and teachers.

If university students(pharmacy) don't know what their rights are, they can't know if their rights are being respected, protected and made real.

All pharmacy students have the right to know their rights.

Knowledge of freedom and rights is a fundamental tool to guarantee respect for the rights of all. Pharmacy education should encompass values such as peace, tolerance and respect for human dignity. Inculcating human rights education and awareness during pharmacy education is the only guarantee of demonstrating our commitment to human dignity, promotion of an

adequate standard of life to everyone and finally for the promotion of world peace and prosperity for all. The main reason for occurrence of incidents of exploitations internationally and nationally is the lack of awareness among groups in society about their basic human rights.

The Public Sector Equality and Human Rights Duty ('the Duty') is a statutory obligation for public bodies in Section 42 of the Irish Human Rights and Equality Commission Act 2014. Section 42(1) requires public bodies, in the performance of their functions, to have regard to the need to eliminate discrimination, promote equality and protect human rights of staff and people availing of their services. Section 42(2) requires public bodies to assess, address and report on progress in relation to equality and human rights in their strategic plan and annual reports in a manner that is accessible to the public.

Public bodies in Ireland are required to comply with the Public Sector Human Rights and Equality Duty ('the Duty'). The definition of a public body for the purposes of the Duty includes: a university or institute of technology.

Equality rights arise under the Constitution and international law, and many of the State's equality and anti-discrimination protections are derived from EU law including the EU Charter on Fundamental Rights and the EU Equality Directives which underpin Ireland's equality legislation. Ireland's principal equality legislation is set out in the Employment Equality Acts 1998-2015 and the Equal Status Acts 2000-2015.

Pharmacy students have the human right to freedom of conscience, religion and belief. This should be part of all Codes of Conduct for pharmacy students. All student Codes of Conduct should made reference to human rights and specifically to freedom of conscience, religion, thought/ belief. A human rights-based approach in education is about empowering people including pharmacy students to know and claim their rights and increasing the ability and accountability of individuals and institutions who are responsible for respecting, protecting and fulfilling rights.

In December 2011, the UN General Assembly adopted the United Nations Declaration on Human Rights Education and Training (HRET). This Declaration asserts that everyone has the right to know, seek and receive information about their human rights and fundamental freedoms. The Declaration reaffirms that everyone has a right to education and that States are "duty-bound" through the Universal Declaration on Human Rights (UDHR) and other human rights instruments to ensure that "education is aimed at strengthening respect for human rights and fundamental freedoms." The World Conference on Human Rights, held in Vienna in 1993, called on Governments to include in the curriculum "of all learning institutions" human rights and humanitarian law.

Unfortunately, there would appear to be a widespread lack of recognition in Ireland of the human right to freedom of conscience, religion and thought and its application to pharmacists and pharmacy. Pharmacists and pharmacy students are excluded from the conscientious objection section in the Health(Regulation of Termination of Pregnancy)Act 2019. Doctors and nurses are included in the conscientious objection section of the Act. This is a grave matter and is of concern to many registered pharmacists and pharmacy students. This will impact on the career prospects and choice of many pharmacy students.

Education for human rights during the education of pharmacists is of great importance. All human beings (including pharmacists and pharmacy students) are equal in dignity.

Human rights are held by all persons/pharmacists/pharmacy students equally, universally and for ever.
Human rights are universal, that is, they are the same for all human beings in every country.
They are inalienable, indivisible and interdependent, that is, they cannot be taken away – ever;
all rights are equally important and they are complementary.

Background:

United Nations Declaration on Human Rights Education and Training (2011)
(Adopted by the General Assembly, Resolution 66/137, A/RES/66/137, 19 December 2011)

Article 1: (1) Everyone has the right to know, seek and receive information about all human rights and fundamental freedoms

and should have access to human rights education and training.

Article 2: (1) Human rights education and training comprises all educational, training, information, awareness-raising and learning

activities aimed at promoting universal respect for and observance of all human rights and fundamental freedoms

and thus contributing, inter alia, to the prevention of human rights violations and abuses by providing persons with

knowledge, skills and understanding and developing their attitudes and behaviours, to empower them to contribute

to the building and promotion of a universal culture of human rights.

