

**Public Consultation on the Draft Statutory Instrument for the five-year fully integrated Master's Degree Programme**

**SUBMISSIONS AND RESPONSES**

This is the final version following approval in principle by the Council of the PSI at its meeting held on 27 March 2014

<b>No.</b>	<b>Name of Individual</b>	<b>In a personal capacity</b>	<b>As an authorised representative of an organisation/body, expressing the views of that organisation/body</b>
1	Caoimhe O'Donoghue	In a personal capacity	
2	Michelle Kirrane, MPSI	In a personal capacity	
3	Fiona McNeela	In a personal capacity	
4	Peter Jacob, MPSI	In a personal capacity	
5	Prof Eilis McGovern, HSE	As an authorised representative	Medical Education and Training Unit, HSE
6	Katarzyna Kunowicz, MPSI	In a personal capacity	
7	Paul Gallagher, MPSI, RCSI	As an authorised representative	School of Pharmacy, RCSI
8	Marian Shanley	In a personal capacity	
9	Pamela Logan, MPSI, IPU	As an authorised representative	Irish Pharmacy Union
10	Anne Teresa Morgan, MPSI, Boots	As an authorised representative	Boots the Chemist Ireland
11	Pat Mac Govern	In a personal capacity	
12	John Barry, MPSI	In a personal capacity	
13	Stephen Byrne, MPSI, UCC	As an authorised representative	School of Pharmacy, University College Cork
14	Claudine Hughes, MPSI, NMIC	As an authorised representative	National Medicines Information Centre
15	Eoin Fleming	In a personal capacity	
16	Prof. Anne Marie Healy, MPSI, TCD	As an authorised representative	School of Pharmacy and Pharmaceutical Sciences, Trinity College Dublin
17	Maureen Reidy, MPSI	In a personal capacity	
18	Sarah Foley, MPSI, HPAI	As an authorised representative	Hospital Pharmacists Association of Ireland
19	Bryan Maguire, QQI	As an authorised representative	Quality and Qualifications Ireland
20	Cliona Loughnane	As an authorised representative	Irish Heart Foundation (General comments received via letter, see end of document)
21	Dr Caitríona M. Fisher, MPSI	As an authorised representative	Irish Medicines Board (General comments received via letter, see end of document)

### Over-arching question

**Do you agree that the Rules are fit for purpose and provide the appropriate legal framework for matters relating to the award of a qualification that is appropriate for practice as a registered pharmacist?**

No	Name	SUBMISSION	PSI RESPONSE
3	Fiona McNeela	Agree  Students are still getting their 12 months of training but I feel it will be more beneficial spreading this over the 5 year course	Noted and agreed. In line with the Directive on the Recognition of Professional Qualifications, the six months' traineeship will continue to be a requirement in law towards the end of the five years of education and training.
15	Eoin Fleming	Strongly Disagree  Key elements relating to the in-service practical training, and which are central to the successful establishment of the 5-year MPharm degree are not adequately dealt with	Your concerns are noted at this stage and will be dealt with in more detail as they are identified throughout the consultation document. Moreover, the PSI's Accreditation Standards for the Five Year Fully Integrated Master's Degree Programmes in Pharmacy together with related PSI Council policy documents will also underpin the implementation of the new structure of the qualification.
16	Prof. Anne Marie Healy, TCD	Disagree  Reasons for disagreement outlined in subsequent sections.	Noted. Individual comments will be dealt with in more detail as they are identified throughout the consultation document.
17	Maureen Reidy	Strongly Agree  I would have some concerns about assessing the eligibility criteria for establishments abroad	Noted. The concern with regard to the assessment of the eligibility criteria for establishments abroad is addressed in the Accreditation Standards for the Five Year Fully Integrated Master's Degree Programmes in Pharmacy whereby academic institutions will be required to have appropriate mechanisms in place to assure and enhance the quality of all practice placements. The evaluation of these mechanisms will form part of the accreditation process undertaken on behalf of the Council of the PSI. The decision to enable practice-placements abroad will be a matter for the discretion of each academic institution.

## RULES 1 – 4

Do you agree that Rules 1 - 4 are adequate for the introductory purposes of these Rules?

No	Name	SUBMISSION	PSI RESPONSE
16	Prof. Anne Marie Healy, TCD	<p>Disagree</p> <p>3. <i>(1) These Rules shall apply to any person who, after the date of coming into force of these Rules, commences or wishes to commence a course of study leading to the award of a qualification appropriate for practice.</i></p> <p><i>(2) The Pharmaceutical Society of Ireland (Education and Training) Rules 2008 (S.I. No. 493 of 2008) shall cease with effect from the 1st June 2014 except for those persons who had commenced before that date, a course of study under those Rules, leading to the award of a qualification appropriate for practice.</i></p> <p>It is not practical for the Rules to have effect from 1<sup>st</sup> June 2014. Apart from the many challenges for the Universities in developing and gaining approval for suitable programmes which make an autumn 2014 start date impossible in the interests of programme quality, it is clearly inappropriate to introduce legislation in June 2014 that affects applicants intending to commence third level education in autumn 2014. The majority of these applicants will have made CAO choices in the expectation of undertaking a '4+1' programme of study. While a CAO 'change of mind' facility exists, it excludes certain courses (which include various medical and paramedical degrees) that applicants might have chosen instead if they had known in advance that the pharmacy degree would be in a 5-year integrated format for the</p>	<p>Noted. The Council of the PSI will determine the appropriate commencement date for these Rules for consideration by the Minister following a review of all submissions received under this public consultation. The PSI recognises the short timeframe of a 1 June 2014 commencement and accordingly Rule 2 has been amended to give effect to these Rules coming into force on 1 June 2015. Similarly, Rule 3 in the public consultation draft has been removed and Rule 23(1) and (2) provide for revocation of Rules and the transitional period.</p>

	<p>2014 intake, with the attendant implications for fees, employment and time management. Other applicants may have given notice to employers or made other significant career decisions on the basis of entering a 4+1 degree programme which cannot easily be overturned. Prior to June 2014 offers will have been made to mature student applicants and graduate applicants for entry in autumn 2014 to a 4 year bachelor degree. While such individuals will not yet have commenced their studies, such offers will need to be honoured.</p> <p>1<sup>st</sup> June 2015 is the earliest possible date that the School of Pharmacy and Pharmaceutical Sciences in TCD could comply with, and this presumes that the School/College has assurance/comfort around availability of adequate numbers of student placements.</p> <p>“4. (1) ...‘<i>medicinal product</i>’ has the meaning assigned to it in section 2 of the Act and includes veterinary medicinal products within the meaning of section 18(2) of the Act;...”</p> <p>Section 2 of the Pharmacy Act 2007 indicates that ‘medicinal product’ has the same meaning as in Directive 2001/83/EC as amended. This definition relates to medicinal products for human use only.</p> <p>Section 18(2) of the Pharmacy Act inappropriately created a localized and different interpretation of this internationally agreed phrase, extending it to include veterinary medicinal products, for the purpose of a subsection of that Act only. This was inappropriate and should not be replicated here; to avoid confusion ‘medicinal product’ should retain its internationally agreed definition</p>	<p>As these Rules are required to give effect to provisions in the Pharmacy Act 2007 which is the primary source, all definitions used in that Act must continue to be used in any secondary legislation arising therefrom.</p> <p>Under EU law, the term ‘medicinal product’ only applies to products intended for human use and similarly in the case of veterinary medicinal products.</p>
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		<p>throughout Irish legislation.</p> <p>If the PSI wishes to avoid the phrase ‘medicinal products and veterinary medicinal products’ on the basis that it is too cumbersome, they may wish to employ alternative terminology that has not already been given a specific meaning in the key directives relating to pharmaceuticals (<i>e.g.</i> ‘medication’) and then indicate that the chosen terminology encompasses both medicinal products and veterinary medicinal products.</p> <p><i>“4. (1) ... ‘qualification appropriate for practice’ has the meaning assigned to it in section 16(1) of the Act as referred to in section 14(1)(e) of the Act, as being one of the requirements essential for registration in the Register of Pharmacists;...”</i></p> <p>Section 16(1) of the Pharmacy Act 2007 indicates that, “A person holds a qualification appropriate for practice if he or she has received in the State the prescribed training and education and has the prescribed qualifications.” However, the proposed Rules indicate that a student may potentially receive part of his/her education and training outside the State.</p>	<p>Section 16 of the Pharmacy Act 2007 deals with the various mechanisms in which an applicant can satisfy the Council that he/she is the holder of a ‘qualification appropriate for practice’ as one of the criteria for registration. Section 16(1) deals with all qualifications that are obtained in Ireland under the auspices of institutions in the State and that are also subject to the accreditation oversight of the PSI Council. The remaining parts of Section 16 deal with all other qualifications obtained outside of the State.</p> <p>Providing for a period of not more than four months outside of the State as part of the 5-year degree does not conflict with section 16(1) of the Act as long as the control of that period outside of the State remains within the jurisdiction of the academic institution. This matter will also be dealt with in some detail in the Accreditation Standards for the Five Year Fully Integrated Master’s Degree Programmes in Pharmacy.</p>
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		<p>Moreover, a qualification appropriate for practice as described in section 16(1) of the Pharmacy Act 2007 will not always be one of the requirements essential for registration in the Register of Pharmacists; a qualification appropriate for practice as described in the remaining subsections of section 16 is a potential alternative.</p> <p><i>“4. (1) ... ‘tutor pharmacist’ means a registered pharmacist who has been recognised as a tutor pharmacist by the recognised institution under Rule 17;...”</i></p> <p>Suggest changing to ‘a registered pharmacist who <u>is</u> recognised’ as recognition will not persist for an indefinite period.</p> <p>The ‘Professional Qualifications Directive’ should be defined in Rule 4. (1).</p>	<p>Section 16(1) deals specifically with qualifications for practice as a registered pharmacist that are obtained in Ireland. That will continue to be the essential criterion for registration for one whose qualification was obtained in Ireland. The new Rules will give effect to this new qualification. All qualifications obtained previously in the State will continue to be recognised for the purposes of Section 16(1). Rule 22 deals with this matter in the amendment to the Registration Rules.</p> <p>As a tutor pharmacist can only be recognised by an academic institution if they have fulfilled all the requirements set down by the academic institution as required under former Rule 17 (now Rule 16), the PSI is satisfied that the original proposed wording does not imply that such recognition should persist for an indefinite period. Indeed, it is a matter for the academic institution under former Rule 17(2) (now Rule 16(2)) to specify the requirements for tutors, following consultation with the Council. In order to capture the notion of recognition as a tutor for a defined period, the PSI has amended former Rule 17 (now Rule 16) to limit the duration of tutor recognition to a 12-month period which shall be renewable at the discretion of the academic institution.</p> <p>Furthermore, the PSI’s Accreditation Standards for the Five Year Fully Integrated Master’s Degree Programmes in Pharmacy, at sections 7.8 and 7.9 will set out the requirements for academic institutions to select, assess, accredit and appoint tutors and training establishments and to have appropriate mechanisms to monitor performance of all staff (...).</p> <p>Noted. However, as this Directive, including its amendments, has been defined in section 16(8) of the Pharmacy Act 2007 (as amended), it is not necessary to repeat this definition in this</p>
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			SI.
19	Bryan Maguire, QQI	A “recognised institution” should be a provider of higher education and training legally entitled to offer programmes leading to awards as specified in the Qualifications Act, 2012. The providers so entitled include Irish universities, RCSI, providers with awarding powers delegated by QQI (e.g. institutes of technology) and providers with programmes validated by QQI. Such providers are subject to a statutory quality assurance regime which includes national guidelines and periodic independent reviews organised by QQI in line with good international practice.	Noted. While in agreement with this statement, it is unclear that all the bodies that would be recognised under the definition of ‘relevant provider’ in the Qualifications and Quality Assurance (Education and Training) Act 2012 would meet the requirements of Article 44 of the Professional Qualifications Directive which requires that the institution delivering the programme must be a university or other higher education institution or is recognised by the State as having an equivalent status, or is under the supervision of a university.

