

## **Public Consultation Responses (January 2016)**

Proposed changes to the Pharmaceutical Society of Ireland (Fees)Rules, Pharmaceutical Society of Ireland (Registration) Rules, and Pharmaceutical Society of Ireland (Education and Training) (Integrated Course) Rules necessitated by changes to Directive 2005/36/EC.

# Published PSI statutory Rules are available on the PSI website.

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No.	SUBMISSION	PSI RESPONSE
1	Wades Pharmacy	
	1. I think that it is vital in the interests of patient safety that candidates seeking registration as pharmacists in Ireland should establish their competency in the English language.  It has long been recognised that the ability to communicate effectively with colleagues and patients is essential to patient well being. It is not sufficient to leave this to individual employers as they will most likely not have the skill set to assess this requirement.	The revised Professional Qualifications Directive clarifies that the checking of the language knowledge of a professional should take place only after the host Member State has recognised the qualification ( <i>i.e. subsequent to recognition of qualification</i> ). In the case of professions with implications for patient safety, competent authorities may carry out systematic language controls. In the case of pharmacists it is proposed that in cases where an applicant has had his/her qualification recognised that, prior to registration in the case of an applicant seeking establishment in the State, the Council will be satisfied as to the language competence of the applicant through the meeting of specified standards or through verifiable practice for a specific period of time in a state in which English is an official language. Language control should be limited to the knowledge of one official or administrative language of the host Member State.
	<ul> <li>2. I feel that it is incumbent on all newly registered pharmacists to have a working knowledge of ALL of the HSE's various schemes before they are allowed to practice on their own in any pharmacy.</li> <li>3. There is the potential for a patient to be denied a vital medicine because the pharmacist is unaware that it may be dispensed under some little known variant of the HSE's sometimes labyrinthine schemes. Similarly foreign pharmacists should be familiar with all of the pharmacy regulations before being allowed to practice unaccompanied</li> </ul>	Noted. This is outside of the remit of this current consultation, and the Professional Qualifications Directive with its primary purpose being the recognition of qualifications, and the free movement of professionals, while at the same time seeking to conserve high standards of service across the EU.

#### 2 David Jordan MPSI

- 1. I think that it is vital in the interests of patient safety that candidates seeking registration as pharmacists in Ireland should establish their competency in the English language to the PSI. There are many recognised international standards which can be used for this purpose. It has long been recognised that the ability to communicate effectively with colleagues and patients is essential to patient well being. It is not sufficient to leave this to individual employers as they will most likely not have the skill set to assess this requirement. It could also lead to a conflict of interest situation where a foreign pharmacist once registered could employ themselves in their own pharmacy.
- 2. I feel that it is incumbent on all newly registered pharmacists to have a working knowledge of ALL of the HSE's various schemes before they are allowed to practice on their own in any pharmacy. There is the potential for a patient to be denied a vital medicine because the pharmacist is unaware that it may be dispensed under some little known variant of the HSE's sometimes labyrinthine schemes. Similarly foreign pharmacists should be familiar with all of the pharmacy regulations before being allowed to practice unaccompanied. Patient safety can be compromised by being returned prescriptions which should have been retained and vice versa. A period of 3-6 months working in an Irish pharmacy with a pharmacist registered with the PSI similar to the current interns should suffice to instil this knowledge.

This should apply to both EU as well as non-EU candidates. Just because a pharmacist has qualified within the EU does not give them any special insight into Irish pharmacy regulations or the workings of the HSE. Neither does it demonstrate any particular ability in the

The revised Professional Qualifications Directive clarifies that the checking of the language knowledge of a professional should take place only after the host Member State has recognised the qualification ( *i.e. subsequent to recognition of qualification*). In the case of professions with implications for patient safety, competent authorities may carry out systematic language controls. In the case of pharmacists it is proposed that in cases where an applicant has had his/her qualification recognised that, prior to registration in the case of an applicant seeking establishment in the State, the Council will be satisfied as to the language competence of the applicant through the meeting of specified standards or through verifiable practice for a specific period of time in a state in which English is an official language. Language control should be limited to the knowledge of one official or administrative language of the host Member State.

