

**Comments received during public consultation on
PSI DRAFT INTERIM ACCREDITATION STANDARDS**

(For the level 8 Bachelor degree awarded on the successful completion of the 4 year undergraduate pharmacy degree programme)

Submission number	Name of organisation or individual
1.	Donal Healy, MPSI
2.	Ciarán Meegan, MPSI, Mater Misericordiae University Hospital (MMUH)
3.	School of Pharmacy & Pharmaceutical Sciences, Trinity College Dublin
4.	Dr. Tamasine Grimes, MPSI
5.	Pharmaceutical Society of Northern Ireland (PSNI)
6.	Hospital Pharmacists Association of Ireland (HPAI)
7.	School of Pharmacy, University College Cork (UCC)
8.	Department of Health
9.	Irish Medicines Board
10.	An Bord Altranais

**Acknowledgement of receipt of public consultation document on
PSI DRAFT INTERIM ACCREDITATION STANDARDS**

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	Name of organisation or individual
1.	Irish Pharmacy Union
2.	Health Information and Quality Authority (HIQA)
3.	Higher Education Authority
4.	Mental Health Commission
5.	Bord Na Radharcmhastóirí

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1. Donal Healy, MPSI		
	<p>My only comment is a reminder that there is a minority of pharmacists who work in the pharmaceutical industry and that while the course contents need to cater for the majority who work in a community / hospital environment, if industry is to remain as a career option for pharmacists, we need to ensure that sufficient industrial content remains on the course to prepare them for this. Staying current with GXP and industrial developments can be a challenge but worthwhile nevertheless for the course. Pharmacists currently do hold significant roles in industry but as many QPs now come from a variety of disciplines, if the industrial option is to remain open to new graduates, this must be reflected in the undergraduate course content.</p>	<p>Noted. The interim accreditation standards are intended to address the preparation of future pharmacists for practice, irrespective of their practice setting. The educational content required to meet the specific needs of pharmacists acting in a QP role in industry is a requirement of Directive 2001/83/EC which has been transposed into the Pharmacy Act 2007 (see Appendix B of the draft interim accreditation standards). The need to ensure content is delivered relating to approaches to quality assurance is specifically identified in Appendix A, in section I. a. (viii) regarding The Practice of Pharmacy and also in sections II and III dealing with The Sources, Isolation, Characterisation, Analysis and Properties of Human and Veterinary Medicines, and The Design and Manufacture of Human and Veterinary Medicines: Materials, Methods and Quality Standards respectively.</p>
2. Ciarán Meegan, MPSI (MMUH)		
	<p>1 There is no direct reference in the document to the requirement of teaching by Practice Based Teacher Practitioners. The engagement of practice based teachers is the only method to ensure that pharmacists will be taught clinically relevant and</p>	<p>Noted. This is a critical point and one which will be addressed comprehensively in the accreditation standards that the PSI will now develop for the implementation of the five-year fully integrated MPharm pharmacist qualification. The current draft</p>

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	<p>contemporary issues regarding evolving drug treatments as well as comparative attitudes to drug and dose selection as well technological advances to patient treatments and treatment escalations.</p> <p>There is little direct reference to the importance of the clinical skills that are required by a pharmacist to critically review patient pharmacotherapies and to suggest dose or drug selection alternatives given co-morbidities etc These issues should be developed in Section 4 - Curriculum and Section 5 Teaching & Learning Strategy and Section 8 Resources</p> <p>2 Reference is made in Section 1 Pharmacy School and Mission to Key Performance Indicators but not what their purpose would be for the School. Additionally there is no reference to the development by the PSI of Key Performance Indicators to audit adherence by the individual Schools to the accreditation standards</p> <p>3 The moral and ethical considerations regarding the capability and capacity of students to transition to a safe and informed practitioner is</p>	<p>interim accreditation standards for the 4-year Bachelor degree programmes are for an interim period of no more than five years and it was not considered prudent to significantly amend the existing programme provision in light of the significant programme changes which the Schools of Pharmacy will be required to introduce with effect from 2013 when the fully integrated degree is due to be rolled out. The need for practice exposure is nevertheless made reference to in standards 4.6 and 8.1.</p> <p>Noted. Reference to clinical skills has been included in Standard 5.1(c).</p> <p>See notes above regarding the development of accreditation standards for the 5-year fully integrated MPharm programme.</p> <p>Noted. Standard 1, section 1.2 has been amended to read as follows: 'The School should have a published statement of its mission and goals and set out its key performance indicators (KPIs) and timescale for their implementation and review. This should include an explanation of how the School will monitor and evaluate its performance against these objectives.'</p> <p>With regard to the PSI's auditing of adherence to the standards, the PSI is developing a separate accreditation process document to accompany the standards that identifies the evidence to be produced by each school of pharmacy to support how it meets each standard.</p> <p>As above, the current draft interim accreditation standards for the Bachelor degree programmes are for an interim period of</p>

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	<p>referred to but in very broad brush strokes i.e. Section 2.2 (d) More specificity as to how they would “pose a risk to patients and the public” or by absence i.e. Section 6 does not stipulate criteria for refusal for entry to NPIP or suggest barriers to progression to underperforming or inappropriate individuals studying Pharmacy. These issue could be dealt with by a 3 strikes and you’re out or criminal prosecution and you’re out approaches. Similarly Section 7.1 could make reference to Criminal Investigation and prosecution with regard to particular offences.</p> <p>With regard to Appendix A there should be reference to the evolution of Medication Safety principles as evidenced internationally through organisations such and the NPSA, ISMP and locally by the Irish Medication Safety Network.</p>	<p>no more than five years and these matters will be addressed more comprehensively in the accreditation standards that the PSI will now develop for the implementation of the five-year fully integrated MPharm pharmacist qualification. In the interim, there is sufficient scope within the interim standards to allow for PSI Council to develop policy in this regard [see Standard 7, section 7.1 (b)]. Criteria for refusal for entry to the NPIP are set out in the PSI (Education and Training) Rules 2008 and therefore patient safety and public protection is assured through these legislative provisions. Garda vetting (standard 7) and fitness to practise mechanisms for student pharmacists (standard 9) are requirements for the interim Bachelor degree programme.</p> <p>Accepted in principle and included for the time being as part of clinical pharmacy practice.</p>
3. School of Pharmacy & Pharmaceutical Sciences, Trinity College Dublin		
	<p>Introduction On the first page of the document, one of the requirements for the pharmacy degree programme is stated as:</p> <p>‘1. The purpose of undergraduate pharmacy education (the pharmacy degree programme) is to produce pharmacy undergraduates who have the knowledge, skills and attributes to safely participate in the National Pharmacy Internship Programme (NPIP). Graduates should be prepared for patient-centred pharmacy practice and their learning should be based upon and underpinned by appropriate and sufficient understanding of the principles and techniques of the pharmaceutical</p>	<p>The Pharmacy Act 2007 sets out as a duty of the PSI the requirement to ‘... determine, approve and keep under review programmes of education and training suitable to enable persons applying for registration to meet those criteria...’. As the prescribed qualification currently encompasses the initial Bachelor degree followed by the in-service practical training programme and the Professional Registration Examination (the latter two comprising the National Pharmacy Internship Programme), the PSI’s interim accreditation standards for the Bachelor degree programme must be conceived in the context of the overall five-year programme of education and training to</p>

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	<p>sciences.'</p> <p>It could be interpreted from the way this requirement is phrased that the <u>sole</u> purpose of the pharmacy degree programme is to produce pharmacy graduates who have the knowledge, skills and attributes to safely participate in the National Pharmacy Internship Programme, when in fact we would regard this as only <u>one</u> purpose of the degree programme. We consider that we prepare our graduates for many other possible future opportunities in addition to participating in the National Pharmacy Internship Programme.</p> <p><u>Draft Standard 4</u> Paragraph 4.2 states that, ' the curriculum should be guided by but not limited to the indicative syllabus shown in Appendix A of this document.¹'</p> <p>In the footnote to this statement is stated that ' the indicative syllabus exists as a general guide to an appropriate scope of curriculum content for the undergraduate degree programme in pharmacy but is not</p>	<p>quality as a pharmacist and therefore, for the purposes of the PSI's duties under the Pharmacy Act 2007, the key purpose of the Bachelor degree programme in pharmacy is to enable the development of a safe and competent future pharmacist as they progress through the five years of education, training and assessment. It is accepted and understood that a university-level degree must and should encompass objectives that go beyond the requirements of an accrediting body.</p>