**On which date should these rules come in to force?**

On which date should these rules come in to force?		No. of respondents	
1st June 2014		5	
1st June 2015		12	
No	Name	SUBMISSION	PSI RESPONSE
5	Prof Eilis McGovern, HSE	<p>1st June 2014</p> <p>While ideally the new rules would come into force as soon as possible, i.e. Jun 2014, if there are any major revisions required following the public consultation, consideration should be given to a postponement</p>	<p>Noted. The Council of the PSI, following a review of all submissions received under this public consultation, decided that the appropriate commencement date for these Rules for consideration by the Minister would be 1 June 2015. The PSI recognises the short timeframe of a 1 June 2014 commencement and accordingly it has amended Rule 2 to give effect to these Rules coming into force on 1 June 2015.</p>
10	Anne Teresa Morgan, Boots	<p>1st June 2015</p> <p>As a community pharmacist employer currently supporting practice placements, there has been very limited engagement with key stakeholders, regarding the structure, content and expectations of the tutor in future practice placements. In light of this I feel a start date of June 2014 is unsuitable as there is still a lot of clarification required regarding practice placements e.g.</p>	<p>Noted. The PSI has engaged in an ongoing and structured engagement with all key stakeholders since the Council decision in June 2010 regarding the implementation of the restructuring of the pharmacist qualification from a 4 year + 1 year structure to a fully integrated 5-year structure. This engagement process is ongoing.</p> <p>The Council of the PSI, following a review of all submissions received under this</p>

		structure, support and remuneration for tutors	public consultation, decided that the appropriate commencement date for these Rules for consideration by the Minister would be 1 June 2015. The PSI recognises the short timeframe of a 1 June 2014 commencement and accordingly it has amended Rule 2 to give effect to these Rules coming into force on 1 June 2015.
11	Pat Mac Govern	1st June 2015  I do not believe that the three Schools of Pharmacy can be ready to introduce new curricula by 1st June 2014.	Noted. The Council of the PSI, following a review of all submissions received under this public consultation, decided that the appropriate commencement date for these Rules for consideration by the Minister would be 1 June 20145  The PSI recognises the short timeframe of a 1 June 2014 commencement and accordingly it has amended Rule 2 to give effect to these Rules coming into force on 1 June 2015.
12	John Barry	1st June 2015  From having served on the National Forum for Pharmacy Education, it is my opinion that a commencement date of 1st June 2014 is totally unachievable.	Noted. The Council of the PSI, following a review of all submissions received under this public consultation, decided that the appropriate commencement date for these Rules for consideration by the Minister would be 1 June 2015.  The PSI recognises the short timeframe of a 1 June 2014 commencement and accordingly it has amended Rule 2 to give effect to these Rules coming into force on 1 June 2015.
13	Stephen Byrne, UCC	1st June 2015  The School of Pharmacy, UCC would strongly encourage the PSI to consider a commencement date of June 2015. Any sooner will lead to a rushed programme been designed. Provision will also have to be made for students who under the old SI who may have to repeat a year, provision should be made in the new SI for students repeating a year under the previous SI	Noted. The Council of the PSI, following a review of all submissions received under this public consultation, decided that the appropriate commencement date for these Rules for consideration by the Minister would be 1 June 2015. The PSI recognises the short timeframe of a 1 June 2014 commencement and accordingly it has amended Rule 2 to give effect to these Rules coming into force on 1 June 2015.  Regarding repeat students, a new Rule has been inserted (Rule 23) and Rule 23(2) of the SI accommodates all such



			students who had commenced their course of study prior to the commencement date of the new SI. For all such students, the Pharmaceutical Society of Ireland (Education and Training) Rules 2008 will continue to apply.
17	Maureen Reidy	1st June 2015  I do not believe that the profession as a whole is prepared for the new rules coming into force in June 2014 – I think we need another year to allow for full and comprehensive discussion	Noted. The Council of the PSI, following a review of all submissions received under this public consultation, decided that the appropriate commencement date for these Rules for consideration by the Minister would be 1 June 2015. The PSI recognises the short timeframe of a 1 June 2014 commencement and accordingly it has amended Rule 2 to give effect to these Rules coming into force on 1 June 2015.

## RULE 5

**Do you agree that sufficient provision is made in Rule 5 for the purposes of placing the Core Competency Framework for Pharmacists on a statutory footing?**

No	Name	SUBMISSION	PSI RESPONSE
12	John Barry	Agree  Here and in other places in the document "the Society's website" is mentioned. Although it may seem inconceivable to us now there may be no such thing in 10 years' time the pace of change in technology. It would be no harm have "society's website" defined to include what could be future iterations of websites.	Noted. However, for current publication purposes, the PSI's website is one of the key public communication vehicles at its disposal and publication on a website ensures immediate placing in the public domain. In the event of technological advancements and other communication mechanisms, the PSI would have to reflect such developments in an amended SI.
16	Prof. Anne Marie Healy, TCD	Neutral  The Society has indicated that the Core Competency Framework for Pharmacists will be used for a number of additional purposes including: <ul style="list-style-type: none"> <li>To inform and develop plans for continuing professional development (CPD) by assisting pharmacists to reflect on their</li> </ul>	Noted. However, it is envisaged that a separate SI will be necessary to give full effect to the PSI's mandatory CPD model for pharmacists. The making of these current Rules will not preclude that objective and it would be inappropriate to attempt to signal the statutory basis for the future use of the Core Competency Framework in this SI.

		<p>practice and identify learning needs; and to provide guidance and structure for CPD over the changing demands of a pharmacist's career.</p> <ul style="list-style-type: none"> <li>To provide a platform for the development of specialisation and advanced practice within pharmacy.</li> </ul> <p>The existence of such additional purposes could be signalled in Rule 5. (1).</p>	<p>Rule 5 has now become Rule 4 in the final and signed SI.</p>
17	Maureen Reidy	<p>Agree</p> <p>Why publish only on the website?</p>	<p>For current publication purposes, the PSI's website is one of the key public communication vehicles at its disposal and publication on a website ensures immediate placing in the public domain. In the event of technological advancements and other communication mechanism, the PSI would have to reflect such developments in an amended SI.</p>
19	Bryan Maguire, QQI	<p>QQI welcomes the clear distinction between the Core Competency Framework for Pharmacists and the qualifications or programmes that might allow a candidate to achieve or demonstrate that they have achieved the relevant occupational competency. We support putting the Core Competency Framework on a statutory footing.</p>	<p>Noted.</p>

## **RULE 6**

**Do you agree that the definition of a qualification appropriate for practice adequately frames the five-year integrated MPharm?**

No	Name	SUBMISSION	PSI RESPONSE
13	Stephen Byrne, UCC	<p>Agree</p> <p>Does this new SI need to make reference to previous qualifications such as a BSc Pharm, BPharm degree with a 12 month pre-reg / internship.</p>	<p>A new Rule has been inserted (Rule 23) and Rule 23(2) of the SI accommodates all students who had commenced their course of study prior to the commencement date of the new SI. Furthermore, all qualifications obtained previously in the State will continue to be recognised for the purposes of</p>

			Section 16(1) of the Pharmacy Act 2007. Rule 22 of the new draft SI deals with this matter in the proposed amendment to the Pharmaceutical Society of Ireland (Registration) Rules 2008.
16	Prof. Anne Marie Healy, TCD	Disagree  As noted above, Section 16(1) of the Pharmacy Act 2007 indicates that, "A person holds a qualification appropriate for practice if he or she has received in the State the prescribed training and education and has the prescribed qualifications." However, the proposed Rules indicate that in the five-year integrated MPharm a student may potentially receive part of his/her training outside the State.	Section 16(1) deals with all qualifications that are obtained in Ireland under the auspices of institutions in the State and that are also subject to the accreditation oversight of the PSI Council. The remaining parts of Section 16 deal with all other qualifications obtained outside of the State.  Providing for a period of not more than four months outside of the State as part of the 5-year degree does not conflict with section 16(1) of the Act as long as the control of that period outside of the State remains within the jurisdiction of the academic institution. This matter will also be dealt with in some detail in the Accreditation Standards for the Five Year Fully Integrated Master's Degree Programmes in Pharmacy.
19	Bryan Maguire, QQI	QQI as an awarding body has not set any standards for pharmacy awards nor does it currently validate any programmes leading to such awards. QQI is not aware of any plans for any providers to seek such validation. If QQI were to receive a request for such awards it would consult with the PSI and have regard to the Core Competency Framework of the PSI in setting award standards.	Noted.

## **RULE 7**

**Do you agree that the structure of the Masters degree in pharmacy, as described in Rule 7, is suitable for the purposes of the five-year integrated MPharm?**

No	Name	SUBMISSION	PSI RESPONSE
<b>NO COMMENTS</b>			

## RULE 8

Do you agree that the criteria for recognition and approval of a five-year integrated MPharm programme are fit for purpose?

No	Name	SUBMISSION	PSI RESPONSE
15	Eoin Fleming	<p>Disagree</p> <p>I believe that there are elements to 8.2(a), including funding and policies that need to be established clearly from the outset in the statutory instrument</p>	<p>The purpose of enabling the development of these 'criteria' (i.e. accreditation standards) in a statutory instrument is that it gives a statutory basis to the standards while enabling their development through the five-yearly cyclical review process [see former Rule 8 (now Rule 7(3))]. It would not be appropriate to develop the suggested level of detail in an SI.</p>
16	Prof. Anne Marie Healy, TCD	<p>Agree</p> <p>The criteria themselves are not set out in this proposed legislation.</p> <p>The School has previously commented on the draft accreditation criteria published by the Society. The level of agreement indicated in Q7 above relates to agreement that the description of the criteria in the proposed legislation (Rule 8) is fit for purpose, not that the criteria themselves are fit for purpose.</p>	<p>Agreed. It is only the mechanism for establishing the criteria that can be provided for in the Rules.</p> <p>Noted.</p>
19	Bryan Maguire, QQI	<p>In specifying eligible masters degrees it would be desirable to refer in the rules to the statutory National Framework of Qualifications (NFQ). This includes a generic descriptor of the outcomes of a master degree which all Irish awarding bodies are required to satisfy (see <a href="http://www.nqai.ie/docs/framework/determinations/determinations.pdf">http://www.nqai.ie/docs/framework/determinations/determinations.pdf</a> page 39).</p> <p>As the Irish NFQ has been referenced to the European meta-frameworks this may facilitate the mobility of Irish graduates, for example for entry into doctoral studies abroad.</p> <p>The rules for recognition of programmes (Part 3) refer to a duration of 5 years. It</p>	<p>Noted and agreed. While this was the intention of the draft SI, in order to make this explicit a new paragraph has been inserted to former Rule 8 (now Rule 7). Rule 7(e) requires that the 'criteria' for the five-year Master's degree programmes in pharmacy (i.e. the Accreditation Standards) have regard to the National Framework of Qualifications.</p> <p>Noted. As Directive 2005/36/EC (and</p>

		would be desirable to complement this with a prescription of minimum academic credit of 300 ECTS. (see <i>Principles and Operational Guidelines for the Implementation of a National Approach to Credit in Irish Higher Education and Training</i> <a href="http://www.nqai.ie/docs/framework/policies/principles%20and%20oper%20guidelines%20green.pdf">http://www.nqai.ie/docs/framework/policies/principles%20and%20oper%20guidelines%20green.pdf</a> ).	the amendment agreed on 20.11.2013) makes reference to a specific time-based duration of five years, which must comprise a six-month traineeship during or at the end of the five year period, and as the amending Directive states that the duration may in addition be expressed with the equivalent ECTS credits, this latter aspect would appear to be accommodated upon the transposition of the amending Directive into Irish law.
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## RULE 9

**Do you agree that the application process for first-time recognition and approval of a five-year integrated MPharm is adequate?**