Noted. This is outside of the remit of this current consultation, and the Professional Qualifications Directive with its primary purpose being the recognition of qualifications, and the free movement of professionals, while at the same time seeking to conserve high standards of service across the EU.

English language.

### 3 Michael Tierney MPSI

There are two major points in my opinion.

Firstly, a qualified pharmacist moving to Ireland must demonstrate a fluency in English. This fluency has to be established by verbal interview. A written confirmation of fluency can be forged or written by someone other than the "pharmacist".

This has already happened in Ireland and demonstrates the flaw in the current procedure. A foreign pharmacist must not be given a PSI registration until a verbal level of fluency has been established. The candidate must also show that they can read English. It is not sufficient to say that the potential employer must establish fluency. Some of the locum agencies use PSI registration as PSI approval and do not verify fluency. A pharmacist who employs a locum via an agency must be sure of fluency.

Theoretically I am qualified to work as a pharmacist in Poland although I do not have a word of Polish.

Secondly, a qualified pharmacist moving to Ireland must work for a designated pharmacy for at least 6 months so that pharmacist can be trained into the use of all HSE schemes and can become familiar with Irish pharmacy legistlation.

The revised Professional Qualifications Directive clarifies that the checking of the language knowledge of a professional should take place only after the host Member State has recognised the qualification (i.e. subsequent to recognition of qualification). In the case of professions with implications for patient safety, competent authorities may carry out systematic language controls. In the case of pharmacists it is proposed that in cases where an applicant has had his/her qualification recognised that, prior to registration in the case of an applicant seeking establishment in the State, the Council will be satisfied as to the language competence of the applicant through the meeting of specified standards or through verifiable practice for a specific period of time in a state in which English is an official language. Language control should be limited to the knowledge of one official or administrative language of the host Member State. In proposing the framework in the amended rules, it is envisaged that particular standards will be deemed by Council to be acceptable and these will be verifiable through an independent assessment made through the mechanism of an IELTS, or TOEFL standard test. The results of these tests can be independently verified by PSI if required.

Noted. This is outside of the remit of this current consultation, and the Professional Qualifications Directive with its primary purpose being the recognition of qualifications, and the free movement of professionals, while at the same time seeking to conserve high

The most dangerous pharmacist is one who is not fluent in English, who has never worked in an Irish pharmacy; being allowed to work as a locum on their own in an Irish pharmacy. This happens currently and is a disaster waiting to happen. A pharmacy in the South East recently had to close for a period because of this type of incident and fortunately nothing serious happened.

standards of service across the EU.

#### 4 Jack Shanahan MPSI

I welcome the proposed change in relation to language competence.

Section 9.3 of the Regulation of Pharmacy Business Regulations of 2008 state specifically "and shall offer to discuss with the patient, or with the carer of such a patient, all such matters as the pharmacist, in the exercise of his or her professional judgement, deems significant....."

It is my belief that it is not possible to discharge these functions without an appropriate command of the english language, both aural and oral. The level required would surpass very basic communication and would be of an intermediate level.

I would suggest that, at a minimum, any pharmacist should meet the criteria that third level Irish colleges place on prospective students, https://myucd.ucd.ie/admissions/english-language-requirement.ezc

Noted – the Council have previously benchmarked language competence standards against those required by other national and international regulators, and will continue to keep this under review.

# Pamela Logan on behalf of the IPU Submission by the Irish Pharmacy Union to the Pharmaceutical Society of Ireland on proposed changes to the PSI (Fees) Rules, PSI (Registration) Rules and the PSI (Education and Training)(Integrated Course) Rules, necessitated by changes to Directive 2005/36/EC 19 January 2016 The Irish Pharmacy Union (IPU), the representative body for 2,160 pharmacists and 1,715 pharmacies, welcomes the opportunity to make a submission, on behalf of our members, to the Pharmaceutical Society of Ireland (PSI) on proposed changes to the PSI (Fees) Rules, PSI (Registration) Rules and the PSI (Education and Training)(Integrated Course) Rules, necessitated by changes to Directive 2005/36/EC (on the recognition of professional qualifications). We understand that, in addition to these changes, the Department of Education will produce a Statutory Instrument, to be called the European Union (Recognition of Professional Qualifications) Regulations 2016, under the European Communities Act, which will nationally implement the general provisions of Directive 2013/55/EU.