Article 4: Human rights education and training should be based on the principles of the Universal Declaration of Human Rights

and relevant treaties and instruments, with a view to:

- (a) Raising awareness, understanding and acceptance of universal human rights standards and principles, as well as guarantees at the international, regional and national levels for the protection of human rights and fundamental freedoms;
- (b) Developing a universal culture of human rights, in which everyone is aware of their own rights and responsibilities in respect of the rights of others, and promoting the development of the individual as a responsible member of a free, peaceful, pluralist and inclusive society.

Article 5: (3) Human rights education and training should embrace and enrich, as well as draw inspiration from, the diversity of

civilizations, religions, cultures and traditions of different countries, as it is reflected in the universality of human rights.

[www.ohchr.org/EN/Issues/Education/Training/Compilation/Pages/UnitedNationsDeclarationonHumanRightsEducationandTraining\(2011\).aspx](http://www.ohchr.org/EN/Issues/Education/Training/Compilation/Pages/UnitedNationsDeclarationonHumanRightsEducationandTraining(2011).aspx)

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From: [REDACTED]
Sent: 22 July 2019 09:53
To: Education
Subject: FW: Daily summary of updates for Members forum from [REDACTED]

Thank-you for allowing us to comment on draft standards for the 5-year integrated programme.

Two important themes included in the standards are

- Patient centred care and
- Learning relationship management with other healthcare professionals.

I feel there could be more scope to develop the role of teacher-practitioners to educate Pharmacy students that would be undertaken both on campus and off-site and would allow greater exposure and therefore experiential learning for the students for what a day-to-day role for their profession entails.

Regards

[REDACTED]

From: [REDACTED]
Sent: 08 July 2019 00:21
To: [REDACTED]
Subject: Daily summary of updates for Members forum from [REDACTED]



Forum [Members forum](#) at [REDACTED]
Updates for 7 Jul 2019

[PSI Public Consultations](#), 1 post(s), [REDACTED], 7 Jul 2019 10:38 AM;

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From: [REDACTED]
Sent: 30 July 2019 21:51
To: Education
Subject: Draft Accreditation Standards Feedback

Dear Education Unit,

The following are the feedback points the [REDACTED] have in relation to the draft accreditation standards for the five-year masters degree programmes in pharmacy.

1. Standard 1: Strategy

- a. Point four mentions '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' are course providers engaging with students for feedback on the new course as it rolls out, and are they taking such feedback on board? It is crucial that course providers engage with students to ensure that the course is delivered with the best interests of students.
- b. Students should be given guidance by the School of Pharmacy in order to carry out each module in the new programme to the best of their ability.

2. Conflict to equality, diversity and fairness

- a. Standard 2: Leadership, Organisation and Governance cannot be based on these values when there is not equal access to education in the Integrated Pharmacy Program with the masters fee, which is not covered by the free fees initiative. This fee does not enable those from all backgrounds to access the training and qualifications needed to become a registered pharmacist in Ireland, refusing a diverse range of students entering the program.
- b. Standard 7: Students; it is impossible for open, fair and non-discriminatory admission and progression through the Professional Degree Programme while there is a full masters fee in place for the fifth year of the programme, which is not covered by the state funding SUSI grant. The current program discriminates based on the wealth of the student or their family.
- c. Standard 3: Resources. Practice educators should provide a link with educators in all three Pharmacy Schools to provide standardised marking and feedback for the placement modules.

3. PSI's ability to respond to the reporting of issues faced by the HEI's and students

- a. Standard 2: Leadership, Organisation and Governance states annual reports to the PSI from the Schools detail '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'. It was reported that there was not enough resources to deliver the Integrated Pharmacy Program without HEA funding, and that the burden will fall on students, which would lead to inequality and diversity issues for

students. The Statutory Instrument for the new program was put forward to the Minister of Health despite these issues being raised. How will the PSI deal with reports of similar issues and to ensure that these issues are addressed?

b. Communication is needed between the PSI, Minister for Health and HEA to address the reported issues of funding and student wellbeing.

c. Standard 2: Point 5 mentions that '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.' The current structure may meet the requirements of National and European law. However, it is not being delivered in a way that the diverse needs of students are met. The current model, as we are aware, is resulting in significant financial burden to students. While there are many contributing factors to this, the two main issues are the masters fee not being covered by HEAI/SUSI and also that several placement providers are no longer offering paid.