No	Name	SUBMISSION	PSI RESPONSE
8	Marian Shanley	Neutral  I think an institution proposing to offer a Pharmacy qualification should either have a school of medicine and nursing or have strong links with a school of medicine and nursing in order to ensure that pharmacy education may develop in an integrated multidisciplinary way in the future.	Noted and agreed. The PSI's Accreditation Standards for the Five Year Fully Integrated Master's Degree Programmes in Pharmacy will make reference to the need for the HEI to support the development of suitable relationships between the School and other academic and service units of the HEI for (...) interprofessional learning. The Programme's educational philosophy must also set out how structured experience of interprofessional working to facilitate team-work in the delivery of patient-centred care can be delivered. The Accreditation Standards will also make reference to the teaching and learning being organised, where appropriate, so that students can learn with and from students of other related healthcare professions. The PSI would consider that the interprofessional aspects of the new 5-year programme will continue to evolve over the coming years and this could be captured in subsequent revisions of the Accreditation Standards.
16	Prof. Anne Marie Healy, TCD	Disagree	Noted. Based on the provisions of

		<p>Rule 9(3) does not state for what duration of time recognition may be granted, although Rule 10(1) indicates that the programme will be reviewed at intervals not exceeding five years.</p> <p>We note that the Society has not provided indicative timelines within which applications for recognition and approval of five-year integrated MPharm programmes may be expected to be processed.</p> <p>Rule 9(7): Depending on the revisions(s) and timeframe of revision, it may be very challenging for the HEI to ensure compliance with the revised criteria by “a date not later than the commencement of the subsequent academic year”.</p> <p>Changes in degree programmes are influenced by a number of institutional procedures and practical considerations which may not be immediately apparent to the Council. In 9. (7) we suggest, “by a date not later than the commencement of the subsequent academic year or by a date as may otherwise be specified by the Council, <u>taking into consideration representations from the recognised institutions.</u>”</p>	<p>former Rules 9(3) and 10(1) [now Rules 8(6) and 9(1)], recognition is given subject to an obligatory review within five years.</p> <p>Noted. The PSI Council will define and agree the process for recognition of programmes under these Rules which will be developed having regard to the views of the academic institutions and the need for compliance with the Rules.</p> <p>As the revised criteria must have been developed in line with former Rules 8(3) and (4) [now Rules 7(3) and (4)] which requires a public consultation and direct invitation to comment issued to relevant stakeholders, it is envisaged that any proposed changes and their implementation date will have already been the subject of representations made by the academic institutions. Council will therefore have taken into consideration representations from the recognised institutions at an earlier stage in the process and will take into account, as necessary, the timelines by which compliance will be required.</p>
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**RULE 10**

If you wish to comment on Rule 10 please do so in the box provided.

No	Name	SUBMISSION	PSI RESPONSE
NO COMMENTS			

## RULES 11 – 12

Do you agree that the manner in which visits and reviews are to be carried out for the purposes of continued recognition and approval of the five-year integrated MPharm is adequate?

No	Name	SUBMISSION	PSI RESPONSE
7	Paul Gallagher, RCSI	<p>Neutral</p> <p>Rules should encompass a situation where there is a conflict of interest on the part of the Visitor(s) and the HEI under review should have a right to comment whether it perceives a conflict of interest</p>	<p>Noted. With regard to issues of perceived or potential conflicts of interest arising for Visitors, it is proposed to insert a new sub-paragraph under former Rule 12 (now Rule 11) to facilitate Council to develop a policy on conflicts of interest. This amendment will prohibit the appointment of Visitors that have an interest that is likely to influence the outcome of the application for recognition or of the review.</p>
12	John Barry	<p>Agree</p> <p>Presuming training establishments include community pharmacies might there be confidentiality, ethical and data protection issues with visitors descending on it?</p>	<p>The operation of visits under former Rule 12 (now Rule 11) would be agreed in advance with the recognised institution and the training establishments/facilities so as to mitigate the impact of such a visit, including the areas identified of confidentiality, etc.</p>
16	Prof. Anne Marie Healy, TCD	<p>Strongly Disagree</p> <p>Rule 12 (1) potentially imposes a significant burden on both the Council and the institution. It would be helpful to have confirmation that such visits are not expected to be routine, e.g. by rephrasing as “the conduct of such visits to a recognised institution as are from time to time necessary in exceptional circumstances for the purpose of ensuring compliance with these Rules.”</p> <p>Depending on the nature of such visits, notice will also be required in order that the visitors may have access to the relevant personnel/materials. Clarity with regard to notice periods would be helpful.</p>	<p>Former Rule 11(1) [now Rule 10(1)] is proposing to deal with visits which fall outside of the review to be carried out within a five-yearly period. The frequency of visits will be based on the views of the Visitors as set out in their report as required under Former Rule 13 (now Rule 12) which would also set out the evidence-base for the frequency of such visits. As these reports are subject to the comments and observations of the recognised institution, both of which form the basis for the Council resolution regarding recognition and approval, it is not foreseen that either the Council or the recognised institution will be subject to a significant burden.</p> <p>The process for the conduct of any such visits will be developed by the Council of the PSI in consultation with the academic institutions.</p>

19	Bryan Maguire, QQI	<p>QQI invites the PSI to have regard to the findings of QQI's quality assurance reviews (see <a href="http://www.qqi.ie/Quality/Pages/Reviews.aspx">http://www.qqi.ie/Quality/Pages/Reviews.aspx</a>) in its engagement with institutions. QQI in turn requests that it inform QQI of any concerns that it has regarding the effectiveness of institution's quality assurance procedures in light of its visits or reviews of institutions providing pharmacy education and training.</p> <p>QQI urges the PSI to have regard to the academic quality assurance procedures operated by institutions for the approval monitoring and review of programmes (see, for example, <a href="http://www.iuqb.ie/info/iuqb-good-practice-guidesed2b.html?article=adf3b2db-44d3-48f8-92dd-5be06100b94e">http://www.iuqb.ie/info/iuqb-good-practice-guidesed2b.html?article=adf3b2db-44d3-48f8-92dd-5be06100b94e</a>) and wherever possible reduce the bureaucratic burden on programmes subject to multiple review processes to the greatest extent compatible with fulfilling statutory obligations. The Irish Higher Education Quality Network, with the cooperation of a range of professional bodies, explored this issue some years ago (see <a href="http://www.iheqn.ie/fileupload/Publications/IHEQN_Report_FINAL_96798829.pdf">http://www.iheqn.ie/fileupload/Publications/IHEQN_Report_FINAL_96798829.pdf</a>) and QQI intends to reopen these explorations later in 2014. We will invite participation of the PSI.</p>	<p>Noted. The PSI welcomes the proposal from QQI to identify synergies across the statutory functions and duties carried out by both organisations to ensure that a streamlining of processes can be achieved in the public interest.</p> <p>It is currently PSI policy to publish summarised accreditation reports on the PSI website.</p> <p>Noted and agreed. A new paragraph has been added to former Rule 8 (now Rule 7). Rule [7(e)] requires that the 'criteria' for the five-year Master's degree programmes in pharmacy (i.e. the Accreditation Standards) have regard to the National Framework of Qualifications (NFQ). This would require any requirements relating to the NFQ to also be considered.</p>
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### **RULE 13**

**Do you agree that the processes by which the Council grants, defers or refuses recognition and approval are adequate?**

No	Name	SUBMISSION	PSI RESPONSE
7	Paul Gallagher, RCSI	<p>Disagree</p> <p>While 2012 Qualifications and Quality Assurance (Education and Training) Act 2012 may not apply to the PSI it</p>	<p>Noted and agreed. The purpose of this Rule is to protect the public interest regarding the competence of all those entering the Register of Pharmacists who have obtained a qualification for</p>



		<p>enshrines an obligation on the HEI to protect enrolled learners. RCSI suggests that 13(4) should be modified to require students currently in course in a programme whose recognition is withheld to be transferred to an accredited programme to permit them to obtain a qualification for practice</p>	<p>practice in Ireland. While the risk may be low of the scenario arising that is provided for in former Rules 13 (3) and (4) (now Rule 12(3) and (4)) due to the other controls that are in place through former Rules 10 and 11 (now Rules 9 and 10) and the annual reporting requirement in former Rule 14 (now Rule 13), the proposed transfer of students already enrolled to another PSI-accredited programme appears reasonable from a student and from a patient safety perspective. Accordingly, former Rule 13 (now Rule 12) has been amended to allow for students to transfer to a new programme that will have been approved by the PSI Council. Any such arrangement will also require the Council to be satisfied that any remedial measures deemed necessary are appropriate in the circumstances.</p>
13	Stephen Byrne, UCC	<p>Agree</p> <p>13 (2) d; seems to be very harsh on students whom are currently registered on an accredited programme. Surely the PSI would have to honour the status of students registered on an accredited programme, yes by all mean insist that remediation work is required but to 'refuse to continue accreditation' would be a very severe sanction that should have been indicated at earlier accreditation visits</p>	<p>Noted and agreed. The purpose of this Rule is to protect the public interest regarding the competence of all those entering the Register of Pharmacists who have obtained a qualification for practice in Ireland. While the risk may be low of the scenario arising that is provided for in former Rules 13 (3) and (4) [now Rules 12(3) and (4)]due to the other controls that are in place through former Rule 10 (now Rule9) and former Rule 11 (now Rule 10) and the annual reporting requirement in former Rule 14 (now Rule 13), the proposal to allow the transfer of students already enrolled to another PSI-accredited programme appears reasonable from a student and from a patient safety perspective. Accordingly, former Rule 13 (now Rule12) has been amended to allow for students to transfer to a new programme that will have been approved by the PSI Council. Any such arrangement will also require the Council to be satisfied that any remedial measures deemed necessary are appropriate in the circumstances.</p>
14	Claudine Hughes,	Agree	Noted. The purpose of this Rule is to

	NMIC	Where the Council refuses to recognise a Masters degree in a particular institution what provision is there for students who embarked on a course of study in good faith in the same institution?	protect the public interest regarding the competence of all those entering the Register of Pharmacists who have obtained a qualification for practice in Ireland. While the risk may be low of the scenario arising that is provided for in former Rules 13(3) and (4) [now Rules 12(3) and (4)] due to the other controls that are in place through former Rules 10 and 11 (now Rules 9 and 10) and the annual reporting requirement in former Rule 14 (now Rule 13), former Rule 13 (now Rule 12) has been amended to allow for students to transfer to a new programme that will have been approved by the PSI Council. Any such arrangement will also require the Council to be satisfied that any remedial measures deemed necessary are appropriate in the circumstances.
16	Prof. Anne Marie Healy, TCD	Neutral  Greater clarity on indicative timelines would be welcome, notably in 13. (3).	Noted. It is proposed that this process will be developed by the Council of the PSI in consultation with the academic institutions.

#### **RULE 14**

**Do you agree that the reporting and notification obligations on recognised institutions are adequate?**

No	Name	SUBMISSION	PSI RESPONSE
7	Paul Gallagher, RCSI	Neutral  The term 'material change' must be formally defined to avoid an inadvertent breach of Rule 14 (by a recognised HEI)	Noted. It would not, however, be usual or indeed helpful if the term were to be defined and may well constitute an impediment to progress. Furthermore, this requirement has been in place since 2008, at least, without any difficulty arising in its interpretation.