#### Changes to PSI (Registration) Rules 2008

We welcome the fact that the amending Directive clearly decouples recognition of the pharmacist's qualification and registration, thus allowing the PSI to assess language skills prior to registration. The IPU has long been concerned that pharmacists from other EU Member States were allowed to register and practise in Ireland, even if they did not have the appropriate language skills to be able to communicate with patients.

We note that the proposed changes to the PSI (Registration) Rules require pharmacists from outside the State to provide a certificate issued by an internationally recognised body or authority, recognised by the Council, attesting that the holder has attained a standard of competence in the English or Irish language sufficient to enable him or her to safely communicate with, and to treat, patients and to generally discharge his or her obligations as a pharmacist in the State, or evidence acceptable to the Council that he or she has lived and practised in a whole-time capacity as a registered pharmacist for three out of the preceding five years in a country that has English or Irish recognised as an official language of that country. We trust that the certificate required will test the pharmacist's medical counselling skills and not just be to a general language standard.

It is not quite clear from the proposed rules how pharmacists who qualified in the UK or Malta will be treated. The only two options seem to be (a) provide a certificate of language competence or (b) work as a pharmacist for 3 years. Surely there should be a third option to deal with this cohort.

Noted – the Council have previously benchmarked language competence standards against those required by other national and international regulators, and will continue to keep this under review. In proposing the framework in the amended rules, it is envisaged that particular standards will be deemed by Council to be acceptable and these will be verifiable through an independent assessment made through the mechanism of an IELTS, or TOEFL standard test. Council may require specific standards going forward which will take account of the role and practice of a pharmacist.

Noted - an amendment has been made to the proposed rules to allow that evidence acceptable to the Council that he or she has trained as a pharmacist in a country that has English or Irish recognised as an official language of that country is appropriate to satisfy language competence issues.

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	Changes to the PSI (Education and Training)(Integrated Course) Rules	
	2014	Noted.
	The current PSI (Education and Training)(Integrated Course) Rules 2014	
	allow up to a maximum of 4 months of the 12 month internship to be	
	undertaken outside the State. It is right that the proposed change	
	facilitates individuals who commenced training under the 2008 Rules to	
	avail of this.	
	Changes to the PSI (Fees) Rules 2014	Noted.
	We concur that the principle of equitable fees should be adhered to	
	irrespective of whether an applicant uses the current paper system for	
	registration or the new European Professional Card system.	
	General Comments	Noted.
	The number of amendments to the Principal Rules under the Pharmacy	
	Act 2007 is fast becoming unwieldy. We know how problematic this has	
	become with our Medicinal Products Regulations and Misuse of Drugs	
	Regulations. We would urge the PSI to ensure that any proposed	
	change to the Principal Rules is done by reprinting the whole Rules as	
	one document, rather than having to contend with lots of individual	
	amendments.	
6	Matthew Lynch on behalf of RCSI	
	RCSI as the education institutional contracted by the PSI to provide the	Noted.
	National Pharmacy Internship Programme (NPIP) on its behalf is	
	pleased to comment as part of the aforementioned public consultation.	
	We understand that the proposed changes to the various PSI Rules arise	
	from the amendment of Council Directive 2005/36/EC (Professional	
	Qualification Directive) by Council Directive 2013/55/EU to include	

Article 55a which provides for the recognition of professional traineeships carried out in another Member State. Insofar as RCSI is concerned, the key rule change proposed is that contained in the draft Pharmaceutical Society of Ireland (Education & Training)(Amendment) Rules 2016 which provides for students completing the NPIP to undertake up to four months of the required twelve month period of supervised training in a training establishment outside of the State.