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	<p>intended to define a contemporary pharmacy programme. To ensure continuity with the existing programme provision and the smooth transition to the transitional standards, the indicative syllabus has not been subject to significant review. Minor changes have, however, been made to reflect changes in the law and in the terminology used in pharmacy health provision.'</p> <p>If the indicative syllabus only exists as a general guide, but is not intended to define a contemporary pharmacy programme, why present it at all? There are specific details within the indicative syllabus that we would have difficulty with for example:</p> <p>Section 1(c)v – We would consider the deletion of 'homeopathic medicines and other alternative therapies' and its replacement by 'homeopathic medicines and other such products' to be a retrograde step, since many alternative therapies – including some for which there is good quality evidence of their worth, such as acupuncture – are not product-based.</p>	<p>It was considered that it might be helpful to maintain the indicative syllabus for the purposes of the interim accreditation standards to ensure continuity from the previous inputs-based criteria for the accreditation of pharmacy degree programmes. The rationale for maintaining the indicative syllabus was to provide certainty to the higher education institutions during the interim phase that these draft interim accreditation standards will cover no more than five years. The indicative syllabus and its relationship with a contemporary pharmacy programme will be addressed comprehensively in the accreditation standards that the PSI will now develop for the implementation of the five-year fully integrated MPharm pharmacist qualification.</p> <p>Section 1c (v) refers to medicines control and therefore this was not considered appropriate in this section. 'Other such products' has been replaced by 'other alternative medicines'. Section IV – 'The actions and uses of Medicines' – was expanded to include 'other healthcare' products as this would be a more appropriate section to cover the actions and uses of alternative and complementary products as well as other</p>

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	<p>Section 1 (c)ix – Why remove the reference to ‘Drugs of Abuse and Chemical Dependence: Treatment of Drug Misusers and the Pharmaceutical Society of Ireland Policy on Drug Abuse; methadone treatment programme’?</p> <p>Paragraph 4.7 states, ‘The curriculum must take account of the recommendations of the Advisory Committee on Pharmaceutical Training (European Commission, 1995)’. These recommendations are given in Appendix B.</p> <p>Appendix B details Relevant Legislation, however, in this section reference to the European Commission’s Advisory Committee on Pharmaceutical Training (1995) Report and Recommendations on pharmaceutical education undergone at higher-education institutions (Ref. XV/E/8341/6/93-EN section 4 – ‘Recommendations on the organisation and structure of training at higher education institutions’ seems dated and in some cases overly restrictive, for example:</p> <p><i>‘At least half the higher education course identical for every student should consist of theoretical instruction, and at least 35% of that course should take the form of practical training.’</i></p> <p>Where does the figure of 35% come from? Should this figure be</p>	<p>healthcare products, such as medical devices. It should be emphasised that the indicative syllabus is to be used as a general guide and there are no accreditation constraints that would prevent teaching in relation to acupuncture, the example that has been cited.</p> <p>This point had been kept in section 1 (c) and the outdated reference to the PSI policy has been updated to the Guidance for Pharmacists on the Safe Supply of Methadone which was published by the PSI in December 2011. Reference to the methadone treatment protocol is retained.</p> <p>These EU-level guidelines are a statutory requirement in Ireland as referred to in the Schedule to the PSI (Education and Training) Rules 2008. These guidelines may be revised in 2012 when Directive 2005/36/EC on the Recognition of Professional Qualifications will undergo its first major revision. In the meantime, their status remains in force in Ireland until such time as the PSI (Education and Training) Rules 2008 are revised.</p> <p>See note above regarding the status of the 1995 report.</p>

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	<p>reconsidered/re-evaluated now, sixteen years after the recommendations were first made?</p> <p><i>'Each student should carry out a personally directed research project covering about three to six months under the supervision of the academic staff and present a paper or dissertation on the project.'</i></p> <p>The European Credit Transfer and Accumulation System (ECTS) which has been adopted by Irish Universities would seem a more appropriate system for defining required workload associated with various aspects of the course (i.e. rather than on a time basis). ECTS credits represent the student workload required to achieve the desired outcomes of modules and programmes. ECTS credits are assigned to course components/modules incorporating their associated assessment exercises and examinations, and also to other forms of structured student input, such as major projects, dissertations, practice elements, etc. where these do not form part of the assessment for a taught component which is itself assigned ECTS credits (Ref http://www.tcd.ie/vpcao/academic-development/ects.php). The standard/level of this research project is not very clear from the document, and therefore the ECTS that should be assigned.</p> <p><u>Draft Standard 5</u> Paragraph 5.3 states, <i>'The Teaching and Learning Strategy should ensure that pharmacy law, ethics, professionalism and pharmacy practice are taught predominantly by pharmacists with contemporary experience of practice, drawn preferably from within the School.'</i> We would consider that pharmacists practicing in academia have 'contemporary experience of practice' in an academic setting. It is our experience that academic pharmacists in the Practice of Pharmacy area are often best placed to keep up to date with changes in pharmacy law and with teaching of same. Equally, professionalism and pharmacy</p>	<p>Noted. Section 4.7 of Standard 4 sets out that a curriculum that is compliant with the ECTS meets the total hours requirement of these recommendations.</p> <p>The standard/level of the research project should be in line with the academic requirements for a level 8 degree programme as awarded by each higher education institution (HEI). It is not the purpose of these standards to be overly prescriptive in terms of the HEI's delivery of the Degree Programme.</p> <p>Noted. The need to balance the input of research and scholarly activities in conjunction with the input of 'contemporary experience of practice' is considered critical to ensure an ongoing iterative evolution and development of the profession of pharmacy in the interests of patient safety. Section 5.3 of Standard 5 is drafted to ensure the development of such an iterative engagement with practitioners. The students' educational experience must reflect current practice and point the way towards practice developments. The School will be required to demonstrate how its teaching staff retain up-to-</p>

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	changes that have been made to the curriculum, either as part of the Head of School's annual report or in separate documentation. The PSI, of course, has the right, through the accreditation process, to review and question curriculum amendments which are made.	Section 9.4 has therefore been amended to read: 'All proposed material changes to the Degree Programme must be documented and submitted prior to implementation to the PSI for approval in line with statutory requirements'.
4. Dr. Tamasine Grimes, MPSI		
	<p><u>Standard 2.2</u></p> <p>The student may be undertaking tasks for which they should develop or gain competence, as part of the learning process. Suggest this point should place the onus on the trainer to check the student's work before it is applied to the patient or in the clinical setting. The student may not always work safely, but this is part of the learning. (For example, failure to identify a drug interaction, caught by the pharmacist before dispensed to the patient).</p> <p>Suggest the wording of this standard might be changed to "are monitored and assessed to assure their development to work and perform safely".</p> <p><u>Standard 3</u></p> <p>Introduction</p> <p>Suggest this should be changed to "Graduates must demonstrate the generic and personal qualities and possess the specialist knowledge, skills, actions and behaviours and professional attributes necessary to apply to enter the NPIP". It is important that graduates not only have the knowledge and cognitive capacity, but that they apply this; that they "do" and perform.</p>	<p>Standard 2, section 2.2 wording has been retained. The students must not be allowed to undertake any activities that are unsafe and nor should they be asked to do anything that would be unsafe.</p> <p>Noted; however, for the purposes of these interim accreditation standards, actions and behaviours are considered to be part of 'professional attributes'. As these interim standards have no requirement for assessment in a practice environment as part of the Bachelor degree programme, it may be difficult to assess behaviours that denote a consistent way of doing things. Assessment in</p>