4. Student Welfare

a. Standard 7: Students; Student Supports 'provision of support for personal, academic, general welfare..' is at conflict given the impact of the extortionate masters fee, which was demonstrated during this year's Pharmacy Student Campaign. Issues such as mental health and financial strain was raised in response to unpaid placements and the fifth year fee. The HEI's do not have control over whether this fee is covered by the HEA. If this point is to remain in the PSI's accreditation standards, the PSI must consult with HEA to ensure funding of the fifth year fee.

5. Changes to practice-placement elements which may be approved by the PSI Council require pharmacy student input and feedback. (Standard 3: Resources, Standard 4 Curriculum: Structure and Evaluation)

6. Responsibilities put on HEIs, which the HEIs have little control over

a. As mentioned fifth year being covered by either SUSI grants or the free fees initiative, this is a decision made by the HEA, not the HEIs. The HEA then must be consulted with regarding this as this is a major factor in relation to resourcing, funding, student impact, student welfare etc.

b. Standard 4 Curriculum: Structure and Evaluation includes '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.' However, external issues such as industrial relation disagreements between hospital pharmacists and the HSE in relation to hospital pharmacist career structure is another example of an element in the accreditation standards which is out of the control of the HEI. PSI should discuss this impact on training future pharmacists to the Department of Health, with respect to future patient safety. This requires the involvement of PSI, IPU, HPAI and PIER to ensure students get to experience all aspects of the pharmacy profession

7. GDPR

a. Standard 2: Leadership, Organisation and Governance '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 'Is this in accordance with GDPR?

8. Infrastructure and Financial Resources.

a. Standard 3: Resources. Point 6 a) acknowledges that the Schools must have the financial resources necessary for delivery of its strategic objectives. Financial Resources of students also needs to be looked at. The current charge of a Masters fee on students is not acceptable 'move to five-year fee charging could decrease the attractiveness of pharmacy as a subject of study and impact upon recruitment' PEARs Report 2010.

All the best,

■

Email Response 4

██████████
The Pharmaceutical Society of Ireland
PSI House
15-19 Fenian Street
Dublin 2
D02 TD72

July 30th 2019

Dear ██████████,



Thank you for the further invitation to engage with the PSI's public consultation on the draft accreditation standards for the MPharm programme.

██████████ have already given detailed feedback when they met with ██████████. ██████████ on 30th May last. I am pleased to note that this has been acknowledged and reflected to a considerable extent in the latest draft currently in circulation for public consultation until 31st July next. We do however have some additional observations.

In relation to Standard 4.8, it is noted that the concerns of ██████████ in relation to the continued obligation to provide hospital placements has been noted and that it has been decided to leave the draft wording of this Standard unchanged for the current public consultation process. ██████████ has further reflected on this draft standard and wish to clarify that its concerns in this matter do not exclusively concern the provision of hospital placements *per se*. The availability of practice-placements in the various practice settings (community, hospital and industry) is entirely outside the control of the three Schools who are completely reliant on the goodwill of personnel in individual practice settings to offer practice placements in any given academic year to their students. While the Schools in conjunction with APPEL work assiduously to provide as large a range of placement opportunities as possible across all three practice settings to fulfil student demand on an ongoing basis, it must be acknowledged that APPEL and the Schools cannot commit to offering sufficient placements across all three practice settings year-on-year. As currently drafted, and in particular its use of the word "*must*", Standard 4.8 could be reasonably interpreted as mandating Schools to provide its students with the opportunity to complete placements in all of the three practice settings specified year-on-year. In the absence of any means for Schools to proactively incentivise practice settings to offer placements, the apparent obligation that this standard seeks to impose is, in the view of ██████████, not tenable.

Accordingly, ██████████ proposes that Standard 4.8 be amended to read as follows:

"There *should be, subject to availability, be a continuum* 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 the achievement of the CCF competencies.....".