In accordance with the existing Pharmaceutical Society of Ireland (Education and Training) Rules 2008 (hereinafter "the Rules") which regulates all matters pertaining to the NPIP, the legal authority for the approval of NPIP training placements, including training establishments and supervising tutors vests exclusively in the PSI. This will remain unchanged should these amendment Rules be promulgated. However, the proposed Rule changes appears to gives rise to a number of concerns for RCSI as follows:

- 1. Overseas Training Establishments: In accordance with PSI requirements, RCSI operates the Central Application and Selection Process (CAASP) to facilitate pharmacy undergraduate students identifying training placements. It will not be possible to extend the scope of this process to include training establishments outside of the State, therefore students will need to engage with the PSI separately to arrange these out of State placements and organise for their approval. This will have implications for these students organising the remaining period of their 12 month training in Ireland which cannot be facilitated through CAASP and will need to be addressed. It would appear that the PSI will also have to determine whether it will approve periods of practical training in all of practice setting types that are currently approved within the State.
- 2. Tutor pharmacist training: The PSI will have to be satisfied that the intended pharmacist supervising the out of State period of training fulfils the legal requirements set down in Rules 19 of the Rules. The PSI

Noted. In relation to the amendment to the Pharmaceutical Society of Ireland (Education and Training) (Integrated Course) Rules 2014 which will amend the Pharmaceutical Society of Ireland (Education and Training) Rules 2008, it will be necessary for the PSI to agree policies and procedures to be developed to give effect to the revised 2008 Rules. A policy in relation to the recognition of training establishments will be required and the PSI would propose to work closely with the RCSI in the development of any such policy and procedure in light of the operation by the RCSI of the NPIP on behalf of the PSI.

Noted. In relation to the amendment to the Pharmaceutical Society of Ireland (Education and Training) (Integrated Course) Rules 2014 which will amend the Pharmaceutical Society of Ireland (Education and

will then need to notify RCSI of the details of the pharmacist who will supervise that training. Furthermore, they will have to complete tutor training as provided by RCSI and approved by the PSI. At present, tutor pharmacists are required to attend a training workshop in a location in Ireland. RCSI will not be able to provide such training outside of the State or facilitate individual requests for training outside the designated training schedule.

- 3. Assessment of Competency –A key function of tutor pharmacists supervising interns in the NPIP is assessing their intern's competency in accordance with the PSI's Core Competency Framework (CCF). In order to be eligible to present for the PRE, tutors must declare that the intern whose training they supervised has reached the required "Level 4" rating in the various behaviours of the CCF. If up to four months of this training is now to be completed under the supervision of a pharmacist outside of the State who is not required to practise in accordance with PSI's CCF, it does give rise as to concern as to whether this pharmacist can be involved in the assessment of competency for that intern.
- 4. Academic programme- In addition to completing the period of supervised practical training, interns are required to complete an academic programme comprising six taught modules and a research module. This programme is predominantly delivered online over the course of the training period and requires interns to actively engage and participate in the delivery of each module over its duration. The nature of the research conducted as part of the research module is determined according to the practice area where the intern is completing their practical training at the time of its conduct. In circumstances where an intern is completing part of their training outside of the State, RCSI would need to be satisfied that this wouldn't interfere with their ability to engage with and discharge the

Training) Rules 2008, it will be necessary for the PSI to agree policies and procedures to be developed to give effect to the revised 2008 Rules. A policy in relation to the recognition of tutor pharmacists, including their training requirements, will be required and the PSI would propose to work closely with the RCSI in the development of any such policy and procedure in light of the operation by the RCSI of the NPIP on behalf of the PSI.

Noted. In relation to the policies and procedures to be developed to give effect to the revised 2008 Rules, a policy in relation to the type of placement to be completed in the State and outside of the State, and the timings of such placements, will be required and the PSI would propose to work closely with the RCSI in the development of any such policy and procedure in light of the operation by the RCSI of the NPIP on behalf of the PSI. The provisions of the 2008 Rules will remain in force with respect to the responsibilities of a tutor pharmacist for statutory declaration submission on the completion of a student's placement.