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	<p>(For example dispense the correct product rather than know that they should do so).</p> <p><u>Standard 3.1</u> Suggest this should change to “They must demonstrate the generic and personal qualities expected of a pharmacy graduate, which include” – this is because the list provided may not be exhaustive.</p> <p><u>Standard 3.2, line 1</u> Suggest the words actions and behaviours should again be included here.</p> <p><u>Standard 3.2</u> Suggest this section needs to give consideration to all aspects of the medication use process: procurement, supply, administration, monitoring, prescribing of medicines. It seems at present it covers prescription and supply only. The pharmacy graduate should be the “drug expert” and as such be competent to undertake or advise on all aspects of the medication use process.</p> <p><u>Standard 3.2e</u> Suggest the graduate needs this knowledge not only to interpret prescriptions, but to monitor and interpret ongoing therapy and patient progress. This suggestion applies throughout all points in section 3.2.</p>	<p>practice settings will, however, constitute a fundamental component of the five-year fully integrated programme and the accreditation standards for this programme will reflect this suggestion.</p> <p>Agreed. Standard 3, section 3.1 has been amended to reflect this suggested wording.</p> <p>Noted; however see comments above.</p> <p>Noted. Standard 3, section 3.2(d) has been amended to reflect this suggested wording</p> <p>Standard 3, section 3.2(f) has been amended to reflect this suggested wording and now reads as: ‘The requisite pharmacological, pharmaceutical and clinical knowledge to safely and effectively interpret and evaluate information about medicines and their proper use and to monitor and interpret ongoing therapy and patient</p>

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	<p><u>Standard 3.2 G</u> Suggest this needs change/ clarification – is this to include diagnosis of minor ailments and decision re referral for more serious ailments? –If so, the skills required therefore include questioning, discerning, recognizing and diagnosing. It should not be restricted to recognition, nor to the presentation of symptoms as these may not always be present or apparent.</p> <p>Point 3.2g Perhaps this point might be more broadly covered by the term “governance” – to include all aspects of quality and safety.</p> <p><u>Standard 3.2i</u> Suggest we want the student to gain an appreciation for the research methodologies applied to one of these disciplines and that it is not feasible in this bachelor programme, level 8, programme for them to cover all. They may be able to understand many of the methodologies, but not apply them all.</p> <p><u>Standard 3.2j</u> Suggest this needs to be stronger – the graduate needs to be able to identify the evidence and the strength of that evidence – without this, many of the above objectives are not possible. This can be achieved at a preliminary level in the bachelor programme and developed further in the NPIP.</p> <p><u>Standard 4,</u></p>	<p>progress;’</p> <p>Original reference to recognition has been retained as it is considered that educating students for diagnostic procedure is not the purpose of the interim 4-year Bachelor degree programme. The words ‘with appropriate referral to other healthcare professionals as necessary’ have been added.</p> <p>Agreed. Notion of ‘safety’ has been incorporated into section 3.2 (i) of Standard 3.</p> <p>The original wording has been retained as the student should have an understanding of the research methodologies relevant to natural, clinical and social sciences but it is understood that they will not be able to apply them all.</p> <p>Agreed. Standard 3.2(k) has been amended to read: ‘An understanding of the need to identify the evidence and strength of that evidence and its application to problem solving and patient-care;’</p>

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	<p>Introduction Suggest there may be a need to include some definitions within this document. What is meant here by interdisciplinary? And by integrated?</p> <p><u>Standard 4</u> Introduction Should replace “knowledge and skills” with “knowledge, skills, actions and behaviours”.</p> <p><u>Standard 4.5</u> Query the feasibility of providing “thorough training” – the student at undergrad level generally gains an introduction to undertaking research in one specific field. If “thorough” is required, some indication of exact proportion of the course to be allocated to this would be helpful. The latter part of this point seems much more achievable, qualified by the words “that meets the requirements of a level 8”.</p> <p><u>Standard 5.1G</u> Suggest care with wording – this may imply that research is exclusively a postgraduate activity.</p>	<p>Noted. The introduction has been reworded to make explicit the use of ‘integrated’ – it now reads as follows: ‘The curriculum is planned and delivered within a programme that combines and coordinates all components in a cohesive manner with clearly defined learning outcomes (...)’. Interdisciplinary is to be understood as practitioners from diverse fields working in a coordinated fashion toward a common goal. It is not considered necessary to amend this part of standard 4.1.</p> <p>As above (standard 3) – actions and behaviours are considered to be part of ‘professional attributes’ for the purposes of these interim accreditation standards.</p> <p>Agreed. Standard 4.5 has been amended to reflect this comment and now reads as: ‘The curriculum should provide appropriately comprehensive training in research methods applicable to scientific and health research. (...)’</p> <p>Agreed. Standard 5.1(h) has been amended to read as: ‘ensure that teaching and learning take place alongside and with reference to research and other scholarly activities;’</p>

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	<p><u>Standard 6.1F</u> Why are these particular skills / activities chosen? I suggest it is essential to ensure competence in all steps of the medication use process (procurement, prescription, dispensing, administration, monitoring). Without such demonstration of competence, our graduates may not be best placed to take on all possible aspects of medicines management, established, emerging and future. (Extemporaneous dispensing is an integral part of dispensing, but not the only aspect which should be listed in the standards).</p> <p><u>Standard 6.2</u> Suggest define “holistic”. How will the PSI assess compliance with this standard?</p> <p><u>Standard 8</u> Introduction Suggest define “contemporary”. As currently drafted, the responsibility here falls on the staff member “This staff must”. Suggest the responsibility should fall to the School and the wording should be changed to “This staff must be supported by the School to ...”. This is essential to ensure appropriate allocation of resources, in particular time.</p>	<p>Noted. The current standards are intended to cover a short interim period pending the commencement of the five-year fully integrated Masters programme and seek to retain the ethos of the existing Bachelor degree programmes currently delivered by the schools of pharmacy. These interim standards should be read in conjunction with the interim standards for the current one-year MPharm programme delivered as part of the NPIP. The interim Bachelor degree standards should be read as minimum criteria and include the skills and activities set out in standard 6.1(f) but are not limited to these skills and activities. The standards do not limit the scope of the schools to deliver more.</p> <p>The PSI develops an accreditation process document that accompanies the accreditation standards. This process document sets out the types of evidence that a school of pharmacy should provide to the PSI to demonstrate its adherence to each of the standards.</p> <p>The proposed wording has been retained. It is considered that it is a matter for a school of pharmacy to justify to the accrediting body how it manages its resources.</p>

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	<p><u>Standard 8</u> Suggest define “service teaching” and “inservice training”</p> <p><u>Standard 8.1d</u> This should include some reference to the breakdown of working hours between teaching, research and administration.</p> <p><u>Standard 8.1e</u> Suggest this might include “Be encouraged and supported to engage in interdisciplinary and multidisciplinary research and be supported in seeking funding to facilitate high quality, high impact research”.</p> <p><u>Standard 8.1f</u> This point is very welcome in the standards. What is meant by “provided with” – does this mean the staff member should be facilitated to undertake; have access to; be funded to undertake; be given study hours ...?</p> <p>Views on Appendix A, Indicative Syllabus</p> <p><u>I. Pharmacy Practice</u> Suggest the categorisation of topics between subsections a, b and c should be revised. Many of these are not mutually exclusive.</p>	<p>This is not considered necessary – each school of pharmacy must account for its use of its resources.</p> <p>The proposed wording has been retained. It is considered that it is a matter for a school of pharmacy to justify to the accrediting body how it manages its resources.</p> <p>The proposed wording has been retained. It is considered that it is a matter for a school of pharmacy to justify to the accrediting body how it manages its resources, including the support for scholarship and research.</p> <p>Noted – the wording has been amended for the sake of clarity and now reads as: ‘have access to an organised professional development programme open to all teaching staff (...)’.</p> <p>Agree with the points made however a substantial review of the indicative syllabus is not foreseen at this time. As indicated, to ensure continuity with the existing programme provision and the smooth transition to the transitional standards, the indicative syllabus has not</p>