#### **RULE 15 (1)**

**Do you agree that the distribution of the 12 months of mandatory in-service practical training is adequately distributed for the purposes of the five-year integrated MPharm?**

No	Name	SUBMISSION	PSI RESPONSE
4	Peter Jacob	Disagree	Noted, however, based on comprehensive

		Should be one block of 12 months	<p>educational research carried out in 2008-2010 (the PEARs Project – see <a href="http://thepsi.ie/gns/education/Publications/pears-project.aspx">http://thepsi.ie/gns/education/Publications/pears-project.aspx</a>), the PSI Council decided in June 2010 that the structure of the five year qualification should evolve from the current four-year Bachelor degree followed by one year of a practical training programme to a five year fully integrated degree in pharmacy. Full integration requires not just the dispersal of placements across the five years in order to ensure contextualisation of learning but also the integration of the curriculum to accommodate these placements. The proposed distribution of the 12 months as set out in the draft SI is as a result of a structured engagement process with practitioners from each of the three main practice settings of community, hospital and industry, under the auspices of the National Forum for Pharmacy Education and Accreditation.</p>
7	Paul Gallagher, RCSI	<p>Neutral</p> <p>The term 'in-service practical training' is antiquated and inaccurate in the context of an integrated M. Pharm. Advanced experiential learning is an alternate.</p> <p>RCSI is concerned as an SI being prescriptive with respect of when advanced experiential learning occurs in Semester as it will may limit flexibility as at future date</p>	<p>Noted. The use of the term 'in-service practical training' is employed in the draft SI to accurately reflect the use of the terms 'practical training' and 'traineeship' used in the Professional Qualifications Directive. 'Practical training' refers to the 'four years of full-time theoretical and practical training at a university (...)' and 'traineeship' refers to the mandatory six month traineeship in a pharmacy which is open to the public or in a hospital under the supervision of that hospital's pharmaceutical department that is required in that Directive. Accordingly, it is not proposed to revise the wording in the SI. The PSI does, however, recognise that experiential learning will be occurring throughout the five years of the programme but the mandatory blocks of such advanced training are the only aspects that are placed on a statutory footing. The Accreditation Standards for the Five Year Fully Integrated Master's Degree Programmes in Pharmacy make reference to 'experiential and practice-based learning' and to 'practice-placements'. The PSI would consider that the Accreditation Standards are the more appropriate vehicle in which to reference educational developments, both generally and specifically.</p> <p>Noted. As students at the end of fifth year will be close to being eligible to apply to enter the Register, it is appropriate to require that they be in clinical training for the last eight months of their education and training. The PSI is therefore not</p>

			proposing to amend the timing of when the training must occur in fifth year. With regard to the minimum of at least four months during the First Semester of the fourth year, the PSI recognises the challenges this may present students, academic institutions and practitioners and is therefore proposing to amend this Rule to allow for the period of at least four months to be undertaken at any time during the fourth year of the course.
9	Pamela Logan, IPU	Disagree  Community pharmacists have reported to us that they would prefer that a 12 month practice placement in Y5 is preferable to splitting the practical training to 4+8 over Y4 and Y5.	Noted, however, based on comprehensive educational research carried out in 2008-2010 (the PEARs Project – see <a href="http://thepsi.ie/gns/education/Publications/pears-project.aspx">http://thepsi.ie/gns/education/Publications/pears-project.aspx</a> ), the PSI Council decided in June 2010 that the structure of the five year qualification should evolve from the current four-year Bachelor degree followed by one year of a practical training programme to a five year fully integrated degree in pharmacy. Full integration requires not just the dispersal of placements across the five years in order to ensure contextualisation of learning but also the integration of the curriculum to accommodate these placements. The proposed distribution of the 12 months as set out in the draft SI is as a result of a structured engagement process with practitioners from each of the three main practice settings of community, hospital and industry, under the auspices of the National Forum for Pharmacy Education and Accreditation.
10	Anne Teresa Morgan, Boots	Whilst we recognise the benefit of a four month and eight month placement allowing the student to have a broader range of experiences, we would have some concerns around the following  1) The omission of direct supervision for the four month placement, we appreciate having more flexibility around the four month placement will allow a broader range of experiences for students, but would have some concerns if there is no requirement for supervision during this first placement period a student could develop or experience bad practices. We do	Noted and agreed. Direct supervision by a registered pharmacist should be a mandatory requirement in all clinical settings for both the fourth and the fifth year placements. Accordingly, former Rule 16 (now Rule 15) has been amended to state that the training must be conducted under the supervision and guidance of a registered pharmacist and that this supervision and guidance must comply with the 'criteria' (the Accreditation Standards). The Accreditation Standards for the Five Year Fully Integrated Master's Degree Programmes in Pharmacy will require the academic institution to have appropriate

		<p>feel there should be some guidelines around supervision during this period to ensure the student gains a quality experience and to ensure safe guard for patients</p> <p>2) The availability of quality assured placements to enable the students to gain an adequate range of experiences</p> <p>3) Timing of the placements - In the case of the four month placement, would be unsure of the quality of experience a student could gain in four months if this is the only exposure a student has to this sector e.g. in community pharmacy November &amp; December are very busy periods, this time pressure will impinge on the amount of time a tutor pharmacist could spend coaching or tutoring a student, for a weaker student would be concerned about the type of experience a student may get during this period</p>	<p>supervision mechanisms by a registered pharmacist in place, particularly in the event of a registered pharmacist not being available in any of the training establishments that fall to be considered under former Rule 16(1) (b), (c) and (d) [now Rule 15(1) (b), (c) and (d)].</p> <p>Following the Council decision in June 2010 and the establishment of the National Forum for Pharmacy Education &amp; Accreditation in Summer 2011, the PSI has actively engaged with a broad range of stakeholders to facilitate the academic institutions in accessing suitable practice placements through the proposed Office of Experiential Learning. The PSI's Accreditation Standards will require the academic institutions to have appropriate mechanisms in place to assure and enhance the quality of all practice placements.</p> <p>With regard to the minimum of at least four months during the First Semester of the fourth year, the PSI recognises the challenges this may present students, academic institutions and practitioners and accordingly, this Rule (now Rule 14) was amended to allow for the period of at least four months to be undertaken at any time during the fourth year of the course.</p>
12	John Barry	<p>Agree</p> <p>There is no mention of the first 3 years of the integrated degree here. While it may be implied that there are integrated elements to each year this should be specified as a requirement whilst giving the academic institution leeway as to how they provide this. From my work on the National Forum I think the integrated degree is only worth it to the student (and to some extent the state) if he/she</p>	<p>Noted. The 'in-service practical training' elements that are stipulated in the SI are intended to give effect to the provisions in the Professional Qualifications Directive that require 'four years of full-time theoretical and practical training at a university (...)' and the mandatory six month traineeship 'in a pharmacy which is open to the public or in a hospital under the supervision of that hospital's pharmaceutical department'. The PSI does, however, recognise that experiential learning will be occurring throughout the five years of the programme but the mandatory blocks of such advanced training are the only aspects that are placed on a statutory footing.</p>

		<p>can be guaranteed that a significant part of the integrated degree is hospital based. I think this should be stipulated in the SI.</p>	<p>In order to ensure that students have practice placement experiences in the three main practice settings of community, hospital and industry across the five years of the programme, the PSI's Accreditation Standards for the Five Year Fully Integrated Master's Degree Programmes in Pharmacy will require the academic institutions to ensure that there is 'a continuum of structured and quality assured practice-placement experiences throughout the curriculum from introductory to advance, 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.' The PSI Council will also be required to develop policy with regard to the structure of practice-placement experiences with which the academic institutions will be required to comply. Using the PSI's Accreditation Standards and PSI Council policy to underpin the development of these practice experiences will create the necessary flexibility for the programmes to evolve.</p>
13	Stephen Byrne, UCC	<p>Agree</p> <p>15 (1) a; the School would appreciate if the PSI would clarify that in this subsection that a registered tutor pharmacist does not have to be present on the same site as the student re the 4 month placement, but that the student must have access too or meet with a dedicated tutor on a regular basis. The School would like clarification on this matter included in the SI.</p> <p>The School would also encourage the PSI to consider removing the specific reference to 'First Semester in the fourth year'. This will lead to problems if students are out of College certified illness / leave. We feel more general wording would be more</p>	<p>Noted. However, direct supervision by a registered pharmacist should be a mandatory requirement in all clinical settings for both the fourth and the fifth year placements. Accordingly, former Rule 16 (now Rule 15) was amended to state that the training must be conducted under the supervision and guidance of a registered pharmacist and that this supervision and guidance must comply with the 'criteria' (the Accreditation Standards). The Accreditation Standards for the Five Year Fully Integrated Master's Degree Programmes in Pharmacy will require the academic institution to have appropriate supervision mechanisms by a registered pharmacist in place, particularly in the event of a registered pharmacist not being available in any of the training establishments that fall to be considered under former Rule 16(1) (b), (c) and (d) [now Rule 15(1)(b),(c) and (d)].</p> <p>With regard to the minimum of at least four months during the First Semester of the fourth year, the PSI recognises the challenges this may present students, academic institutions and practitioners and accordingly this Rule (now Rule 14) was amended to allow for the period of at least four months to be undertaken at any time during the fourth year of the course.</p>

		welcomed and should be considered.	
15	Eoin Fleming	<p>Strongly Disagree</p> <p>The provision of in-service practical training is a worthwhile ambition and it is important to incorporate this into the new 5-year MPharm programme. However the provision of such training has proven the most contentious issue during the development of the MPharm. Key to the successful establishment of the programme is the provision of adequate positions and the VOLUNTARY provision of training by tutor pharmacists. It is essential that this be incorporated into the legislation to make it clear to the profession that without this voluntary engagement the provision of qualified individuals will be curtailed. Furthermore, considering that the provision of placements is to be dealt with through a central office of experiential learning it is I believe critical that the legislation recognises this office as the sole route through which placements recognised by the PSI can be established (if this is indeed what the PSI want). Without these two elements being legislated for (i.e. the voluntary provision of adequate placements, and recognition of the OEL as the sole provider of placements) it remains possible that an Institutional provider may opt to pay tutors through privately organised placements to provide training for a proportion of their students. I believe the establishment of such a two tiered system for the education of pharmacists in Ireland would be very damaging, leading potentially to competition between the OEL and the</p>	<p>Noted. Each academic institution must remain individually responsible for the quality of the programme it delivers. The PSI is not proposing at this juncture to require that an Office of Experiential Learning (OEL) be placed on a statutory footing. However, the PSI Accreditation Standards for the Five Year Fully Integrated Master Degree Programmes in Pharmacy will provide, in Standard 7.8, that there must be <i>'appropriate levels of collaboration with regard to the quality assurance of practice placements between the School and the other Schools of Pharmacy in the State so as to facilitate and maximise the benefits of practice placements as a critical national resource'</i>. The Accreditation Standards (Standard 3.6) will also provide for Council of the PSI to approve requirements relating to consistency of approaches to placements.</p> <p>Regarding the placing on a statutory footing of a requirement that tutors operate on a voluntary basis, this could give rise to competition concerns, as could indeed a scenario where tutors are paid to supervise a discrete cohort of students on an exclusive basis.</p>

		universities for the delivery of paid placements.	
16	Prof. Anne Marie Healy, TCD	Disagree  'Pharmaceutical Department of a hospital' should be replaced by 'Pharmacy or Pharmaceutical Department of a hospital'	Noted and agreed. The wording in former Rule 15(1)(b)[now Rule 14(1)(b)] has been revised to reflect the wording in former Rule 16(1)(a) [now Rule 15(1)(a)] which makes reference to 'the pharmacy department of a hospital'.
18	Sarah Foley, HPAI	No definition available of either "retail pharmacy" or "pharmaceutical department of a hospital in the state" (Rule 15(1)(b)) or in Rule 16 (1)(a), "a pharmacy open to the public" or "the pharmacy department of a hospital" in the SI <i>Interpretation</i> in Rule 4.  Training must be at least 12 months of in-service practical training. The first 4 months will take place during year 4 and the second placement (eight months) during year 5 of the course must be under direct supervision of a tutor pharmacist in a registered pharmacy business or in the 'pharmaceutical' department of a hospital. This term needs to be changed to 'pharmacy' department.	Noted. The terminology in the SI is intended to give effect to the provisions in the Professional Qualifications Directive that require 'four years of full-time theoretical and practical training at a university (...)' and the mandatory six month traineeship 'in a pharmacy which is open to the public or in a hospital under the supervision of that hospital's pharmaceutical department'.  Noted and agreed. The wording in former Rules 15(1)(b) [now Rule 14(1)(b)] and former Rule 16(1)(a) [now Rule 15(1)(a)] has been revised to assure consistency and will refer to 'the pharmacy department of a hospital'.