Noted. In relation to the policies and procedures to be developed to give effect to the revised 2008 Rules, a policy in relation to the type of placement to be completed in the State and outside of the State, and the timings of such placements, will be required and the PSI would propose to work closely with the RCSI in the development of any such policy and procedure in light of the operation by the RCSI of the NPIP on behalf of the PSI.

requirements of the academic programme for that duration. Furthermore, interns are required to attend at RCSI for sessions associated with NPIP e.g. Block Attendance Week and Induction Day. RCSI would need to be satisfied that an intern completing training outside of the State would still attend these mandatory events.

- 5. 4 month period of training The draft Rules propose that a period of training, up to a maximum of four months of the overall 12 months may be completed outside of the State. At present, the minimum period of practical training recognised by the PSI is of six months duration. Periods of training of less than six months are only approved in exceptional circumstances by the Council on the recommendation of the Professional Development & Learning Committee. The provision in law now for a 4 month period of training outside of the State appears to be conflict with the Rules and may require further consideration.
- 6. Student Support Services RCSI provides comprehensive support services to interns completing the NPIP including the provision of a Practice Liaison Pharmacist and a Programme Director of Student Affairs. RCSI would be concerned that interns completing periods of practical training outside of the State may be at a disadvantage in terms of accessing and availing of these student supports. RCSI would therefore need to be satisfied that this would not arise and that interns could be adequately supported while completing training outside of the State.
- 7. Existing PSI RCSI Agreement RCSI wishes to note that its current agreement with the PSI does not provide for any intern completing part of their training outside of the State. Accordingly, the introduction of these draft Rules would appear to necessitate a review of the current agreement. RCSI in accordance with its agreement with the PSI for the delivery of the NPIP receives a fixed application fee from the PSI in respect of each intern completing the programme. This fee has been determined on the basis that all interns would complete their practical training within the State. RCSI wishes to note that it is not in a

Noted. The proposed amendment is requiring PSI approval in advance of the circumstances in which a period of in-service practical of less than 6 consecutive months' duration shall be recognised by the Council, thereby removing any conflict with the 2008 Rules.

Noted. As mentioned above, in relation to the policies and procedures to be developed to give effect to the revised 2008 Rules, a policy in relation to the type of placement to be completed in the State and outside of the State, and the timings of such placements, will be required and the PSI would propose to work closely with the RCSI in the development of any such policy and procedure in light of the operation by the RCSI of the NPIP on behalf of the PSI.

Noted. It is not foreseen that this amending provision will require any additional costs to be borne by the PSI or by the RCSI as the provider of the in-service practical training programme. As contractual matters fall outside of the scope of this public consultation, the PSI does not propose to comment on the contract in this document. It is worth noting that the 2008 Rules will remain the underpinning legislation for the operation of the contract once the Directive has been transposed

position to bear any additional costs that may accrue from interns completing part of their training outside of the State.

RCSI acknowledges in full the legal imperative that requires an amendment to the Rules arising from Article 55a of Council Directive 2013/55/EU. In light of the aforementioned concerns, RCSI has reviewed the proposed rule change and requests that the PSI consider the following proposed changes to the draft text.

a. RCSI is concerned that the proposed amendment contained in Draft Rule 5 may not provide a sufficiently robust legal basis to address its concerns identified herein. Furthermore, it is concerned that in its current form, it creates contradicting legal provisions without any legal mechanism to address any fall-out that may arise as a result.

Article 55a.2 of Council Directive 2005/36/EC (as amended by Council Directive 2013/55/EU) provides as follows

"Recognition of the professional traineeship shall not replace any requirements in place to pass an examination in order to gain access to the profession in question. The competent authority shall publish guidelines on the organisation and recognition of professional traineeships carried out in another Member State or in a third country, in particular on the role of the supervisor of the professional traineeship."

Accordingly, RCSI advises that Draft Rule 5 be amended to include the following:

"The Council , in agreement with any party contracted to provide the educational in-service practical training programme on its behalf , shall publish guidelines which detail its requirements for the recognition of any period of in-service practical training completed outside of the

into Irish law.