The introduction of the integrated MPharm programme and the attending placement requirements have introduced significant on-going financial outlay for the three Schools of Pharmacy that must be met from their already constrained financial resources. Draft Standard 3.6 requires that the Schools must have the financial resources necessary for the delivery of their strategic objectives. While [REDACTED] is fully committed to providing its students with as complete and varied practice placement opportunities as possible, there are both resource and availability imperatives that RCSI are of the view need to be acknowledged and provided for in the PSI's accreditation standards.

I am happy to discuss further if that would be of assistance.

Yours sincerely,



DRAFT ACCREDITATION STANDARDS

FOR THE FIVE-YEAR INTEGRATED
MASTERS DEGREE PROGRAMMES IN
PHARMACY

June 2019

Approved for Consultation by PSI Council
on 20 June 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;
- (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 centeredness 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.

Commented [JW1]: S.I. No. 377/2014 uses terminology 'Higher Education Institution' (as do some of the standards below).

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 **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.

Commented [JW2]: As above

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.

Commented [JW3]: Suggest adding 'insofar as possible' or 'insofar as practical' since this clearly cannot be accomplished absolutely.

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 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. 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

Commented [JW4]: As before, this is impossible. Suggest 'insofar as possible/practical'.

Commented [JW5]: This does not match the statutory declaration in SI 377 of 2014, which states: *Certification by Head of School*
20. No Masters degree in pharmacy shall be awarded to any person by a recognised institution, for the purpose of being recognised under these rules as a qualification appropriate for practice, unless the head or acting head of the school of pharmacy in the said institution has confirmed—
(a) the satisfactory demonstration of the competencies by the person as set out in the Core Competency Framework for Pharmacists,
(b) that he or she has not become aware of any health problems that may compromise, in his or her belief, the ability by the person concerned to discharge properly the duties and responsibilities of a registered pharmacist, and
(c) his or her overall satisfaction that the person concerned is fit to be a registered pharmacist.
A balance needs to be struck between multiple factors, including:
- what a Head of School may reasonably be expected to know,
- the importance of students feeling free to present with and seek treatment for health problems, and
- the desirability of having an overall evaluation of a graduate's suitability to apply for registration.
The version in these draft standards strikes a better balance in this regard, but presumably will require legislative change if it is to prevail.

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

Commented [JW6]: Suggest 'any reasonably foreseeable deficiencies'.

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 services.
- 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 be guided by, but not limited to, the indicative syllabus shown in Appendix A of this document¹ and it should take account of, and be responsive to, developments in pharmaceutical science and services and in pharmacy practice.
- 4) 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.
- 5) 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-focussed 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.
- 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.
- 7) 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.

Commented [JW7]: Suggest 'services' is limited in perspective and could be replaced by 'practice'.

Commented [JW8]: Likely to lead to repetition in accreditation documentation. Suggest merging with (1) above to facilitate more streamlined documentation.

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

- 8) 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.
- 9) 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.
- 10) 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 practise.

The regulations must be supported:

- a) by fitness to practise 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
- 11) 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.

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 5 CURRICULUM: TEACHING, LEARNING AND ASSESSMENT

The curriculum must **include** 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.

Commented [JW9]: Strategies are not part of the curriculum. Suggest 'guided by' or similar. Alternatively, "The curriculum documentation must include..."

- 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
- 2) 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
- 3) 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 Miller⁴.

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.

Commented [JW10]: Evidence-base (hyphen rather than dash)

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.

Commented [JW11]: practise

- i. 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.
- ii. The duty of care to the patient and the wider public: concept, scope and application of healthcare ethics.
- iii. 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.
- iv. Principles of organisation in the workplace, including procedures and policies, resources requirements, management roles and structures within pharmacy settings.
- v. Oversight and development of those working in the pharmacy team.
- vi. Communication skills relating to multidisciplinary working and getting the best outcome from medicines for patients.
- vii. The obligations of pharmacists as professionals requiring registration in order to practice including their compliance with statutory codes of conduct.
- viii. 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.
- ix. Evidence-based policy and practice: use of evidence-based knowledge to develop policy and translate into practice.
- x. Use of information technology in pharmacy and more widely in health care.
- xi. Medicines safety – reporting of errors/critical incidents and systems-based risk minimisation (including root cause analysis).

Commented [JW12]: practise

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.