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	<p>I.a.ii Suggest that all steps in the meds use process should be identified (procurement, supply, prescription, administration, monitoring). Suggest medicines information is a subject in itself which should be addressed and which involves not only provision of the information but the resolution of medicines related queries and problems. ADRs – suggest this should include “recognition and management” rather than just “recognition and reporting” as reporting is only one aspect of management. (Again, facilitating the student’s performance capacity). Interactions – suggest this should include identification and management. (Again, facilitating the student’s performance capacity). “measuring outcomes in support of evidence-based practice and achieving maximum clinical effectiveness” - Why measuring – should this be assessing therapy against relevant outcomes and goals.</p> <p>I.a.iii - What does this mean? Does this pertain to research</p>	<p>been subject to significant review. While a comprehensive review of the indicative syllabus was not appropriate at this point in time, minor changes have, however, been made to reflect changes in the law and in the terminology used in pharmacy health provision. A more comprehensive review will be undertaken in the development of the accreditation standards for the 5-year integrated programme.</p> <p>Agreed in principle and included for the time being as part of clinical pharmacy practice section I (a) (ii)</p> <p>Agreed to include management.</p> <p>This section has not been changed in this review. We are</p>

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	<p>methodologies?? Does it pertain to concepts? Suggest this should include insights into medication and patient safety, organizational culture, organizational safety culture, safety science, ethics, patient behaviours, communication.</p> <p>I.a.iv - Query the feasibility of including pharmacoeconomics and pharmacoepidemiology in the undergraduate, level 8, course in a meaningful way. Perhaps this might be suggested as an “introduction to”.</p> <p>I.a.v - Suggest communication skills should be covered within behavioural and social science. Suggest study skills should be a distinct point. This is important so as not to dilute the emphasis on the importance of each of “study” and “communication” skills. Suggest communication skills should include reference to communication with patients and communication with colleagues, peers and other members of the healthcare team.</p> <p>I.b.ii and iv - Sub-categorisation of topics is unclear – why does health promotion sit in section b? This should form an integral part of pharmacy practice and should be integrated into all medicines management, rather than viewed as a distinct and separate activity.</p> <p>I.b.iii - “Results” of what – perhaps this might be better termed “evidence based practice” and the student should be taught to identify and apply evidence based practice.</p>	<p>reluctant to make significant changes in this area at this point in time; however, the comments are noted for future consideration in the development of the accreditation standards for the 5-year integrated programme.</p> <p>Point I(a)(iv) has been updated to ‘Health policy and concepts of health economics, including those related to pharmacoeconomics and pharmacoepidemiology.’</p> <p>Agreed in principle; however, as this section has not been changed in this review, the comments are noted for future consideration in the development of the accreditation standards for the 5-year integrated programme.</p> <p>This section has not been changed in this review. The PSI is reluctant to make significant changes in this area at this point in time; however, the comments are noted for future consideration in the development of the accreditation standards for the 5-year integrated programme.</p> <p>Agreed. This point has been updated to ‘Health services research and welfare services research: research methods and applying results to support evidence-based practice.’</p>

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	<p><u>Overall comment</u> There is an absence of teaching regarding patient safety in the indicative syllabus. Suggest this should be included, with particular emphasis on medication safety, clinical governance, identification and management of patient safety incidents, risk management, reflective practice.</p>	<p>Agreed. This is an important point. This has been included in section 1(a)(i).</p>
5. Pharmaceutical Society of Northern Ireland (PSNI)		
	<p><u>Overall</u> Overall the draft accreditation standards appear robust, fit for purpose and well formulated. We have no major recommendations for amendment or addition. However, in the process of review, the Committee considered it could be helpful in the context of the PSI’s workstream in this area if two emerging and developing aspects of the PSNI/GPhC approach to accreditation were described in our response in case of interest to the PSI project team.</p> <p>1. Student fitness to practise procedures as part of accreditation requirements In the UK, health professional regulators have been giving additional attention in the last number of years to the issue of student fitness to practise. This has been in part spurred by a Council for Healthcare Regulatory Excellence (CHRE) report (February 2010)¹ on whether regulatory bodies should receive notification of student fitness to practise outcomes. CHRE</p>	<p>Noted – the PSI welcomes these contributions.</p> <p>Noted. This is a matter of critical concern to the PSI and in this regard a requirement has been added to standard 9.3 - ‘Quality Assurance’ as follows: ‘(...). Fitness-to-practise mechanisms for student pharmacists must be in operation and routinely reviewed.’ The standards to be developed for the five-year fully integrated programme will address</p>

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	<p>concluded this should take place, citing research from the USA on doctors' fitness to practise before and after registering with medical regulators that found that 'unprofessional behaviour' as a student is associated with regulators taking action on fitness to practise issues at a later date.</p> <p>In 2009 and 2010 the GPhC (formerly RPSGB) and PSNI developed a Student Code of Conduct and Student Fitness to Practise Guidelines for Universities and made it a requirement that all accredited schools put student fitness to practise procedures in place from the beginning of the 2010-2011 academic year. The guidelines require Universities to inform the regulatory body of any sanctions it imposes. The proposed GPhC/PSNI standards for future accreditation will make these explicit conditions of accreditation.</p> <p>2. Patient safety and accreditation requirements The standards that GPhC/PSNI applies for the accreditation of Schools of Pharmacy are currently in the process of review. In the proposed future framework for accrediting UK schools of pharmacy the onus on the University to assure a graduate is not a risk to the public is made unambiguous. For example, the very first set of Accreditation Standards are described under the heading "Patient Safety". These state "<i>There must be clear procedures to address concerns about patient safety arising from initial pharmacy education and training. Concerns must be addressed immediately</i>" and that "<i>by awarding an accredited degree a University is confirming that a pharmacy graduate is fit to enter pre-registration training</i>". We consider these changes</p>	<p>the requirement for student fitness-to-practise outcomes to be notified to the PSI.</p> <p>Noted. The Teaching and Learning Strategy set out in Standard 5(a) now requires that it must: 'take account of the NPIP competence standards and the core competency framework as approved by the PSI Council from time to time to ensure graduates are properly prepared to apply for entry to the NPIP and so ensure patient safety and public protection; (...)'. The current draft interim accreditation standards for the Bachelor degree programmes are for an interim period of no more than five years and these matters will be addressed more comprehensively in the accreditation standards that the PSI will now develop for the implementation of the five-year fully integrated MPharm pharmacist qualification.</p>

Point No.	Comments received	Response
	leave less room for confusion in terms of Universities understanding their responsibility to ensure a graduate is fit to practise as a pre-registration trainee upon graduation.	These interim standards should be read in conjunction with the interim standards for the current one-year MPharm programme delivered as part of the NPIP.
6. Hospital Pharmacists Association of Ireland (HPAI)		
	<p><u>Draft Standard 1.3 (c)</u></p> <p>The strategic plan, missions, goals and KPIs of each School should be cognisant of the demands any such KPIs place on the tutor pharmacist and/or pharmacist colleagues in the workplace.</p> <p><u>Draft Standard 2.1</u></p> <p>The identification of who is responsible for what at each stage must not be unduly burdensome on the tutor and/or workplace colleagues.</p> <p><u>Draft Standard 2.2</u></p> <p>The workplace systems put in place for supervision, monitoring and assessment of the students must not be unduly burdensome on the tutor and/or pharmacist colleagues/workplace environment (See also Standard 6, Standard 8 and Standard 9)</p> <p><u>Draft Standard 6</u></p> <p>The benefit of a formal examination of pharmacy law if similar to the formal examination undertaken by previous students is unclear. A summative assessment may be more appropriate to the culture of lifelong learning being promoted.</p>	<p>Noted. This comment will be of particular importance in the development of accreditation standards for the five-year fully integrated MPharm programme.</p> <p>Noted. This comment will be of particular importance in the development of accreditation standards for the five-year fully integrated MPharm programme.</p> <p>Noted. This comment will be of particular importance in the development of accreditation standards for the five-year fully integrated MPharm programme.</p> <p>Noted. The current standards are intended to cover a short interim period pending the commencement of the five-year fully integrated Masters programme and seek to retain the ethos of the existing Bachelor degree</p>