Noted. As set out above, the PSI recognises that it will be necessary for the PSI to agree policies and procedures to be developed to give effect to the revised 2008 Rules and would propose that it would work closely with the RCSI in the development of any such policy and

	State in another Member State of the EU/EEA".	procedure in light of the operation by the RCSI of the NPIP on behalf
		of the PSI.
	These guidelines could then address the various concerns identified by	
	RCSI and provide a means to address any contradictory legal situations	
	that may arise from the introduction of draft Rule 5 in its current form.	
	b. Draft Rule No.5 proposes permitting up to a maximum of 4	Noted. Article 55a of Directive 2013/55/EU makes specific reference
	months of the 12 months in service practical training programme to be	to the recognition of the professional traineeship in either another
	undertaken "outside of the State". Article 55a.1 limits this to	Member State or in a third country. Limiting 'outside of the State' to
	traineeships carried out in another Member State. Accordingly, RCSI	another EU Member State only may not reflect the requirements
	advises that "outside of the State" be amended to "outside of the State	agreed by the European Parliament and the Council of the European
	in any other Member State of the EU/EEA".	Union when agreeing this aforementioned Directive.
7	Thomas Doody MPSI	Official when agreeing this aforementioned birective.
,	•	Note that the control of the control
	I would like to raise concern in relation to the proposed extra fees to be levied due to this EU directive.	Noted – there are no new fees proposed. The proposal relates to the
	be levied due to this EU directive.	ability to levy a fee when an applicant uses the new EPC route for
	I do not find it acceptable that the current high fees will not be able to	recognition, and the intent is to ensure that all applicants will be
	cover this extra cost of producing cards and other duties ancillary to	subject to the same fee regime irrespective of application route.
	these proposed changes.	
	these proposed changes.	
	Keeping Ireland in line with such changes should be viewed as a core	
	part of the remit of the PSI and not as an excuse to charge more fees.	
	These EU directives are to be welcomed however it must be done to fit	
	in with your current fee structure.	
8	Peter Twomey MPSI	
	A. Proposed draft Pharmaceutical Society of Ireland (Registration)	
	<u>Rules</u>	
		Noted - an amendment has been made to the proposed rules to allow
	S 11 of the draft Pharmaceutical Society of Ireland (Registration)	that evidence acceptable to the Council that he or she has trained as a
	(Amendment) Rules 2016 states;	pharmacist in a country that has English or Irish recognised as an
		official language of that country is appropriate to satisfy language
		ornered language of that country is appropriate to satisfy language

"In the case of an applicant whose professional qualification in pharmacy was awarded outside the State, the application shall be accompanied by—

- (a) a certificate issued by an internationally recognised body or authority, recognised by the Council, attesting that the holder has attained a standard of competence in the English or Irish language sufficient to enable him or her to safely communicate with, and to treat, patients and to generally discharge his or her obligations as a pharmacist in the State, or
- (b) evidence acceptable to the Council that he or she has lived and practised in a whole-time capacity as a registered pharmacist for three out of the preceding five years in a country that has English or Irish recognised as an official language of that country."

I believe a further amendment should be made to this rule to exempt pharmacists who received their professional qualification in principally English speaking jurisdictions within the EEA, i.e. Great Britain, Northern Ireland or Malta or where they have undergone studies in a pharmacy course taught through the medium of the English language within the EEA (e.g. the English programme at the School of Pharmacy, Semmelweis University, Budapest, Hungary), from being required to provide evidence of English language proficiency. Studying pharmacy through the medium of English demonstrates appropriate knowledge of the English language and any extra proof of language competence requested for such pharmacists is an unnecessary barrier to the freedom of movement of professionals.

competence issues

Furthermore, the draft rules do not address assessing the requirement for an applicant to have appropriate knowledge of Irish pharmacy legislation. It should be noted that a registrant who was trained in Ireland undertakes a module in pharmacy law during their undergraduate degree and is examined on pharmacy law during the professional registration exam. Registrants trained outside of the Sate do not have such a luxury, an in the interests of patient safety, I believe such an applicant should demonstrate knowledge of Irish pharmacy law. I propose the inclusion of a requirement for such an applicant to either provide a certificate that they have undertaken appropriate training in Irish pharmacy legislation from a body recognised by the PSI, or undertake a three month in service practical training programme under the direct supervision of a tutor pharmacist in a registered pharmacy within the State with a specific training focus on pharmacy law and best practice in Ireland.