Commented [JW13]: fit... operate

- i. The political and legal framework, requirements and processes relevant to pharmacy in Ireland and within the EU.
- ii. The role of public health, health promotion, and health economics, particularly pharmaco-economics.
- iii. Scientific, clinical, health services and social services research relevant to pharmacy, translation of evidence into policy and practice.
- iv. 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.

- i. Molecular basis of drug action and the actions of drugs within living systems; molecular, cellular, pharmacogenomics, biological and physical aspects.
- ii. Clinical therapeutic uses of drugs and medicines in people 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, age 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, 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.

- i. Sale, supply, administration and monitoring of medicines,
- ii. Medicines: schedules of medicines and controlled substances; consumer protection, including product liability and professional negligence.
- 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 standardisation of medicines for administration 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 labelling: 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.

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 2001/83/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

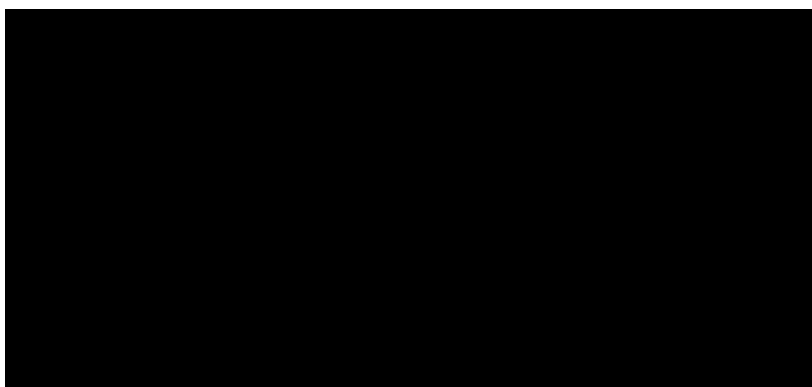
European Communities (Recognition of Professional Qualifications Relating to the Profession of Pharmacist) (No. 2) Regulations 2008, S.I. NO. 489 of 2008

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’

Pharmaceutical Society of Ireland (Education and Training) Rules 2008 (S.I. No. 493 of 2008)

Commented [JW14]: Consider also the corresponding requirements for QP in veterinary context: Art. 53 of Dir2001/82/EC.

Commented [JW15]: S.I. No. 377/2014 - Pharmaceutical Society of Ireland (Education and Training) (Integrated Course) Rules 2014



**Written Submission to PSI Draft Accreditation Standards for
Five-Year Integrated Masters Degree Programme**

July 2019

[Redacted]

[Redacted]) [Redacted]
[Redacted] Founded in 1959, [Redacted]
now represents more than 374,000 students in over thirty colleges across the island
of Ireland. The goal of [Redacted] is to work for the rights of students and a fair and equal
third-level education system in Ireland.

[Redacted] is a full member of the [Redacted] which represents
students from 46 National Students' Unions in 39 countries.

[Redacted] Response to the PSI Draft Accreditation Standards for Five-Year Integrated
Masters Degree Programme

[Redacted] welcomes the opportunity to respond to the
draft accreditation standards for the five-year integrated Masters Degree Programme
in Pharmacy. [Redacted] has worked for many years on issues of quality and enhancement
of education, primarily at third-level, and welcomes efforts to include student
representation in the work carried out on quality assurance and accreditation by
professional bodies.

[Redacted] has worked closely with the Irish Pharmaceutical Students' Association (IPSA)
over the last number of years, on issues relating to the experience of pharmacy
students and last year, they jointly launched the Pharmacy Students' Campaign
which led to the lifting of the ban on payment for 4th and 5th year students
undertaking placement. We continue to work with IPSA in raising awareness of the
negative impact of the fifth year Masters' Fee on the progression and wellbeing of
Pharmacy Students, and calling for it to be covered under the SUSI grant or the

'Free Fees' initiative. To this end, ■■■ has worked closely with IPSA in developing this response.