Point No.	Comments received	Response
	<p>Minor comments relating to the standards are outlined below:</p> <p><u>Draft Standard 3.2(g)</u></p> <p>The requisite knowledge and skills to recognise common disease states and make appropriate responses to presented symptoms with appropriate referral to other healthcare professionals as necessary;</p> <p><u>Draft Standard 3.2 (i)</u></p> <p>An understanding of the need for and application of an evidence-based approach to problem solving and patient care.</p> <p><u>Draft Standard 3.2 (Additional point)</u></p> <p>An understanding of the practice of pharmacy in hospital, industrial, academic and community pharmacy settings.</p> <p>This is one of the recommended training requirements from the 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). Section 4 – ‘Recommendations on the organisation and structure of training at higher education</p>	<p>programmes currently delivered by the schools of pharmacy. These interim standards should be read in conjunction with the interim standards for the current one-year MPharm programme delivered as part of the NPIP.</p> <p>Agreed. Standard 3, section 3.2 (h) has been amended to reflect the proposed wording.</p> <p>Agreed. Standard 3, section 3.2 (k) has been amended to reflect the proposed wording.</p> <p>Agreed. Standard 3, additional point has been added to reflect the proposed wording.</p>

Point No.	Comments received	Response
	<p>institutions’</p> <p><u>Draft Standard 5.3</u> The Teaching and Learning Strategy should ensure that pharmacy law, ethics, professionalism and pharmacy practice are taught predominantly by pharmacists with contemporary experience of practice, drawn preferably from within the School. Relevant input from external lecturers with expertise in specific areas is appropriate.</p> <p><u>Draft Standard 6.1 (c)</u> Amend punctuation, sentence not clear.</p> <p><u>Draft Standard 6.1 (h)</u> Should a ‘satisfactorily high standard’ be defined? 40%/50% pass mark?</p> <p><u>Appendix I(a)(i)</u> Make practice settings explicit: The pharmacist’s role in patient-care in hospital, industrial, academic and community pharmacy settings.</p>	<p>Noted. The involvement of external lecturers is considered important but rather than incorporating their involvement in standard 5.3, an additional section has been added to standard 8 – ‘Resources’ – to read as follows: ‘The School should ensure that relevant input from external specialist lecturers is provided to enhance the students’ contextual understanding of specific areas.’</p> <p>Agreed. Wording has been revised to read: ‘... there must be...’ instead of ‘...there are...’.</p> <p>Noted. It was considered that rather than prescribing the pass mark, the school of pharmacy must illustrate to the PSI the standard setting methodologies it uses to set a pass mark that is of a ‘satisfactorily high standard’.</p> <p>Agreed. Point 1(a)(i) updated to ‘ The pharmacist’s role in patient-care and safety in community, hospital, industrial and academic pharmacy settings.’</p>

Point No.	Comments received	Response
7. School of Pharmacy, University College Cork (UCC)		
	<p>General Observation</p> <p>The focus in the document is on the preparation of students to enter the NPIP. It is considered by the School that in contrast, the NPIP should not be separated from the BPharm but should be a final step in the integrated programme preparing graduates for patient centred pharmacy practice.</p> <p>Page 1</p> <p>The purpose of undergraduate pharmacy education (the pharmacy degree programme) is to produce pharmacy graduates who have the knowledge, competencies, skills and attributes to safely participate in the National Pharmacy Internship Programme (NPIP). Graduates should be prepared for patient-centred pharmacy practice (this extends to pharmacists in primary and secondary care settings, pharmaceutical industry, government and non-government agencies and agencies) and their learning should be based upon and underpinned by appropriate and sufficient understanding of the principles and techniques of the pharmaceutical , biomedical and social sciences.</p>	<p>The PSI notes and agrees with this point and it will be a fundamental underlying aspect of the development of the accreditation standards for the fully integrated five year MPharm programme. For the purposes of these interim accreditation standards, the qualification is currently split along a 4+1 structure and for this reason the standards must reflect this structure.</p> <p>Noted. The word competencies has not been inserted as the purpose of these interim accreditation standards is to cover a short interim period pending the commencement of the five-year fully integrated Masters programme and to seek to retain the ethos of the existing Bachelor degree programmes currently delivered by the schools of pharmacy. These interim standards should be read in conjunction with the interim standards for the current one-year MPharm programme delivered as part of the NPIP.</p> <p>With regard to preparation of graduates for different practice settings, as patient-centredness is considered as core to all pharmacy practice, it has not been considered necessary to qualify this section. A new section under standard 3 (3.1) has been inserted to require all graduates to have: ‘an understanding of the practice of pharmacy in community, hospital, industrial and academic pharmacy settings.’</p>

Point No.	Comments received	Response
	<p>2c the capability to adapt to and instigate developments in pharmacy and medicine</p> <p><u>Draft Standard 2</u> Page 3 Add The establishment of transparent fitness to practice schemes in the Schools should be considered.</p> <p><u>Draft Standard 3</u> Page 4 Add to 3.1: confidence; patient awareness; technology and information literacy.</p> <p>Add to 3.2 The application of Clinical Pharmacy Practice in Community and Hospital settings ensuring the patient is the primary focus of practice</p>	<p>Point number 1 on page 1 has been amended to incorporate the proposed additional wording of the 'biomedical and social sciences.'</p> <p>Noted – however, the ability to instigate developments in pharmacy and medicine would not be considered appropriate for the current interim level 8 programme. Will be considered in the context of the development of the 5-year fully integrated MPharm programme.</p> <p>Agreed, however, the need for fitness to practise mechanisms has been incorporated under Standard 9 – 'Quality Assurance'. The last sentence of standard 9.3 now reads as: 'Fitness to practise mechanisms for student pharmacists must be in operation and routinely reviewed.'</p> <p>Agreed to add 'confidence' to list in Standard 3.1; technology literacy has not been added as it is not considered as a generic or personal quality. The need to promote patient awareness is considered to be captured in point 1 of the Introduction on page 1 whereby: 'Graduates should be prepared for patient-centred pharmacy practice...'</p> <p>See below.</p>

Point No.	Comments received	Response
	<p data-bbox="289 272 1142 378">Biomedical and social sciences A requisite knowledge in how medicines exert a therapeutic effect.</p> <p data-bbox="289 428 932 456"><u>The following point should be considered for 3.2e</u></p> <p data-bbox="289 506 1129 727">Pharmacological knowledge is included in this point but only in terms of safely and effectively interpreting prescriptions and orders which is a narrow field. Pharmacists work in a wide range of areas, for example those working in government agencies also need to be knowledgeable in this area. Point 3.2e should be expanded to reflect this diverse role. Add to 3.2:</p> <p data-bbox="289 777 506 846"><u>Draft Standard 4</u> Page 4</p> <p data-bbox="289 896 1136 1235">4.1 to read as follows: The curriculum should ideally be delivered by interdisciplinary teams in order that the subject matter of the degree is integrated, is patient focused, and the student is provided with the knowledge and experience that will facilitate an understanding of the key aspects of the manufacture, preparation, quality control, distribution, actions, application and uses of medicines for patients in an evidence based manner including health screening, health promotion, pharmaceutical care and medication management [remove outcome analysis]</p>	<p data-bbox="1171 506 1929 727">Noted. Standard 3.2(f) has been amended and now reads as: ‘The requisite pharmacological, pharmaceutical and clinical knowledge to safely and effectively interpret and evaluate information about medicines and their proper use and to monitor and interpret ongoing therapy and patient progress;’.</p> <p data-bbox="1171 857 1929 1349">Agreed – Standard 4, section 4.1 has been amended to reflect the proposed wording and now reads as: ‘The curriculum should ideally be delivered by interdisciplinary teams in order that the subject matter of the degree is integrated (i.e. combining and coordinating all components in a cohesive manner) and delivered in a patient-focussed manner. The student must be provided with the knowledge and experience that will facilitate an understanding of the key regulatory and scientific aspects of the manufacture, preparation, quality control, distribution, actions, application and evidence based use of medicines by patients to include health screening, health promotion and pharmaceutical care.</p>