### **RULE 15 (2) – (4)**

**Do you agree that the definition of a "connected person" is adequately defined for the purposes of the in-service practical training elements of the 5-year programme?**

No	Name	SUBMISSION	PSI RESPONSE
2	Michelle Kirrane	Disagree  <i>"...if a connected relative is exercising any supervisory or management role in that establishment..."</i>  I expect in this case that the supervisory or management role referred to relates directly to the pharmacy department or	Noted. The purpose of former Rule 15(2) [now Rule 14(2)] and the concept of 'connection' is to remove the risk of any undue influence being exercised over the tutor-student relationship. In this Rule, the 'establishment' that is referred to should be construed as linked to the definition of 'training establishment' in former Rule 4 (now Rule 3). Therefore,



		<p>to a pharmacist role within the department. Does this need to be clarified? If the aunt of a person on placement is a technician with a management role e.g. Purchasing Manager in the pharmacy department, will this be restricted establishment for the trainee? I would expect not but I am not sure whether this statement is very clear in such potential cases.</p> <p>Furthermore, if the connected person has a management or supervisory role elsewhere in the establishment e.g. a ward manager in a hospital, I would expect that this will not restrict the trainee. This may not be clear to persons reading the document.</p>	<p>to remove any ambiguity, former Rules 15(2) and 15(3) [now Rules 14(2) and 14(3)] have been amended to make specific reference to ‘training establishment’ and not ‘establishment’.</p>
3	Fiona McNeela	<p>Agree</p> <p>This rule is important to prevent any student from having an unfair advantage with regard their tutor</p>	<p>Noted and agreed.</p>
14	Claudine Hughes, NMIC	<p>Agree</p> <p>Schedule 1 not attached - assume that connected relative also includes husband/wife and parent?</p>	<p>Yes. For ease of reference, Paragraph 9 of Schedule 1 of the Pharmacy Act 2007 defines “connected relative” as: <i>‘in relation to a person, means a spouse, a man and woman who are not married to each other but are co-habiting as husband and wife, parent, brother, sister, child or spouse of a child of the person;’</i></p>
16	Prof. Anne Marie Healy, TCD	<p>Neutral</p> <p>Since the definition of ‘connected relative’ has been extended to include a grandparent, uncle, aunt, niece or nephew of the person, it no longer matches that in paragraph 9 of Schedule 1 to the Act. Accordingly, it would be more straightforward to provide the full definition here.</p> <p>Suggest to insert ‘also’ as follows:</p> <p>(4) In this Rule, the term ‘connected relative’ has the same meaning as in paragraph 9 of Schedule 1 to the Act and includes <u>also</u> a grandparent,</p>	<p>Noted. It is standard practice in legislative drafting to make reference to sections contained in primary sources of legislation without reciting in full the referenced section.</p> <p>Noted and agreed. The word ‘also’ has been inserted into former Rule 15(4) [now Rule 14(4)].</p>

		<p>uncle, aunt, niece or nephew of the person.</p> <p>With regard to 15 (3), “the pharmacy owner” suggests a single owner. Clarity is required with regard to corporate bodies and shareholders, who may not necessarily exercise a management or supervisory role.</p>	<p>Noted. Section 2 in the Pharmacy Act 2007 defines “pharmacy owner” as meaning ‘a person carrying on a retail pharmacy business and, as such, being entitled to the profits and liable to sustain the losses of the business and “pharmacy”, when used with reference to a pharmacy owner, means a retail pharmacy business.’ The definition in the Pharmacy Act provides the necessary clarity and removes any potential for ambiguity.</p>
17	Maureen Reidy	<p>Neutral</p> <p>What if the connected person is related by marriage? What if the connected person is a close friend or close family friend?</p>	<p>Noted. The draft SI extends the connected relationship to include, as per Paragraph 9 of Schedule 1 of the Pharmacy Act 2007: ‘in relation to a person, means a spouse, a man and woman who are not married to each other but are co-habiting as husband and wife, parent, brother, sister, child or spouse of a child of the person;’. Those connected by marriage that are covered by this definition are spouses, son/daughter-in-law. As parents-in-law and brother/sister-in law are not covered by this definition, former Rule 15(4) [now Rule 14(4)] has been amended to include these additional connected relationships.</p> <p>The constraints of a legislative instrument would limit the ability to suitably define a ‘close’ friend. However, it must be borne in mind that a tutor pharmacist must also, at all times, be operating under the statutory Code of Conduct for Pharmacists.</p>
18	Sarah Foley, HPAI	<p>The person pursuing the Master’s degree must have no connection with the establishment or the pharmacist tutor (Rule 15(2)) – does this imply that the student cannot have a relation or connection in the Hospital or just the pharmacy department of the Hospital?</p>	<p>In this Rule, the ‘establishment’ that is referred to should be construed as linked to the definition of ‘training establishment’ in former Rule 4 (now Rule 3). Therefore, to remove any ambiguity, former Rules 15(2) and 15(3) [now Rules 14(2) and 14(3)] have been amended to make specific reference to ‘training establishment’ and not ‘establishment’.</p>

**RULE 16 (1) – (2)**

**Do you agree that the types of training establishments are adequate for the purposes of the mandatory four months of in-service practical training?**

No	Name	SUBMISSION	PSI RESPONSE
14	Claudine Hughes, NMIC	<p>Agree</p> <p>Is it the responsibility of the institution or the student to obtain such placements?</p>	<p>Under the restructuring of the qualification, the responsibility for the sourcing of placements will move from the student to the academic institution. All academic institutions will be required under the PSI's Accreditation Standards for the Five Year Fully Integrated Master's Degree Programmes in Pharmacy to have <i>'appropriate mechanisms in place to assure and enhance the quality of all practice placements including: (...) the allocation of students to training establishments.'</i> Also, each institution will be required to have appropriate and timely mechanisms in place for students to support them in <i>'securing and maintaining placements for the practice-placement elements of the Professional Degree Programme with appropriate supervision and tutor pharmacists who meet the recognition requirements as approved by the PSI Council from time to time)'</i>.</p> <p>The Accreditation Standards will also require the academic institutions to collaborate with regard to the sourcing and the quality assurance of placements as well as the support mechanisms available to both tutors and students on placement. The academic institutions are in the process of establishing a proposed 'Office of Experiential Learning' as a shared service resource to facilitate the practice-placement elements of the new programme for all stakeholders.</p>
15	Eoin Fleming	<p>Agree</p> <p>I believe additional clarification is needed regarding the definition of a Pharmaceutical Science department in 1.b, so as to unambiguously include</p>	<p>Noted. The intention of former Rule 16(1)(b) [now Rule 15(1)(b)] is that it should encompass those pharmaceutical science departments that are involved in the education and training of pharmacists. This is stated explicitly in</p>

		biological and life science departments	former Rule 16(1)(b) [now Rule 15(1)(b)] and would therefore appear to be unambiguous.
16	Prof. Anne Marie Healy, TCD	<p>Disagree</p> <p><i>“16. (1) (c) (ii) the wholesaling of medicinal products by an authorised wholesaler;”</i></p> <p>Suggest this should be extended to include the wholesaling of medicinal products by a person who has manufactured or imported those products under and in accordance with the provisions of a manufacturer’s authorisation, as recognised by the Medicinal Products (Control of Wholesale Distribution) Regulations 2007 as amended.</p> <p>Part (d) could be amended to include ‘the health service’ – it would be difficult to use HIQA, as the wording stands at the moment.</p>	<p>Noted. However, the persons being referred to here are already covered in item (i) in this sub-paragraph and no amendment is required.</p> <p>Noted and agreed. It would be important that an agency such as HIQA be included as a potential practice placement for student pharmacists other than in their fifth year. Accordingly former Rule 16(1)(d) [now Rule 15(1)(d)] has been amended to include the delivery of health services in the list of areas.</p>
18	Sarah Foley, HPAI	<p>No definition available of either "retail pharmacy" or "pharmaceutical department of a hospital in the state" (Rule 15(1)(b)) or in Rule 16 (1)(a), "a pharmacy open to the public" or "the pharmacy department of a hospital" in the SI <i>Interpretation</i> in Rule 4.</p> <p>Undergraduate training may take place entirely in hospital pharmacy based on the 'establishments' listed under Rule 16(1)(c). 'Hospital pharmacy' is not a term mentioned either in the primary legislation of the Pharmacy Act 2007, nor in Rule 4 – <i>Interpretation</i>.</p>	<p>Noted. The terminology in the SI is intended to give effect to the provisions in the Professional Qualifications Directive that require ‘four years of full-time theoretical and practical training at a university (...)’ and the mandatory six month traineeship ‘in a pharmacy which is open to the public or in a hospital under the supervision of that hospital’s pharmaceutical department’.</p>

### RULE 16 (3)

Do you agree that the restrictions on the eligibility of training establishments are adequate for the purposes of the mandatory four months and eight months of in-service practical training?

No	Name	SUBMISSION	PSI RESPONSE
7	Paul Gallagher, RCSI	Neutral  Formal recognition of training establishments must be the remit of the PSI since it is the statutory obligation of the PSI to enforce pharmacy legislation	Noted. The PSI ensures compliance with pharmacy and medicines legislation. The PSI must also ensure that those persons seeking to become pharmacists obtain appropriate experience. One of the mechanisms whereby this latter function is implemented is through the PSI Council decision to move to a five-year fully integrated degree with all students having placement experiences across the three main practice settings of community, hospital and industry. While the PSI ensures compliance of all registered retail pharmacy businesses with the Regulation of Retail Pharmacy Business Regulations 2008, it has no regulatory oversight of any other potential training establishment covered by former Rule 16(3) [now Rule 15(3)]. The PSI Accreditation Standards for the Five Year Fully Integrated Master's Degree Programmes in Pharmacy will place a responsibility on each of the academic institutions to have <i>'appropriate mechanisms in place to assure and enhance the quality of all practice placements including: (...) the process to select, assess, accredit and appoint tutors and training establishments; (...) appropriateness of training establishments;'</i> . The means whereby the PSI will evaluate the appropriateness of these mechanisms will be through the accreditation process. It is nevertheless accepted that an ongoing oversight by the PSI of such mechanisms would be important and this will be captured through the PSI's Accreditation Standards for the Five Year Fully Integrated Master's Degree Programmes in Pharmacy. It is therefore proposed to make this explicit in the SI and to amend to state the requirement that the approval of any training establishment by an academic institution

			must be in accordance with relevant Accreditation Standards and any related PSI Council policy/guidelines.
8	Marian Shanley	Disagree  I would suggest a four year period from a statutory or indictable offence conviction. Also, what about a summary conviction? Should there not be a lesser period of restriction for such convictions?	Noted and agreed that it should be a two year restriction for summary offence convictions and a four year restriction for a statutory or an indictable offence conviction. Accordingly, former Rule 16(3) [now Rule 15(3)] has been amended to reflect this point.
9	Pamela Logan, IPU	Agree  It is reassuring to see that a definite period of ineligibility has been applied.	Noted. Based on the submissions received regarding a two year restriction for summary offence convictions and a four year restriction for a statutory or an indictable offence conviction, former Rule 16(3) [now Rule 15(3)] has been amended to reflect this point.
16	Prof. Anne Marie Healy, TCD	Disagree  Suggest “within the two years prior to the date of commencement” if this is what is intended, so as not to invalidate in-service practical training where the owner is convicted, for example, 23 months after the date of commencement (being 19 months after a four-month training period concluded, for an offence that took place after the training concluded.  Disciplinary sanctions and convictions that arise during and after the training period need to be addressed separately. Where both the offence and the conviction take place after the training period, the training should not be invalidated.	Noted. The intention of former Rule 16(3) [now Rule 15(3)] is to enable the approval of tutors and training establishments. The two year (or four-year – see above) prohibition is intended to cover any relevant convictions received in a two/four-year period prior to the commencement of the training. In the event of a conviction occurring during a training placement, such approval would be revoked with immediate effect and any student in that facility would have to be moved to another training establishment. In order to give effect to this ‘saver’ for students, it is proposed to insert a new Rule in Part 4 that would allow the academic institution to transfer any student impacted so that the prescribed period of in-service practical training may be completed.  The PSI agrees that the training should not be invalidated if the conviction takes place after the conclusion of the training period. The construction of former Rule 16 (now Rule 15) does not give rise to a

			retrospective invalidation of training.
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**RULE 16 (4) – (5)**