Standard 2: Leadership, Organisation and Governance:

- ■■■ is concerned about the ability to fulfil section five on promoting 'the principles of equality, diversity and fairness' given that equal access is not currently afforded on this integrated masters' programme due to the masters fee, which is not covered by the free fees initiative. This fee does not enable those from all backgrounds to access the training and qualifications needed to become a registered pharmacist, meaning that students from a diverse range of backgrounds are restricted from entering the program.
- Section 6 states that the School must submit data on ... any equality and diversity issues which could have an impact on students.' At the point of establishing the Integrated Masters programme, it was stated that there were not adequate resources to run the programme without HEA funding, and that the burden must fall on students. This has, and will continue to lead to a range of equality and diversity issues, with many students being unable to continue on the course due to the fee barrier. We would be interested to understand how the PSI proposes to respond to issues of this nature that are reported.

Standard 4: Curriculum, Structure and Evaluation:

- Section 8 states that '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.' Whilst we agree with the principle of this section, it must be noted that external factors that may influence this such as industrial disputes between hospital pharmacists and the HSE are not within the control of the PSI, or the Schools running the degree programmes. PSI should discuss scenarios such as this with the Department of Health, with regard to its' impact on the training of future pharmacists, and future patient safety,

Standard 7: Students

- ■■■ does not believe that it is possible to ensure fair, open and non-discriminatory admission procedures and progression whilst there is a full Masters fee in place for the fifth year of the programme, which is not eligible for the state funded SUSI grant. The current programme discriminates on the basis of the wealth of the student or their family.

- Section 2 speaks of the importance of ‘provision of support for personal, academic, general welfare.’ ■■■ does not believe that this standard is currently being met, given the impact of the extortionate masters fee on the experience of students on the programme. Issues such as mental health, and financial strain were previously raised by ■■■ and IPISA earlier this year, when launching the Pharmacy Students’ Campaign. These issues were partially addressed through the lifting of the placement payment ban, but continue to be neglected through the imposition of the extortionate masters fee. HEIs do not have control over whether this fee is covered by the HEA. PSI must engage with the HEA to ensure the funding of the fifth year of the programme, if it wishes to deliver successfully upon this section,

Concluding Statements

■■■ would welcome the opportunity to meet with PSI, the Department, and the HEA alongside IPISA to discuss the issues previously outlined in relation to the masters fee and its subsequent impact on student wellbeing.

■■■ notes with disappointment the fact that the Irish Pharmaceutical Students’ Association did not receive an invitation to participate in this consultation, and would encourage PSI to make itself available for more regular communication with IPISA, as the leading representative body for pharmacy students in Ireland, and ■■■, as the leading representative body for students in Ireland.



AN RIALTÓIR CÓGAIŚÍOCHTA
THE PHARMACY REGULATOR

DRAFT ACCREDITATION STANDARDS

FOR THE FIVE-YEAR INTEGRATED
MASTERS DEGREE PROGRAMMES IN
PHARMACY

June 2019

Approved for Consultation by PSI Council
on 20 June 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;
- (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 centeredness 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. 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 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.

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 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. 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 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 services.
- 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 be guided by, but not limited to, the indicative syllabus shown in Appendix A of this document¹ and it should take account of, and be responsive to, developments in pharmaceutical science and services and in pharmacy practice.
- 4) 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.
- 5) 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-focussed 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.
- 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.
- 7) 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.

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

- 8) 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.
- 9) 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.
- 10) 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 practise.

The regulations must be supported:

- a) by fitness to practise 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
- 11) 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.

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 5 CURRICULUM: TEACHING, LEARNING AND ASSESSMENT

The curriculum must include 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
- 2) 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
- 3) 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 Miller⁴.

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



Five-Year Integrated Masters Degree Programme Proposed Revised Accreditation Standards 2019

Introduction

One of the principal functions of the Pharmaceutical Society of Ireland (PSI) is to, 'promote and ensure a high standard of education and training for persons seeking to become pharmacists' (Section 7 of the Pharmacy Act 2007).

Rule 7 of The Pharmaceutical Society of Ireland (Education and Training) (Integrated Course) Rules 2014, as amended, sets out the criteria for recognition and approval of the five year integrated programme of education and training leading to award of Master's degree in pharmacy. Under Rule 7(3), the Council of the PSI is obliged to review the Accreditation Standards for the programmes of education (MPharm) at intervals not exceeding five years.

Accreditation Standards for the five-year Master's degree programme in pharmacy were first approved by the Council of the PSI on 2 October 2014, with the first year of the programme commencing in September 2015.