Point No.	Comments received	Response
	<p>4.6 to read as follows: Where appropriate and possible, the curriculum should be reinforced by practice experience that is designed to integrate the student’s experience gained with their study of biomedical, social and pharmaceutical sciences and the disciplines relevant to the practice of pharmacy.</p> <p>4.7 The last sentence to read the total breadth of study requirement of these recommendations.</p> <p>Add 4.8 The Curriculum should be reviewed and revised to adapt to developments in medical and pharmaceutical science and services</p> <p><u>Draft Standard 5</u> Page 6 Add Point: 5.2: The indicative Syllabus should be able to clearly and transparently map to the individual components of the curriculum as set out in 5.1 and 3.1 and 3.2.</p>	<p>Agreed – Standard 4.6 has been amended to reflect the proposed wording.</p> <p>Noted. However, as ‘breadth of study, could include more than hours, the original wording has been maintained in the interim accreditation standards.</p> <p>Agreed, but this notion has been added to Standard 4.2, the last sentence of which now reads as: ‘The curriculum should take account of, and be responsive to, developments in pharmaceutical science and services and in pharmacy practice.’</p> <p>Agreed in principle with this point however a substantial review of the indicative syllabus is not foreseen at this time. As indicated to ensure continuity with the existing programme provision and the smooth transition to the transitional standards, the indicative syllabus has not been subject to significant review. While a comprehensive review of the indicative syllabus was not appropriate at this point in time, minor changes have, however, been made to reflect changes in the law and in the terminology used in pharmacy health provision. A comprehensive</p>

Point No.	Comments received	Response
	<p>5.5 (was 5.4) to read The Teaching and Learning Strategy must incorporate a pragmatic and enforceable code of conduct that is communicated to students and used to promote professional behaviour.</p> <p><u>Draft Standard 6</u> 6.1 (e) add literacy after numeracy</p> <p>6.2 To read Emphasis also needs to be placed on the role of pharmacists in the position of Qualified Persons as defined in the DIRECTIVE/2001/83/EC (AC)</p> <p><u>Draft Standard 7</u> 7.1 (b) To read Include a clear statement of the entry requirements and the requirements for progression on the Degree programme in the form of knowledge, skills, attitudes and competencies and for its successful completion and these must also conform to any requirements that are laid down by the PSI Council from time to time;</p>	<p>review will be undertaken in the development of the accreditation standards for the 5-year integrated programme.</p> <p>Agreed – Standard 5.4 has been amended to reflect the proposed wording and now reads as: ‘The Teaching and Learning Strategy must incorporate a clear and realistic student code of conduct that is explained, communicated and enforced to promote professional behaviour.’.</p> <p>Noted. Original wording retained however as amendment not considered necessary.</p> <p>See below</p> <p>Agreed – Standard 7.1(b) amended but with wording change to reflect interim nature of the standards and need to retain ethos of existing programmes. Reads now as: ‘include a clear statement of the requirements for entry, progression and successful completion, in the form of the knowledge, skills and professional attributes needed alongside any requirements that are laid down by the PSI Council from time to time.’</p>

Point No.	Comments received	Response
	<p><u>Draft Standard 8</u></p> <p>8.1 Academic Staff Mention should be made that industry experience is also desirable.</p> <p>8.1 (c) To read Liaise with any staff involved in ‘service teaching’ to support the adaptation of examples used in teaching and learning to contemporary pharmacy context and ensure it is patient centred.</p> <p>8.1 (d) be provided with the resources, support and academic environment which allows them to maintain their knowledge at the leading edge of biomedical, social and pharmaceutical science and clinical pharmacy practice [remove pharmaceutical science and pharmacy practice]</p> <p>8.2 Support Staff Technical staff should have a higher degree in one of the main Pharmacy subject areas or a related discipline. Technical staff should be proficient in the operation and maintenance of scientific instrumentation and equipment associated with the teaching and research activities of the School/Department. Technical staff should take an active role in the preparation and delivery of laboratory practice sessions and projects.</p> <p>8.3 The School must ensure that accommodation (including teaching</p>	<p>Noted. However, as all settings where pharmacy is practised are relevant, not necessary to identify one and not all others – original wording has been retained.</p> <p>Agreed – Standard 8.1(c) amended to reflect the proposed wording.</p> <p>Agreed, but with amended wording – Standard 8.1(d) now reads as: ‘(...)which allows them to maintain their knowledge at the leading edge of pharmaceutical science and clinical pharmacy practice;’.</p> <p>Noted, however the original wording has been retained as the manner in which staff are deployed is a matter for each institution.</p> <p>Agreed – Standard 8.3 has been amended to reflect</p>

Point No.	Comments received	Response
	<p>rooms and laboratories), equipment, library facilities, IT (including appropriate interactive distance learning technology/VLE) and subject specific IT specialist software (for example dispensing software) and other resources available to it are sufficient for the effective delivery and examination of the planned Degree Programme to the numbers of students in each year of the Degree programme and overall; properly taking account of the other teaching and research commitments of the School.</p> <p><u>Draft Standard 9</u> Pg 10 Add 9.3 FTP systems must be in operation and routinely reviewed.</p> <p>Appendix A 1. Pharmacy Practice a) The Practice of Pharmacy li To read Problem-solving in all main aspects of managing medicines (dispensing only being a part of this), clinical pharmacy practice responding to symptoms, provision of drug and patient information, recognition and reporting of adverse drug reactions and assessment of drug interactions, drug utilisation evaluation, and measuring outcomes in support of evidence-based practice and achieving maximum clinical effectiveness, minor illness management, medicines management, vaccinations vi Reword as follows: The role of the Pharmacist pharmacists in the position of Qualified Persons as defined</p>	<p>proposed wording.</p> <p>Agreed, but with minor wording change. Last sentence of Standard 9.3 now reads as: 'Fitness-to-practise mechanisms for student pharmacists must be in operation and routinely reviewed.'</p> <p>Agreed in principle however it is not considered appropriate to include extended services in this limited review. The comments are noted, however, for future consideration in the development of the 5-year integrated programme.</p> <p>Will leave as current wording as suggested change may</p>

Point No.	Comments received	Response
	<p data-bbox="384 272 766 302">in the DIRECTIVE 2001/83/EC</p> <p data-bbox="289 391 1115 496">ix Pharmacy Law and ethics and professionalism, their role and importance within pharmacy and other health care settings.</p> <p data-bbox="384 545 1079 574">b Improvement and Development of Pharmacy</p> <p data-bbox="289 583 1079 651">i Professional and inter-professional audit of pharmacy practice with a view to continuous improvement.</p> <p data-bbox="289 699 1136 805">ii Promotion of good health and disease prevention through health promotion and screening, the pharmacist's contribution (public health role of the pharmacist)</p> <p data-bbox="289 894 1115 1000">v Roles of Pharmacists in the development and evaluation of novel pharmaceutical and medical therapies and services</p> <p data-bbox="384 1049 747 1078">c Pharmacy in Society</p> <p data-bbox="384 1086 1121 1235">add ii Exposure and awareness to best pharmacy practice in countries outside Ireland and to policy documents underpinning future practice developments</p> <p data-bbox="289 1284 1037 1390">II THE SOURCES, ISOLATION, CHARACTERISATION, ANALYSIS AND PROPERTIES OF HUMAN AND VETERINARY MEDICINES</p>	<p data-bbox="1171 272 1927 341">limit the role of the pharmacists as the qualified person in industry.</p> <p data-bbox="1171 391 1927 496">Agree in principle. Point has been broadened to 'Pharmacy Law and ethics and professionalism, their role and importance within pharmacy and society.'</p> <p data-bbox="1171 583 1272 612">Agreed.</p> <p data-bbox="1171 699 1927 849">It is not considered appropriate to include extended services in this limited review however the comments are noted for future consideration in the development of the 5-year integrated programme.</p> <p data-bbox="1171 894 1927 963">Agreed in principle for future consideration in which case the words clinical trials should also be included.</p> <p data-bbox="1171 1049 1927 1235">It is not considered appropriate to include during this limited review however the comments are to be noted for future consideration in the development of the accreditation standards for the 5-year integrated programme.</p>