**Do you agree that the number of students to be supervised by one pharmacist during the mandatory four months of in-service practical training should be at the discretion of the academic institution?**

No	Name	SUBMISSION	PSI RESPONSE
NO COMMENTS			

**Do you agree that the number of students to be supervised by one tutor pharmacist during the mandatory eight months of in-service practical training can be increased, at the discretion of the academic institution, as an exception to the 1:1 student/tutor relationship, provided that the academic institution can satisfy itself as to appropriate access by students to the tutor pharmacist at the placement premises?**

No	Name	SUBMISSION	PSI RESPONSE
3	Fiona McNeela	<p>Disagree</p> <p>I think it's important that each tutor has responsibility for one student only as it gives that student a better opportunity during the placement. If the tutor/student ratio increased I don't think students would be in agreement with this</p>	<p>Noted. Former Rule 16(5) [now Rule 15(5)] is providing an exception to the 'sole pupil/student' requirement in former Rule 16(4) [now Rule 15(4)] for all fifth year student pharmacists during their in-service practical training. Former Rule 16(5) [now Rule 15(5)] can only apply to training establishments at which other pharmacists are available and in a position to assist with a student's training and development. In order to ensure that satisfactory arrangements are in place, former Rule 16 (now Rule 15) has been amended to include a specific reference to the requirement in the Accreditation Standards that will require an academic institution's approval of any training establishment to comply with the relevant Standards and any related Council policy/guidelines.</p> <p>With regard to student feedback, the PSI's Accreditation Standards for the Five Year Fully Integrated Master's Degree Programmes in Pharmacy will require the academic institutions to have <i>'appropriate support for students including processes to monitor, review and take necessary corrective action'</i> with respect to assuring and enhancing</p>

			the quality of all practice placements.
5	Prof Eilis McGovern, HSE	Agree  Deviations from the 1;1 ratio should be audited on a regular basis, with a view to a more definitive recommendation in future.	Noted and agreed. The operation of this exception will be evaluated by the PSI as part of the accreditation process that will evaluate the new programmes with reference to the PSI's Accreditation Standards for the Five Year Fully Integrated Master's Degree Programmes in Pharmacy. See also comment above.
7	Paul Gallagher, RCSI	Strongly Agree  The legislation must not be too prescriptive. The PSI has adequate powers through the accreditation processes to satisfy itself with respect of quality assurance of experiential learning	Noted and agreed.
10	Anne Teresa Morgan, Boots	Agree  Whilst agree in principle that in certain approved circumstances it may be appropriate for a pharmacist to supervise more than one student for the four month period, we would have concerns that a number of students in one establishment could impinge on patient safety and the quality of experience a student may receive. We do feel there should be some guidelines detailing the circumstances that would be appropriate for more than one student so as to ensure patient safety and the quality of the experience for the student. These guidelines should also ensure that allowing more than one student per placement it is to benefit the students getting a broader range of experiences as opposed to just fulfilling the requirements of a student to get a placement.  Welcome the fact a tutor can be acting as a tutor for both a student completing their four month placement at the same time as a student completing their eight month placement.  With regard the eight month placement,	Noted and agreed. In order to ensure that satisfactory arrangements are in place, former Rule 16 (now Rule 15) has been amended to include a specific reference to the requirement in the Accreditation Standards that will require an academic institution's approval of any training establishment to comply with the relevant Standards and any related Council policy/guidelines. For instance, Standard 4.9 of the PSI's Accreditation Standards for the Five Year Fully Integrated Master's Degree Programmes in Pharmacy will require that the structure of the practice placement experiences must meet PSI Council policy as approved from time to time. This policy development will allow for the necessary mechanisms to be put in place to safeguard the quality of both the 4 month placement and the 8 month placement.  Noted.  Noted and agreed. Former Rule 16(5)



		<p>we welcome the concept that in approved situations a tutor pharmacist may take on up to two further pupils, if other pharmacists are in the position to assist in the supervision, but do feel there would need to be some approval process by the institution of the other pharmacists involved in supporting the tutor. It would be important that the institution should not only be satisfying itself as to the appropriate access by students to the tutor pharmacist at the placement premises but also to the quality of the tutoring offered by the support pharmacists</p>	<p>[now Rule 15(5)] is providing an exception to the ‘sole pupil/student’ requirement in former Rule 16(4) [now Rule 15(4)] for all fifth year student pharmacists during their in-service practical training. Former Rule 16(5) [now Rule 15(5)] can only apply to training establishments at which other pharmacists are available and in a position to assist with a student’s training and development. In order to ensure that satisfactory arrangements are in place, the above-mentioned proposed amendment to former Rule 16 (now Rule 15) will also pertain with respect to this point.</p> <p>Standard 7.8 of the above-mentioned PSI Accreditation Standards should also manage these concerns as it will require the academic institution to have appropriate mechanisms in place to assure and enhance the quality of all practice placements, including: the process to select, assess, accredit and appoint tutors and training establishments; (...) appropriateness of training establishments; (...). The intention is that this Standard will extend to all supports available to students in training establishments.</p>
14	Claudine Hughes, NMIC	<p>Disagree</p> <p>The number of students at the training establishment needs to be at the discretion of both the institution and training establishment. Would suggest a maximum of two students per institution</p>	<p>Noted. Former Rule 16(5) [now Rule 15(5)] is providing an exception to the ‘sole pupil/student’ requirement in former Rule 16(4) [now Rule 15(4)] for all fifth year student pharmacists during their in-service practical training. Former Rule 16(5) [now Rule 15(5)] can only apply to training establishments at which other pharmacists are available and in a position to assist with a student’s training and development. In order to ensure that satisfactory arrangements are in place, former Rule 16 (now Rule 15) has been amended to include a specific reference to the requirement in the Accreditation Standards that will require an academic institution’s approval of any training establishment to comply with the relevant Standards</p>

			and any related Council policy/guidelines.
16	Prof. Anne Marie Healy, TCD	<p>Neutral</p> <p>While it is agreed that the academic institution should have discretion with regard to the number of students supervised by an individual tutor pharmacist in both the 4 month and 8 month training periods, it would be appropriate for the Society to provide guidance on what would be considered ‘appropriate access’, and any other influencing factors the Society considers relevant, such as the eligibility criteria and quality control measures considered appropriate for non-tutor pharmacists.</p> <p><i>“16. (4) Subject to paragraph (5), the in-service practical training required under Rule 15(1)(b) shall be undertaken under the direct supervision of a tutor pharmacist, as his or her sole pupil, and who is based at the premises or, in the case of a hospital, at the group of premises where the in-service training is to be undertaken, notwithstanding that a person referred to in Rule 15(1)(a) may also be undertaking practical training with that tutor pharmacist.”</i></p> <p>Suggest “...notwithstanding that a person referred to in Rule 15(1)(a) or another individual not subject to training under these Rules may also be undertaking practical training with that tutor pharmacist” to accommodate situations where students of other types (e.g. on specialist postgraduate pharmacy programmes or non-pharmacy undergraduate degrees) may also be in training.</p> <p><i>“16. (5) ...other pharmacists who would be in a position to assist in the supervision of the pupil...”</i></p>	<p>Noted and agreed. The PSI Accreditation Standards for the Five-Year Fully Integrated Master’s Degree Programmes in Pharmacy will provide a requirement for Council policy to be developed with respect to ‘appropriate supervision’ of students [see Standard 8.2(c)]. Council policy will also be required in relation to the structure of the practice-placement experiences which must meet the PSI Council policy as approved from time to time (see Standard 4.9). Moreover, direct supervision by a registered pharmacist should be a mandatory requirement in all clinical settings for both the fourth and the fifth year placements. Accordingly, former Rule 16 (now Rule 15) has been amended to state that the training must be conducted under the supervision and guidance of a registered pharmacist and that this supervision and guidance must comply with the ‘criteria’ (the Accreditation Standards). The Accreditation Standards for the Five Year Fully Integrated Master’s Degree Programmes in Pharmacy will require the academic institution to have appropriate supervision mechanisms by a registered pharmacist in place, particularly in the event of a registered pharmacist not being available in any of the training establishments that fall to be considered under former Rule 16(1)(b), (c) and (d) [now Rule 15 (1)(b), (c) and (d)].</p> <p>Noted. However, as these Rules are intended to cover only the structure for the qualification appropriate for practice as a registered pharmacist, it would not be appropriate to extend their remit into the jurisdiction of other training and education programmes. The current construction of former Rule 16(4) [now Rule 15(4)] would not appear to prohibit the scenario that the proposed additional wording is seeking to address.</p>

		Clarity is required on whether such 'other pharmacists' would be required to be registered with the Society. If so, this should be specified.	As it is only those persons whose names have been entered into the Register of Pharmacists who can use the title of 'pharmacist', this Rule (now Rule 15) has been amended for the sake of clarity to reflect this registered status and now reads as 'other registered pharmacists'.
17	Maureen Reidy	Disagree  I cannot see how any busy pharmacist would have adequate to teach more than one student and also maintain his/her professional competence and standards	Noted and agreed. Former Rule 16(5) [now Rule 15(5)] is providing an exception to the 'sole pupil/student' requirement in former Rule 16(4) [now Rule 15(4)] for all fifth year student pharmacists during their in-service practical training. Former Rule 16(5) [now Rule 15(5)] can only apply to training establishments at which other pharmacists are available and in a position to assist with a student's training and development. In order to ensure that satisfactory arrangements are in place, former Rule 16 (now Rule 15) has been amended to include a specific reference to the requirement in the Accreditation Standards that will require an academic institution's approval of any training establishment to comply with the relevant Standards and any related Council policy/guidelines. Only those training establishments that have the capacity to take more than one student at any one time will be allowed to do so under the this Rule.
18	Sarah Foley, HPAI	Under Rule 16(5) there is a maximum of 3 students to one tutor pharmacist if there are other pharmacists in the establishment that would be in a position to assist in the supervision of the pupil. It is not clear from Rule 16(4) if a student is allowed to train for the full 12 months with one tutor, i.e. in the same place?	Noted. An intention of the five-year fully integrated degree is that students will have had a practice-placement experience across each of the main practice settings of community, hospital and industry. This policy will be set out in the PSI's Accreditation Standards for the Five Year Fully Integrated Master's Degree Programmes in Pharmacy which will require that there must be: '(...) a continuum of structured and quality assured practice-placement experiences throughout the curriculum from introductory to advanced, and across the

			<p><i>main practice settings of community, hospital and industry, (...)'.</i></p> <p>Accordingly, a student would therefore not be in a position to benefit from these rotations if he/she was able to remain in the same training establishment for the mandatory 12 months. Accordingly, former Rule 15(1)(b) [now Rule 14(1)(b)] has been amended to reflect this limitation and to explicitly state that the 4-month and the 8-month placements cannot take place in the same training establishment.</p>
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### **RULE 17**

**Do you agree that the eligibility criteria for tutor pharmacists are adequate for the purposes of supervising final year students in their final eight months of in-service practical training?**

No	Name	SUBMISSION	PSI RESPONSE
<b>NO COMMENTS</b>			

**Do you agree that the restrictions on the eligibility of tutor pharmacists are adequate for the purposes of supervising final year students in their final eight months of in-service practical training?**

No	Name	SUBMISSION	PSI RESPONSE
7	Paul Gallagher, RCSI	<p>Neutral</p> <p>RCSI is of the view from experience of the operation of a NPIP that under exceptional circumstance the SI must provide a mechanism to deprive a pharmacist of tutor status</p>	<p>Noted. However, as a tutor pharmacist can only be recognised by an academic institution if they have fulfilled all the requirements set down by the academic institution as required under former Rule 17 (now Rule 16), the PSI is satisfied that such recognition should not persist for an indefinite period. Indeed, it is a matter for the academic institution under former Rule 17(2) [now Rule 16(3)] to specify the requirements for tutors, following consultation with the Council. In order to explicitly state the recognition as a tutor for a defined period, former Rule 17 (now Rule 16) has been amended to limit the duration of tutor recognition to a 12-month period which shall be renewable at the discretion of the academic institution. Furthermore, the PSI's Accreditation Standards for the Five Year Fully</p>