The five-year Mpharm programmes are currently in the fourth year and the PSI is in the process of reviewing the accreditation standards which underpin these programmes. Following stakeholder engagement and expert advice, the following draft accreditation standards have been proposed. It is hoped that the proposed standards will be robust and comprehensive and still permit education providers flexibility in demonstrating their continuous compliance with the accreditation standards while ensuring the quality of the programmes and competence of the graduates. A guidance document will be provided to each school of pharmacy, with regard to what types of evidence can be used to demonstrate compliance with the accreditation standards.

A copy of the proposed new standards are here. We invite your feedback at this time and would be grateful if you would complete the following survey. Responses can also be submitted to education@psi.ie

This consultation process will close on the 31st July at 5pm.

Five-Year Integrated Masters Degree Programme Proposed Revised Accreditation Standards 2019

Data Protection and Freedom of Information

This survey is voluntary. By completing it you are agreeing to allow your responses to be processed and analysed by the PSI for the purpose of seeking feedback on the proposed new PSI (Registration) Rules 2018. A consultation report will be compiled and this report, will be published on the PSI website in due course. The information you provide to this survey will be stored in a secure and confidential manner by the PSI, it will only be used for the purposes outlined above and it will be deleted in line with the PSI's record retention policy. The PSI uses SurveyMonkey to gather feedback to our public consultations. Full details of how your information is processed via SurveyMonkey is documented in this [privacy policy](#). Submissions made to public consultations carried out by the PSI are subject to the provisions of the Freedom of Information Act 2014.

* 1. Do you agree to the terms above? By selecting 'Yes' you are confirming you consent to providing your answers to the questions in this survey

☐ Yes

☐ No

Five-Year Integrated Masters Degree Programme Proposed Revised Accreditation Standards 2019

Demographics

2. Which category best describes you?

- | | |
|---|--|
| <input type="checkbox"/> Registered Pharmacist | <input type="checkbox"/> Representing public/patient interests |
| <input type="checkbox"/> Pharmacy Student | <input type="checkbox"/> Employer of healthcare professionals |
| <input type="checkbox"/> Patient and/or Member of the Public | <input type="checkbox"/> Government body or department |
| <input type="checkbox"/> Pharmacy Owner | <input type="checkbox"/> Regulator |
| <input type="checkbox"/> Member of a pharmacy team (non-pharmacist) | <input type="checkbox"/> Industry |
| <input type="checkbox"/> Involved in healthcare education or training | <input type="checkbox"/> Instructor or Professor in higher education |
| <input type="checkbox"/> Other (please specify) | |

3. Are you responding on your own behalf or the behalf of an organisation?

- ☐ Own behalf
- ☐ On behalf of an organisation



Five-Year Integrated Masters Degree Programme Proposed Revised Accreditation Standards 2019

Standard 1: Strategy

4. The purpose of this Standard is to assure that the appropriate strategic planning is in place to deliver a high quality pharmacy training programme.

Do you agree that this is achieved by the proposed Standard 1?

- | | |
|--|---|
| <input type="radio"/> Strongly agree | <input type="radio"/> Disagree |
| <input type="radio"/> Agree | <input type="radio"/> Strongly disagree |
| <input type="radio"/> Neither agree nor disagree | |

Five-Year Integrated Masters Degree Programme Proposed Revised Accreditation Standards 2019

Standard 2: Leadership, Organisation, and Governance

5. The purpose of this Standard is to assure that appropriate governance, organisation, and leadership structures are in place to deliver a high quality pharmacy training programme.

Do you agree that this is achieved by the proposed Standard 2?

- | | |
|--|---|
| <input type="radio"/> Strongly agree | <input type="radio"/> Disagree |
| <input type="radio"/> Agree | <input type="radio"/> Strongly disagree |
| <input type="radio"/> Neither agree nor disagree | |

Five-Year Integrated Masters Degree Programme Proposed Revised Accreditation Standards 2019

Standard 3: Resources

6. The purpose of this Standard is to assure appropriate quality of resources and personnel to deliver a high quality pharmacy training programme.

Do you agree that this is achieved by the proposed Standard 3?