Noted. This is outside of the remit of this current consultation, and the Professional Qualifications Directive with its primary purpose being the recognition of qualifications, and the free movement of professionals, while at the same time seeking to conserve high standards of service across the EU. In recognising a qualification the PSI is not in a position to assess the knowledge outlined.

I would like to state that I disagree with the continued inclusion of the provision which prevents a pharmacist from registering with the PSI in the case of undischarged bankruptcy (s14 (1) (f) of the Pharmacy Act 2007 and s10 (g) of the Pharmaceutical Society of Ireland (Registration) Rules 2008), as this is out of step with other healthcare professions and I believe that this is an opportunity for the PSI to encourage the legislature to remove it.

Noted. This is outside of the remit of this current consultation. PSI position has been supportive of the removal of this provision.

B. <u>FAQ document on Modernisation of the Professional</u>
Qualifications Directive

Question 7 of the FAQ document (available from: http://europa.eu/rapid/press-release\_MEMO-13-867\_en.htm) states; "The European professional card will in essence be an electronic

Noted – consideration will be given to the retention of the current Pharmacist Card distributed at the time of Continued Registration.

certificate to be exchanged between competent authorities via the Internal Market Information System (IMI). It should accordingly **not** take the form of a smart card or any other type of physical card as this would run the risk of falsification or becoming outdated".

I have found the physical European Professional Card currently received by pharmacists registered with the PSI to be useful in proving my qualification as a pharmacist throughout Europe. I believe some form of a physical universally recognised card should be retained by the PSI.

This submission does not purport to represent the views of my employer(s), clients or business partners and is made on a personal basis

This however will not be linked to the EPC as outlined in the Directive and Implementing Regulation.

## 9 Margaret Doherty MPSI

Changes that simplify the process by which pharmacists qualified in Ireland can move to other EU counties and by which pharmacists from other EU countries can move to Ireland are to be welcomed but the the key requirement of patient safety must always be to the forefront. The needs of patients supersede those of professionals. Two matters have to be addressed in any proposed changes.

The main problem that free movement has posed to date has been in influx of pharmacists who do not have the high standard of English that is required for patient-facing practice. Existing provisions for self-declaration have been woefully inadequate and passing the burden of establishing the standard of English onto employers is impractical and unfair. Only a recognised English language qualification that specifically tests for knowledge of the language in a healthcare setting should be acceptable. Having worked in an English speaking country is NOT an acceptable alternative as there is no way of checking how much English, if any, the applicant used in their daily work. Those who have been working in an English speaking country should have no difficulty

Noted - an amendment has been made to the proposed rules to allow that evidence acceptable to the Council that he or she has trained as a pharmacist in a country that has English or Irish recognised as an official language of that country is appropriate to satisfy language competence issues.

acquiring a recognised qualification. The only exception should be for those who have gained their primary degree through the medium of English.

Another issue is a lack of understanding of Irish pharmacy law and practice, particularly among pharmacists from EU counties where it is not the usual practice to engage directly with patients in the manner that is necessary here. Applicants should be required to complete a module in Irish pharmacy law so that they can safely deal with matters like knowing which medicines are prescription-only and the requirements for supply of controlled drugs and to engage in supervised practice before taking on any role where they are in sole charge of a pharmacy.

Noted. This is outside of the remit of this current consultation, and the Professional Qualifications Directive with its primary purpose being the recognition of qualifications, and the free movement of professionals, while at the same time seeking to conserve high standards of service across the EU. In recognising a qualification the PSI is not in a position to assess the knowledge outlined.