			Integrated Master's Degree Programmes in Pharmacy, at sections 7.8 and 7.9, will set out the requirements for academic institutions to select, assess, accredit and appoint tutors and training establishments and to have appropriate mechanisms to monitor performance of all staff (...).
8	Marian Shanley	Disagree  Not sure that two years is a long enough restriction, particularly if a pharmacist has been guilty of drug offences.	Noted and agreed that it should be a two year restriction for summary offence convictions and a four year restriction for a statutory or an indictable offence conviction. Accordingly, former Rules 16 and 17 (now Rules 15 and 16) have been amended to reflect this revised position.
10	Anne Teresa Morgan, Boots	Disagree  With regard point 17. (1) (A) - The current Education and Training rules state the tutor has a minimum of 3 years' experience with 1 years' experience in the field of pharmacy practice in which he /she intends to act as a tutor. If the tutor is fulfilling the other requisite standards of knowledge, skills and experience as required by the recognised institution, One years' experience in the field of pharmacy practice should be adequate	Noted. Based on a review of the requirements in other jurisdictions which range from 1 to 3 years' experience in the field of pharmacy practice in which he/she intends to act as a tutor, the PSI is proposing to require the minimum of two years of experience for the purposes of a tutor supervising the final 8 months of a student's training under former Rule 15(1)(b) [now Rule 14(1)(b)].
16	Prof. Anne Marie Healy, TCD	Disagree  <i>"17. (1) (e) has not, within two years of the date of commencement of the relevant in-service practical training, been convicted of an offence referred to in Rule 16(3)(ii)"</i>  See comments above (Q15) [Rule 16(3)] in relation to avoiding the inappropriate retrospective invalidation of training. Suggest "within the two years prior to the date of commencement". Disciplinary sanctions and convictions that arise during and after the training period need to be addressed separately. Where both the offence and the conviction take place after the	Noted. The intention of former Rule 17(1)(e) [now Rule 16(1)(e)] is to enable the approval of tutors. The two year (or four year) prohibition is intended to cover any relevant convictions received in a two-year (or four-year) period prior to the commencement of the training. In the event of a conviction occurring during a training placement, such approval would be revoked with immediate effect and any student in that facility would have to be moved to another training establishment. In order to give effect to this 'saver' for students, a new Rule in Part 4 (Rule 17) has been inserted that allows the academic institution to transfer any student impacted so that the prescribed period of in-service practical training may be

		training period, the training should not be invalidated.	completed.  The PSI agrees that the training should not be invalidated if the conviction takes place after the conclusion of the training period. The construction of former Rule 17 (now Rule 16) does not give rise to a retrospective invalidation of training.
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## RULE 18

**Do you agree that the format and content on which students are assessed adequately addresses the requirements of a professional registration examination as part of the five-year integrated MPharm?**

No	Name	SUBMISSION	PSI RESPONSE
7	Paul Gallagher, RCSI	<p>Neutral</p> <p>Rule 18 should be expanded to include provisions specifically governing the administration of the PRE. This must be a national examination with appropriate input from recognised HEIs. The SI could mandate the creation of a supra institutional structure to facilitate this such as has occurred in Surgery with the Inter-Collegiate Committee for Basis Surgical Examinations</p>	<p>Noted. In the new SI, the qualification appropriate for practice is the Master's degree in pharmacy which must comprise a final summative examination known as the registration examination. To mandate a national examination that falls outside of the MPharm could undermine the integrity of the five year integrated degree as the qualification appropriate for practice. The PSI's Accreditation Standards for the Five Year Fully Integrated Master's Degree Programmes in Pharmacy will require each academic institution to include: '(...) a final formal summative objective structured clinical examination as part of the statutory professional examination at the end of year five that seeks to assess in an integrated manner the performance of students based on the curriculum delivered over the five years of the Professional Degree Programme.'</p> <p>The PSI, therefore, through the accreditation process, will be in a position to monitor the standard, content and format of assessment across each academic institution that delivers a 5-year Master's degree in pharmacy.</p> <p>As the Accreditation Standards will require appropriate levels of collaboration between the Schools of Pharmacy in the State with regard to the quality assurance of practice</p>

			placements, there would be no restriction on a collaborative approach by the academic institutions to the professional examination from the PSI's perspective.
12	John Barry	Disagree  To emphasise legislation and not to mention clinical competence seems a strange mix to me and a retrograde step. The Interim program has moved away from the old legislation only examination and is the better for it.	Noted. The PSI considers the assessment of clinical competence to have been encompassed by requiring the examination to also include 'performance-based assessments'. However, to render this explicit, Rule 18(2) has been amended to include a reference to the need to also assess patient consultation and counselling skills.
16	Prof. Anne Marie Healy, TCD	Neutral  The proposed Rule refers to 'the recognised institution' but in reality there are likely to be multiple recognised institutions. Clarity is required on whether there is a requirement to have a single Professional Registration Examination that is harmonised across all recognised institutions, or whether such harmonisation would be at the discretion of the institutions.	Noted. In the new SI, the qualification appropriate for practice is the Master's degree in pharmacy which must comprise a final summative examination known as the registration examination. To mandate a national examination that falls outside of the MPharm could undermine the integrity of the five year integrated degree as the qualification appropriate for practice. The PSI's Accreditation Standards for the Five Year Fully Integrated Master's Degree Programmes in Pharmacy will require each academic institution to include: <i>'(...) a final formal summative objective structured clinical examination as part of the statutory professional examination at the end of year five that seeks to assess in an integrated manner the performance of students based on the curriculum delivered over the five years of the Professional Degree Programme.'</i> The PSI, therefore, through the accreditation process, will be in a position to monitor the standard, content and format of assessment across each academic institution that delivers a 5-year Master's degree in pharmacy.  As the Accreditation Standards will require appropriate levels of collaboration between the Schools of Pharmacy in the State with regard to the quality assurance of practice

			placements, there would be no restriction on a collaborative approach by the academic institutions to the professional examination from the PSI's perspective.
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## RULE 19

Do you agree that a Code of Conduct for pharmacy students be accorded statutory effect?

No	Name	SUBMISSION	PSI RESPONSE
5	Prof Eilis McGovern, HSE	<p>Agree</p> <p>1. Rather than each institution drawing up its own code of conduct for pharmacy students, consideration should be given to the PSI drawing up a single code of conduct document.</p> <p>2. Important to emphasise the issue of professionalism in the code of conduct</p>	<p>Noted. The PSI has no legal basis in primary legislation on which to introduce a code of conduct for pharmacy students. The PSI can, however, require each academic institution to have a code of conduct for student pharmacists and this can be placed on a statutory footing.</p> <p>Noted and agreed. The PSI's Accreditation Standards for the Five Year Fully Integrated Master's Degree Programmes in Pharmacy will require that the Teaching and Learning Strategy must: <i>'(...) develop a culture of professionalism in which all teaching staff can lead by example, collegiality, civility and respect among students and staff and this must be underpinned by a clear and realistic student code of conduct that is explained, communicated and enforced to assure professional behaviour.'</i></p>
7	Paul Gallagher, RCSI	<p>Disagree</p> <p>HEIs should have discretion to prepare and approve their own code without recourse to PSI. The envisaged mechanism will create a distinct code for pharmacy student in RCSI as opposed to the current code which covers all students and foster inter-professional identity</p>	<p>Noted. The PSI would expect significant shared principles in a code of conduct that relates to all healthcare students. It would also seem necessary for such students to relate those principles to the codes of conduct that pertain to the healthcare profession for which they are preparing to enter through their education and training. For this reason, the draft SI is requiring each academic institution to establish a code of conduct that is aligned with the statutory code of conduct for registered pharmacists.</p>
10	Anne Teresa Morgan,	Agree	Noted and agreed.



	Boots	As students will be in practice placements and patient facing, it is important that their behaviour will be reflective of that of a professional.	
12	John Barry	Agree  Should there be a code of conduct for tutors?	Noted. Tutor pharmacists are also at all times operating under the statutory Code of Conduct for Pharmacists. The PSI's Accreditation Standards for the Five Year Fully Integrated Master's Degree Programmes in Pharmacy will require that: <i>'(...) 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.'</i> (Standard 3.5). Furthermore, the academic institution will be required to have to have appropriate mechanisms in place to: <i>'(...) monitor performance of all staff and the School should provide evidence as to how this is carried out and how this links to the quality enhancement through a development programme (...).'</i>
16	Prof. Anne Marie Healy, TCD	Neutral  Agreement/disagreement with Q21 would depend on the nature of the Council's influence.  At present, the Codes of Conduct for pharmacy students operated by the Schools of Pharmacy have been drawn up independently. Clarity is required on whether harmonisation across the recognised institutions is expected, resulting in a single Code of Conduct for pharmacy students, and whether it is anticipated that the Council will also influence the fitness to practise/disciplinary procedures associated with the Code. Requirements unique to individual institutions are likely to make complete harmonisation of procedures impossible.	Noted.  Noted. The PSI has no legal basis in primary legislation on which to introduce a code of conduct for pharmacy students. The PSI can, however, require each academic institution to have a code of conduct for student pharmacists and this can be placed on a statutory footing.  The PSI's Accreditation Standards for the Five Year Fully Integrated Master's Degree Programmes in Pharmacy will make specific reference to the fitness to practise mechanisms for students and how they must operate (see Standards 1.2, 2.2, 2.8, 5.4, 7.5). The intention in the new SI is not to prescribe each

			academic institution's disciplinary regimes as long as they comply with the Accreditation Standards.
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## RULE 20

**Do you agree that the provisions relating to the Certification by the Head of School of Pharmacy are adequate for the purposes of the five-year integrated MPharm leading to the qualification for practice as a registered pharmacist?**

No	Name	SUBMISSION	PSI RESPONSE
5	Prof Eilis McGovern, HSE	<p>Neutral</p> <p>20(b) in particular may be very difficult to implement in practice. The head of school would not have the professional requirements to make such a statement (psychiatrist, specialist physician etc.) and would therefore have to request this from a suitably qualified professional. This would require the consent of the student, and brings into question issues of confidentiality, voluntary disclosure etc. This also raises the issue of disability as opposed to illness - dyslexia, blindness, deafness etc. How would these be addressed?</p>	<p>Noted. However, in the interests of patient safety, it is critical that the certification by the Head of School must have regard to matters that could impact on a person's future ability to practise in a safe and competent manner.</p> <p>It must be borne in mind that all persons, when making application for registration, are required to submit a certificate that has been completed by his/her medical practitioner attesting that he/she is not aware of any reason on grounds of physical or mental health why the applicant might be unable to discharge the responsibilities of a registered pharmacist. Also, the statutory Code of Conduct for Pharmacists requires that a pharmacist should: <i>'not practise under conditions which compromise their ability to exercise their professional judgement and integrity or the quality of their practice.'</i> As the draft SI intends the student code of conduct under these Rules to have regard to the statutory Code of Conduct for registered pharmacists, this principle should be extended to students, thereby also placing the responsibility for open disclosure on students as well.</p>
7	Paul Gallagher, RCSI	<p>Neutral</p> <p>RCSI is concerned as the over-emphasis on the acquisition of competency which</p>	<p>Noted. The Pharmacy Act 2007 sets out as a function of the PSI the requirement to <i>'(...) promote and ensure a high standard of education and training for</i></p>

		is not consistent with a Level 9 (NFQ) qualification.	<i>persons seeking to become pharmacists, to ensure that those persons and pharmacists obtain appropriate experience (...)</i> . For the purposes of the PSI's duties under the Pharmacy Act 2007, the key purpose of the 5-year Master's 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. Former Rule 8 (now Rule 7) has been amended to require the PSI to have regard to the National Framework of Qualifications when developing the 'criteria' (i.e. the Accreditation Standards for the Five Year Fully Integrated Degree Programmes in Pharmacy).
12	John Barry	Neutral  Surely not allowing someone become a pharmacist for reasons of physical ill-health is discriminatory? The same could be argued about mental health. Surely if one is fit enough to complete and pass a degree it is unnecessary to have this additional caveat that gives far too much credence to "the beliefs" of a Head of School.	Noted. However, in the interests of patient safety, it is critical that the certification by the Head of School must have regard to matters that could impact on a person's future ability to practise in a safe and competent manner. Accordingly, Rule 20(b) has been amended to make reference to 'health problems' and to delete the reference to 'mental or physical ill-health problems'.
16	Prof. Anne Marie Healy, TCD	Disagree  Suggest 20(a) be rephrased as: "(a) the satisfactory demonstration of competencies as set out in the Core Competency Framework for Pharmacists".  20(b) Remove the term "mental or physical" from the above statement under b). If the word "mental" is included students may be unlikely to disclose their condition and seek the appropriate treatment. Secondly, with the appropriate medication they may	Noted and agreed. Rule 20(a) has been amended to incorporate the proposed wording.  Noted. However, in the interests of patient safety, it is critical that the certification by the Head of School must have regard to matters that could impact on a person's future ability to practise in a safe and competent manner. Accordingly Rule 20(b) has been amended to make reference to 'health