- | | |
|--|---|
| <input type="radio"/> Strongly agree | <input type="radio"/> Disagree |
| <input type="radio"/> Agree | <input type="radio"/> Strongly disagree |
| <input type="radio"/> Neither agree nor disagree | |

Five-Year Integrated Masters Degree Programme Proposed Revised Accreditation Standards 2019

Standard 4: Curriculum - Structure and Evaluation

7. The purpose of this Standard is to assure the quality of the curriculum for the pharmacy training programme. This includes that the curriculum is delivered in an integrated way, meets all legal requirements, including that graduates are equipped with the knowledge, skills, attitudes, and behaviours to meet the Core Competency Framework for Pharmacists, and that the curriculum is subject to regular review, monitoring, and evaluation.

Do you agree that this is achieved by the proposed Standard 4?

- | | |
|--|---|
| <input type="radio"/> Strongly agree | <input type="radio"/> Disagree |
| <input type="radio"/> Agree | <input type="radio"/> Strongly disagree |
| <input type="radio"/> Neither agree nor disagree | |

Five-Year Integrated Masters Degree Programme Proposed Revised Accreditation Standards 2019

Standard 5: Curriculum - Teaching, Learning, & Assessment

8. The purpose of this Standard is to quality assure the Teaching, Learning, and Assessment Strategy for the pharmacy training programme.

Do you agree that this is achieved by the proposed Standard 5?

- | | |
|--|---|
| <input type="radio"/> Strongly agree | <input type="radio"/> Disagree |
| <input type="radio"/> Agree | <input type="radio"/> Strongly disagree |
| <input type="radio"/> Neither agree nor disagree | |

Five-Year Integrated Masters Degree Programme Proposed Revised Accreditation Standards 2019

Standard 6: Quality Assurance & Enhancement

9. The purpose of this Standard is to assure that a demonstrable and continuous quality assurance and enhancement programme is in place for all aspects of the pharmacy training programme.

Do you agree that this is achieved by the proposed Standard 6?

- | | |
|--|---|
| <input type="radio"/> Strongly agree | <input type="radio"/> Disagree |
| <input type="radio"/> Agree | <input type="radio"/> Strongly disagree |
| <input type="radio"/> Neither agree nor disagree | |

Five-Year Integrated Masters Degree Programme Proposed Revised Accreditation Standards 2019

Standard 7: Students

10. The purpose of this Standard is to assure quality support and guidance processes are in place for students and prospective students undertaking the pharmacy training programme.

Do you agree that this is achieved by the proposed Standard 7?

- | | |
|--|---|
| <input type="radio"/> Strongly agree | <input type="radio"/> Disagree |
| <input type="radio"/> Agree | <input type="radio"/> Strongly disagree |
| <input type="radio"/> Neither agree nor disagree | |

Five-Year Integrated Masters Degree Programme Proposed Revised Accreditation Standards 2019

Appendix A: Indicative Syllabus

11. Do you agree that Appendix A: Indicative Syllabus complements the Core Competency Framework for Pharmacists and provides sufficient non-prescriptive guidance to the Pharmacy Programme Provider to design and implement a patient-centred syllabus?

- | | |
|--|---|
| <input type="radio"/> Strongly agree | <input type="radio"/> Disagree |
| <input type="radio"/> Agree | <input type="radio"/> Strongly disagree |
| <input type="radio"/> Neither agree nor disagree | |

Five-Year Integrated Masters Degree Programme Proposed Revised Accreditation Standards 2019

12. Would you agree the draft standards are fit for purpose and capture all the elements necessary to support the development of a contemporary and quality pharmacy degree programme?

- | | |
|--|---|
| <input type="radio"/> Strongly agree | <input type="radio"/> Disagree |
| <input type="radio"/> Agree | <input type="radio"/> Strongly disagree |
| <input type="radio"/> Neither agree nor disagree | |

13. Do you agree the proposed standards are easy to read and understand?

- | | |
|--|---|
| <input type="radio"/> Strongly agree | <input type="radio"/> Disagree |
| <input type="radio"/> Agree | <input type="radio"/> Strongly disagree |
| <input type="radio"/> Neither agree nor disagree | |

14. What additional areas, if any, do you believe should **be included** or emphasised in the standards?

--

15. Are there any requirements which should **be removed** or are overly demanding?

--