Point No.	Comments received	Response
	<p>Add xi What makes a chemical “druggable?”</p> <p>IV THE ACTION AND USES OF MEDICINES AND OTHER HEALTHCARE PRODUCTS</p> <p>I Normal and abnormal bodily function: biochemistry, genetics, microbiology, nutrition, immunology, infective processes, pathology, pathophysiology and anatomy.</p> <p>v Recognition of disease states and responding to symptoms of such illness. Differentiation between minor illness and major disease</p> <p>Add xv Developing areas in therapeutics, horizon scanning, Vaccination and vaccination regimes, Gene and SiRNA and stem cell therapies .</p>	<p>The suggested changes were not considered appropriate to include during this limited review however the comments are to be noted for future consideration in the development of the accreditation standards for the 5-year integrated programme.</p>
8. Department of Health		
	<p><u>General Comments</u></p> <p>On page 1 it is suggested that point 2 (c) might include ‘and healthcare’ after ‘in pharmacy medicine.’ Pharmacy education should prepare students to adapt to developments, not only in pharmacy practice or how medicine is practised, but also to developments in how care is delivered to patients and how healthcare systems will develop in the future.</p> <p>Page 2 onwards – it is submitted that the order of the standards might be rearranged to improve the flow, as the ultimate output is the Graduate, this section might appear last as the culmination of all of the other standards. The standards would then follow as</p>	<p>Agreed - text has been amended to reflect proposed wording.</p> <p>Noted, however the original structure has been retained to reflect the structure of the current interim MPharm accreditation standards. The structure will be reviewed</p>

Point No.	Comments received	Response
	<p>below.</p> <ol style="list-style-type: none"> 1. Pharmacy School and Mission 2. Leadership, Organisation and External Relationships 3. Governance 4. Resources 5. Teaching and Learning Strategy 6. Currciulum 7. Assessment Strategy 8. Quality Assurance 9. Students 10. Graduates <p>A further suggestion is that standard 2 might be expanded to include External Relationships (as explained under heading 2 below) and that Governance (as explained under heading 3 below) might be presented as a separate standard.</p> <p><u>Comments on the individual draft standards</u></p> <ol style="list-style-type: none"> 1. Pharmacy School and Mission <p>It is suggested that a requirement to include a timescale for the implementation and review of KPI's in the mission statement might also be included at point 1.2.</p>	<p>when developing the standards for the five-year fully integrated MPharm programme.</p> <p>Noted – see above.</p> <p>Agreed – text has been amended to reflect proposed wording. Standard 1.2 now reads as: 'The School should have a published statement of its mission and goals and set out its key performance indicators (KPIs) and timescale for their implementation and review relating to how the School will monitor and evaluate its performance against its strategic plan's goals and objectives.</p>

Point No.	Comments received	Response
	<p data-bbox="331 272 1075 305">2. Leadership, Organisation and External Relationships</p> <p data-bbox="289 313 1138 378">It is suggested that this draft standard is split in two as follows: 1. Leadership and Organisation and 2. Governance.</p> <p data-bbox="289 427 1123 735">Facilitating external relationships or collaborations with the pharmacy profession to foster overall teaching, learning and research capabilities and the development of the profession might be considered under this section. The Schools of Pharmacy, the Heads of School and the academic staff are key members and leaders of the pharmacy profession and therefore schools and colleges should encourage their engagement in the profession and within healthcare more generally.</p> <p data-bbox="289 1011 1144 1352">The Head of School is a very important post, not only in terms of the administration and management of a school of pharmacy and within the university, but also as regards leadership of the pharmacy profession. We would suggest that this should be emphasised in document. In addition, where the Head of School is not a pharmacist it should be emphasised that the identified pharmacist who can provide professional leadership, is at a senior level within the School and can contribute at a senior level within the pharmacy profession as a leader.</p>	<p data-bbox="1171 313 1423 345">Noted – see above.</p> <p data-bbox="1171 427 1911 768">Agreed. However, while this can be seen as desirable, there are elements that go beyond the context of the present degree (which is to be replaced by the five-year fully integrated degree in 2013). Notwithstanding, a new section has been added to reflect a variation of the proposed wording. New Standard 2.4 now reads as: ‘External relationships or collaborations with the pharmacy profession must be facilitated to foster teaching, learning and research capabilities.’</p> <p data-bbox="1171 1011 1932 1385">Agreed. Standard 2.3 now reads as: ‘The Head of the School must be in a position to influence the HEI and the School policy in relation to pharmacy. In the event that the Head is not a pharmacist registered in Ireland, there must be an identified pharmacist who can provide leadership in the practice and profession of pharmacy and have the authority for effective advocacy for pharmacy within the HEI. This person must be at senior level within the School and be registered in the Register of Pharmacists held by the PSI and thereby be familiar with</p>

Point No.	Comments received	Response
	<p>3. Governance It occurs to us that greater clarity might be helpful in the standards regarding the governance arrangements, in order to make them more visible. The standards could emphasise more clearly obligations on Schools to report key issues to the PSI which are pertinent to the delivery of the pharmacy programmes.</p> <p>4. Resources A bullet point on the need to have contingency plans developed and documented that would cover deficiencies in infrastructure, IT and/or personnel could be included under this heading.</p> <p>5. Teaching and Learning Strategy This standard could include a bullet point after 5.1 (g) to ‘ensure that pharmacy students realise the importance of working as part of a multidisciplinary team and that teaching and learning in this area is provided.’</p> <p>A bullet point emphasising the need for the active engagement of pharmacy students with other health professional students in the learning process could be included here. Students of the various health professions can develop a greater understanding of the approaches of other professions and what each profession brings to the care of a patient.</p>	<p>and subject to the statutory code of conduct.</p> <p>Noted – see above.</p> <p>Agreed. Introduction to Standard 8 now reads as: ‘The School must have sufficient allocated resources, financial, physical and staff and have developed and documented contingency plans to cover deficiencies in order to ensure effective delivery of a Degree Programme (...)’.</p> <p>Agreed. Revised wording introduced as new section 5.1(i) which reads as: ‘ensure that pharmacy students realise the importance of working as part of a multidisciplinary team.’</p> <p>Noted. The suggested emphasis was not considered appropriate to include for the interim Bachelor degree standards. However, the comments are noted for future consideration in the development of the accreditation standards for the 5-year fully integrated programme.</p>

Point No.	Comments received	Response
	<p>6. Curriculum It is important that the curriculum prepares graduates for the changes in the delivery of healthcare services. It is suggested stronger emphasis could be placed on the need for curriculum development to take account of and be responsive to the developments in pharmacy practice. Schools need to be very responsive to these challenges.</p> <p>It is welcomed that the standard requires that the curriculum have a focus on the research and science aspects.</p> <p>7. Assessment Strategy It is important that students are fully aware of the assessment process, what it entails and that the process is continually reviewed and updated.</p> <p>It is also important that the inputs of students are considered and that the assessment process takes account of developments in pharmacy practice.</p> <p>8. Quality Assurance It is important that robust measures are in place to ensure that all processes and activities are quality managed and assured.</p> <p>9. Students Additional bullet point after 7.2 (F) suggested to include ‘access to counselling regarding poor progress, learning difficulties, impairment and disability issues, health and social problems etc.’</p>	<p>Agreed. New last sentence has been added to Standard 4.2 which now reads: ‘The curriculum should take account of, and be responsive to, developments in pharmaceutical science and services and in pharmacy practice.’</p> <p>Noted.</p> <p>Agreed. For the sake of clarity, Standard 6.1 now incorporates the words ‘to students’ and reads as: ‘provide clear guidance to students relating to assessment of stated professional and learning outcomes, (...)’.</p> <p>Noted. Standard 7.2(c) requires that there be mechanisms in place to ensure that the views and experiences of students on the quality of the Degree Programme are considered.</p> <p>Noted. Standard 9.2 is considered to capture this requirement.</p> <p>Agreed. New Standard 7.2(g) added to reflect the proposed wording which now reads as: ‘access to counselling in relation to poor progress, learning</p>