	<p>be perfectly fit to practice.</p> <p>Suggest 20(b) be rephrased as: “that he or she has not become aware of any ill-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”</p>	<p>problems’ and to delete the reference to ‘mental or physical ill-health problems’.</p>
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## RULE 21

**Do you agree that eight years is a reasonable timeframe in which a student is required to complete their education and training leading to the qualification for practice as a registered pharmacist?**

No	Name	SUBMISSION	PSI RESPONSE
5	Prof Eilis McGovern, HSE	<p>Agree</p> <p>While I agree with Q 28, there will surely be a circumstance arising where unforeseen issues will result in an application being made for an individual to complete the course in more than 8 years.</p>	<p>Noted and agreed. In order to deal with such circumstances arising, Rule 21 has been amended to provide for an extension of one year by the academic institution for exceptional circumstances. The PSI’s Accreditation Standards for the Five-Year Fully Integrated Master’s Degree Programmes in Pharmacy will provide for each academic institution to have a clear statement in place on requirements for progression through the programme which will take account of Rule 21.</p>
7	Paul Gallagher, RCSI	<p>Disagree</p> <p>7 years</p>	<p>Noted. However, based on the overall comments received during this public consultation, and based also on the UK experience which limits completion of the five year programme to an 8 year period, it is proposed to retain the period of 8 years.</p>
16	Prof. Anne Marie Healy, TCD	<p>Disagree</p> <p>In the context of a five year programme, 8 years may be too short a period of time for completion in the context of “<u>exceptional</u> student circumstances”. We recommend changing ‘shall’ to ‘should’.</p>	<p>Noted and agreed. In order to deal with such circumstances arising, Rule 21 has been amended to provide for an extension of one year by the academic institution for exceptional circumstances. The PSI’s Accreditation Standards for the Five-Year Fully Integrated Master’s Degree Programmes in Pharmacy will provide for each</p>

		<p>In the context of a 5 year degree programme, 8 years (<i>i.e.</i> three additional years) could be too short for a student who has experienced major illness/disability to resume and complete the programme. While recognising the importance of ensuring that each student's knowledge and skills are current at the point of entry to the register there should be scope for dealing with exceptional cases.</p> <p>Clarification is required with regard to the relevant starting time for students who transfer to a course from a similar course in another institution.</p>	<p>academic institution to have a clear statement in place on requirements for progression through the programme which will take account of Rule 21.</p> <p>The PSI's Accreditation Standards for the Five-Year Fully Integrated Master's Degree Programmes in Pharmacy will provide for each academic institution to have a clear statement in place on requirements for entry that must include policies on transfer credit and course waivers (...) alongside any requirements as approved by the PSI Council from time. In this connection, regard must be had to the Council policy on the Recognition of Prior Learning approved in September 2012 which sets out, <i>inter alia</i>, the requirement that credit transfer exemptions should apply only to the first year of study (policy published on the PSI website).</p>
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## RULE 22

If you wish to comment on Rule 22 please do so in the box provided.

No	Name	SUBMISSION	PSI RESPONSE
NO COMMENTS			

## SCHEDULE

Do you agree that the Schedule adequately captures the minimum standards of knowledge, skills and attitudes necessary to obtain a qualification for practice as a registered pharmacist?

No	Name	SUBMISSION	PSI RESPONSE
7	Paul Gallagher, RCSI	This Schedule should be reviewed in light of the changing role of pharmacists across EU and the focus on outcomes and competency based curricula. RCSI would like to see the professional elements strengthened with particular	Noted. The Schedule is intended to reflect the requirements set out in Directive 2005/36/EC on the recognition of professional qualifications and any amendments thereto. The PSI's Accreditation Standards for the Five-Year

		reference to professionalism, ethics, collaborative practice, behavioural science, management and leadership. RCSI also believes that the clinical side could be strengthened with particular reference to clinical pharmacy, therapeutics and prescribing science.	Fully Integrated Master's Degree Programmes in Pharmacy would be a more appropriate vehicle to reflect the developments in pharmacy practice as they evolve through the indicative syllabus.
9	Pamela Logan, IPU	<p>Disagree</p> <p>In the recent revision of the Directive on Recognition of professional Qualifications, the following activities were included in the text for pharmacists:</p> <ul style="list-style-type: none"> <li>• Preparation of the pharmaceutical form of medicinal products;</li> <li>• Manufacture and testing of medicinal products;</li> <li>• Testing of medicinal products in a laboratory for the testing of medicinal products;</li> <li>• Storage, preservation and distribution of medicinal products at the wholesale stage;</li> <li>• Supply, preparation, testing, storage, distribution and dispensing of safe and efficacious medicinal products of the required quality in pharmacies open to the public;</li> <li>• Preparation, testing, storage and dispensing of safe and efficacious medicinal products of the required quality in hospitals;</li> <li>• Provision of information and advice on medicinal products as such, including on their appropriate use;</li> <li>• Reporting of adverse reactions of pharmaceutical products to the competent authorities;</li> <li>• Personalised support for patients who administer their medication;</li> <li>• Contribution to local or national public health campaigns.</li> </ul> <p>This should be mirrored in the Schedule</p>	Noted and agreed. However, as Directive 2013/55/EU which amends Directive 2005/36/EC has yet to be transposed into Irish law, these provisions as set out will become part of the legislative framework in Ireland as Article 45(2) is specifically referenced in paragraph 1(3) of the Schedule.
12	John Barry	<p>Agree</p> <p>IT skills should be included in the list of minimum standards.</p>	Noted. The Schedule is intended to reflect the requirements set out in Directive 2005/36/EC on the recognition of professional qualifications and any amendments thereto. The PSI's

			Accreditation Standards for the Five-Year Fully Integrated Master's Degree Programmes in Pharmacy will be a more appropriate vehicle to reflect this requirement which will form part of the indicative syllabus.
13	Stephen Byrne, UCC	Agree  The PSI have omitted from the list the subject areas of Clinical Practice / Pharmacy Practice, Why?	Noted. The Schedule is intended to reflect the requirements set out in Directive 2005/36/EC on the recognition of professional qualifications and any amendments thereto. The PSI's Accreditation Standards for the Five-Year Fully Integrated Master's Degree Programmes in Pharmacy will include these requirements as core elements of the indicative syllabus.
16	Prof. Anne Marie Healy, TCD	Disagree  Under subjects in 1. (1), the study of Biopharmaceuticals/Biotechnology should be included.  The 'Professional Qualifications Directive' should be defined in Rule 4. (1).	Noted. The Schedule is intended to reflect the requirements set out in Directive 2005/36/EC on the recognition of professional qualifications and any amendments thereto. The PSI's Accreditation Standards for the Five-Year Fully Integrated Master's Degree Programmes in Pharmacy will be a more appropriate vehicle to reflect these requirements which will form part of the indicative syllabus.  Noted. However, as this Directive, including its amendments, has been defined in section 16(8) of the Pharmacy Act 2007 (as amended), it is not necessary to repeat this definition in this SI.
17	Maureen Reidy	Neutral  There is no mention of clinical and diagnostics skills, also communication skills. These skills are of profound importance in the practice of pharmacy	Noted. The Schedule is intended to reflect the requirements set out in Directive 2005/36/EC on the recognition of professional qualifications and any amendments thereto. The PSI's Accreditation Standards for the Five-Year Fully Integrated Master's Degree Programmes in Pharmacy will include these requirements as core elements of the indicative syllabus.
18	Sarah Foley, HPAI	4. 'pursue the profession of pharmacist' – should this read profession of 'pharmacy'?	Noted. The Schedule is intended to reflect the requirements set out in Directive 2005/36/EC on the recognition

			of professional qualifications and any amendments thereto. The Directive makes reference to the pursuit of the profession of pharmacist.
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**GENERAL COMMENTS**

No	Name	SUBMISSION	PSI RESPONSE
20	Cliona Loughnane, Irish Heart Foundation	<p>Over the last two years, the Irish Heart Foundation (IHF) has supported the work of the PSI as the patient representative on the National Forum for Pharmacy Education and Accreditation. The IHF will continue to work with the PSI to promote the profession's role in providing the highest level of care to patients.</p> <p>The IHF supports the reorientation of the health service to primary and community care, with a focus on health promotion, risk factor reduction and management of chronic conditions. For the cardiovascular patients we represent, pharmacy care is a frontline service, with potential to support prevention, continuing care and chronic disease management.</p> <p>The IHF promotes policy and practice changes that reduce premature death and disability from cardiovascular disease and advocates for better patient treatment and services. Without a particular expertise in the education of pharmacists, the IHF will only comment in an overall sense on the intention behind the 2014 rules. The IHF supports the development of the PSI (Education and Training) (Integrated Course) Rules 2014. The IHF supports efforts by the pharmacy profession to develop the care-giving role of pharmacists through a modernisation of the pharmacy education programme. The IHF supports all efforts to develop the role of pharmacists in patient care, including through increased integration of work placements with academic learning. In particular, we welcome the future development of a Code of Conduct for pharmacy students. The 2014 rules offer the potential to develop student</p>	Noted. The PSI welcomes the ongoing support of, and engagement with, the IHF in its efforts to develop the education model of pharmacists to first registration.



		<p>and newly qualified pharmacists with an earlier and more sustained exposure to patient care, enabling them to develop early the skills needed to meet patients' needs. In tandem with developments in the mode of education for student pharmacists, it would be favourable to see similar evolution in continuing training and post-graduate training for qualified pharmacists.</p> <p>All attempts by the pharmacy profession to improve the provision of care to patients and ultimately the health of population are to be welcomed.</p>	
21	Dr Caitríona M Fisher, Irish Medicines Board	<p>I refer to your letter of 31st January 2014 outlining the publication of a draft statutory instrument on the education and training of pharmacists, which will allow for the commencement of five year integrated Masters Degree programmes in pharmacy.</p> <p>I would like to thank you for inviting us to participate in the public consultation. We have reviewed the draft statutory instrument and generally support the approach outlined. However, we would like to raise a point in relation to Rule 16 which outlines the establishments in which in-service practical training may be taken. We would like to suggest that under Rule 16(1)(d) the range of health products over which the establishment may have remit be extended to also include blood products, tissues and cells and controlled drugs as these additional areas are also relevant to pharmacy practice.</p> <p>The main focus of the statutory instrument is on areas outside of the IMB's remit. As such we have not completed the accompanying questionnaire.</p> <p>If you have any queries, or require further clarification in relation to the issues outlined above, please do not hesitate to contact me.</p>	Noted and agreed. Former Rule 16(1)(d) [now Rule 15(1)(d)] has been amended to reflect the range of health products identified and now includes blood products, tissues and cells. The PSI considers controlled drugs to have been captured appropriately in the other categories.

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