Point No.	Comments received	Response
	<p>10. Graduates A bullet point to link the requirements under draft standards on students and assessment might be included here.</p> <p>The skills referred to in point 3.2 appear to be primarily directed towards the current role of pharmacists and while it is important, the standards should ensure that new roles taken on by pharmacists can be incorporated into these skills and attributes. For example, the developing role of pharmacists in evaluating symptoms, determining appropriate treatment, engaging in referral or signposting to other health services could also be emphasised and reflected in this standard.</p>	<p>difficulties, impairment and disability issues, including any health or social problems.’</p> <p>Noted. This point will be addressed comprehensively in the accreditation standards that the PSI will now develop for the implementation of the five-year fully integrated MPharm pharmacist qualification. The current draft interim accreditation standards for the 4-year Bachelor degree programmes are for an interim period of no more than five years and it was not considered prudent to significantly amend the existing programme provision in light of the significant programme changes which the Schools of Pharmacy will be required to introduce with effect from 2013 when the fully integrated degree is due to be rolled out.</p>
9. Irish Medicines Board		
	<p><u>Draft Standard 3</u> In 3.2 (a), we suggest the addition of knowledge as to <u>why</u> medicines are developed as well as to <u>how</u> they are developed.</p> <p>We also suggest the addition of a requirement under 3.2 regarding the requisite knowledge of the regulatory framework</p>	<p>Noted. It was not considered necessary to amend the existing programme to this degree in the context of interim accreditation standards (see point above) – this will nevertheless be considered in the context of the development of standards for the five-year fully integrated programme.</p> <p>Agreed. New Standard 3.2(a) has been added to reflect proposed wording and reads as: ‘The requisite knowledge</p>

Point No.	Comments received	Response
	<p>and their role in it.</p> <p><u>Draft Standard 4</u> Under 4.1 we suggest an amendment of the phrase ‘...an understanding of the key aspects of...’ to ‘...an understanding of the key regulation and scientific aspects of...’ as graduates in practice will need to understand both aspects. In the last line of this paragraph, we suggest adding ‘administration’ after ‘uses’</p> <p>In or after 4.4, it may be appropriate to require that sufficient time is provided to develop knowledge and understanding of the health sector in Ireland.</p> <p>Requirement 4.6 might be rewritten for better clarity.</p> <p><u>Draft Standard 8</u> A reference in this standard to non-academic staff is suggested. Besides service teachers, there may be specialist lecturers from regulatory authorities or service providers. Academic staff should ensure that these other staff have an appropriate understanding of the goals and objectives of the pharmacy degree, and of the particular subject areas to be taught by them. II(vi) add microbiological tests IV add epidemics, population health and use of vaccines</p> <p><u>Appendix A</u> In 1. a. (ii), the reporting of quality defects should be included (now or when a more substantive revision is undertaken).</p>	<p>of the regulatory framework and the role of pharmacists within it’.</p> <p>Agreed – Standard 4.1 has been amended to reflect proposed wording. The word ‘application’ has been added before ‘uses’.</p> <p>Agreed – text has been amended to reflect proposed wording and Standard 4.4 now ends with words: ‘(...)and to develop knowledge and understanding of the health sector in Ireland.’</p> <p>Noted but original wording retained.</p> <p>Noted. A new Standard 8.2 – ‘External Experts’ – has been added to reflect this concern. It reads as follows: ‘The School should ensure that relevant input from external specialist lecturers is provided to enhance the students’ contextual understanding of specific areas.’</p> <p>Agreed.</p>

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	<p>1. c (v) might also include reference to human medicines and blood products.</p> <p>1. c might also include reference to the regulatory framework for the health services and healthcare products.</p> <p>II. (vi) should also include microbiological tests</p> <p>IV. might also include a reference to epidemics, population health and the use of vaccines.</p>	<p>Agreed.</p> <p>Agreed in principle for future consideration in the development of the accreditation standards for the 5-year integrated programme.</p> <p>Agreed.</p> <p>Considered that this is covered indirectly in sections I and IV however explicit inclusion can be considered for the development of the accreditation standards for the 5-year integrated programme.</p>
10. An Bord Altranais		
	<p><u>Draft Standard 1</u> An Bord Altranais supports this standard and the content of the strategy plan. It is important as stated that there needs to be a statement regarding how the degree programme will ensure that graduates are prepared for entry to and participation with the National Pharmacy Internship Programme and to prepare graduates that are competent and embrace a commitment to lifelong learning.</p> <p><u>Draft Standard 2</u> An Bord Altranais commends this standard. It is evident that there is a commitment to patient safety and protection of the</p>	<p>Noted. Section 2 on page 1 makes reference to the need for undergraduate pharmacy education to seek to develop in the student a commitment to lifelong learning.</p> <p>Noted. See Standard 2.3 for the manner in which this is to be managed by the HEI.</p>

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	<p>public and patients. The Board would suggest that if possible the Head of the School of Pharmacy should be a pharmacist registered in Ireland in the Register of Pharmacists held by the Pharmaceutical Society of Ireland (PSI) and be subject to the statutory code of conduct.</p> <p>The mechanism of reviewing the annual reports is an important aspect of the approval process and the quality education framework.</p> <p><u>Draft Standard 3</u> The Board welcomes this standard.</p> <p><u>Draft Standard 4</u> The Board welcomes the content of this standard. It is important as stated that the curriculum should be guided but not limited to the indicative syllabus outlined. It is important that the curriculum design and development reflect current, evidence/research based educational pharmaceutical theory and health care practice. The curriculum model chosen should be dynamic and flexible to allow for changes in practice and health care and the development of evidence based practice. In addition it is advisable that the statutory and regulatory requirements of the PSI and European directives are met and declared in the documentation forwarded to the PSI for approval. An Bord Altranais supports the principle regarding the use of the National Framework of Qualifications (NQAI).</p>	<p>Noted. This is also a statutory requirement.</p> <p>Noted.</p> <p>Noted and agreed. See amended Standard 4.2 which reflects this concern and which now reads as: ‘The Curriculum should be guided by but not limited to the indicative syllabus shown in Appendix A of this document. The curriculum should take account of, and be responsive to, developments in pharmaceutical science and services and in pharmacy practice.’</p>

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	<p>The assessment of learning should be a continuous process and demonstrate a balanced and integrated distribution throughout the education programme.</p> <p><u>Draft Standard 5</u> The Board welcomes the emphasis regarding student centredness and commitment to meeting the learning needs of individual students and the identification of the role of the graduate regarding the healthcare environment. An Bord Altranais supports the concept of student responsibility for their own learning and importance of ensuring that graduates develop a culture of continuous professional development and lifelong learning.</p> <p><i>'It is important that the curriculum utilized a range of teaching and learning strategies to assist the development of knowledgeable, competent, reflective practitioners willing to accept personal and professional accountability for evidence based practice, practitioners equipped with the lifelong skills for problem solving and self directed learning.'</i> [Requirements and Standards for Nurse Registration Education Programmes (An Bord Altranais, 2005)].</p> <p><u>Draft Standard 6</u> The Board supports the principles outlined in this standard. It is important that the assessment of learning should be a continuous process and demonstrate a balanced and integrated distribution throughout the education programme. It is important that the curriculum articulates how the student is enabled to achieve the</p>	<p>Noted and supported.</p> <p>Noted. It is hoped that these comments are appropriately reflected in Standard 6.</p>

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	<p>expected learning outcomes of the programme. The Board welcomes the inclusion of a robust appeals process regarding assessment.</p> <p><u>Draft Standard 7</u> In general, An Bord Altranais supports the principle outlines. Setting admission requirements contribute to the goal of professional regulation and public protection. The support structures and the guidance mechanisms are an important function and the mandating of this by the PSI is to be commended.</p> <p><u>Draft Standard 8</u> An Bord Altranais commends this standard.</p> <p><u>Draft Standard 9</u> An Bord Altranais commends this standard. It is evident that clear structures are in place regarding the role of the regulator to ensure patient safety and public protection.</p>	<p>Noted.</p> <p>Noted.</p> <p>Noted.</p>