



Consultation Report:
Consultation on proposed Rules to amend the
Pharmaceutical Society of Ireland (Registration)
Rules 2008 as amended

Version 1

14 May 2020

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Introduction

This report summarises the feedback received during the short public consultation (28 April – 4 May 2020) process on the proposed Rules to amend Pharmaceutical Society of Ireland (Registration) Rules 2008 as amended

Background

The PSI decided to propose changes to the existing statutory rules which set out requirements for first time recognition and registration for applicants who first qualified in a Third Country. This is being done as a part of current initiatives to meet challenges arising in the context of the COVID-19 emergency and will be linked to the duration of the emergency.

The PSI along with other regulatory and public bodies has had to examine how it carries out its regulatory functions during this unprecedented time. It has been and will be necessary to make changes to deal with real and potential challenges that are evolving and arising.

In the context of the current Covid-19 public health emergency, and possible shortfall of health professionals and/or skills, the PSI proposes an amendment to the Rules that will provide limited flexibility around consideration of third country applications for recognition of qualifications, with subsequent entry to the Pharmacist Register.

Under the current Pharmaceutical Society of Ireland (Registration) Rules 2008, a qualified third country applicant has to undertake an Equivalence Examination and the Professional Registration Examination in order to have their qualification as a pharmacist recognised as a qualification appropriate for practice.

The proposed amendment will facilitate the PSI Council to adjust its processes, and in certain circumstances allow the Council to recognise an applicant's third country qualification without requiring the candidate to undertake the two examinations. This will only occur in circumstances where the Council, in accordance with the requirements of the Pharmacy Act 2007 as amended, and its public safety remit, has absolutely no doubt that the training and education, standard of examinations and qualifications are of a standard not lower than the national qualification standard.

The proposed amendment will allow the Council to implement a process which will be grounded in an evidence-based assessment of the applicant's qualification. The evidence-based assessment process will be informed by:

- knowledge of the historic outcome of equivalence examinations over the last 10 years,
- knowledge of the accreditation and quality structures of the country of origin of the qualification, and
- an assessment of the equivalence of the qualification with the minimum requirements of the Professional Qualifications Directive.

The amendment will also enable the PSI Council subsequent to making a decision, to issue a certificate to the applicant which recognises that the applicant holds a qualification

appropriate for practice.

The proposed amendment will only apply for the duration of the COVID-19 pandemic.

The proposed Rules to amend Pharmaceutical Society of Ireland (Registration) Rules 2008 as amended (see Appendix C) were presented to Council at its meeting on 23 April 2020. The Council approved the proposed Rules for public consultation.

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

About the consultation

The public consultation opened on 28 April 2020 and closed on 4 May 2020.

The consultation was notified to PSI registrants in a Covid-19 email update and notified more broadly to the public on the PSI website, and through social media.

12 targeted stakeholders (see Appendix A) were made aware of the consultation through email. The targeted stakeholders were chosen as they were deemed to be particularly affected by, or would have competencies of relevance for, the proposed changes.

Response to the consultation

In total **n=257** email responses were received to the public consultation.

Responses are in the form of emails, in the respondents' own words. An estimation of the number of submissions touching on the main themes was conducted and is included below.

Approximately 10% of the respondents agreed with the proposed change to the statutory rules.

A number of themes emerged and this report identifies the main themes, and provides further information to address issues arising.

Discussion

Targeted Consultation

Of the 12 targeted stakeholders emailed, 3 responded to the consultation (see appendix B). All 3 respondents agreed with the proposed changes to the legislation without further comments.

Summary of themes and PSI responses to issues raised.

The main themes and suggestions of the 257 responses are described and addressed below.

I. Competency and Patient Safety

Concerns over whether the pharmacists that will register under the amendment will have adequate competence, as the exams will not be in place for assessment

Concerns that patient safety will be at risk

Over 40 % of responses expressed concerns for patient safety and competencies

PSI Response

The amendment will allow for the PSI Council in certain circumstances to recognise an applicant's third country qualification without requiring the candidate to undertake the two examinations currently required through the TCQR assessment route. This will only occur in circumstances where the Council has absolutely no doubt that the applicant has received in a third country such training and education, passed such examinations and obtained such qualifications as are in the opinion of Council of a standard not lower than the standard of those necessary for practice in the State. This requirement derives from the Pharmacy Act and cannot be compromised. The Act gives the Council the ability to require a Third Country Applicant to undertake examinations, but it does not make this an absolute requirement, and the proposed amendment is to facilitate the exercise of this discretion.

Any qualification presented for evaluation will be assessed based on:

- knowledge of the historic outcome of equivalence examinations over the last 10 years,
- knowledge of the accreditation and quality structures of the country of origin of the qualification, and
- an assessment of the equivalence of the qualification with the minimum requirements of the Professional Qualifications Directive.

II. English Language Competency

Concerns that patient safety will be compromised by pharmacists without adequate English language competency

Over 15% of responses expressed concern over English language competencies

PSI Response

Language competence requirements apply to all qualified pharmacists who have completed their training outside of Ireland and who are seeking registration with the PSI. There will be no derogations from these requirements which are as follows:

1) Training to become a qualified pharmacist has been carried out in a country that has English or Irish recognised as an official language of that country.

OR

2) The applicant has lived and practiced 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. (Satisfactory independent evidence must be provided if relying on this criteria)

OR

3) A certificate issued by an internationally recognised body or authority, recognised by the PSI Council, attesting that the holder has attained a standard of competence in the English language.

The proposed amendments relate to the recognition of the qualification presented; this is one criteria of the registration process. All other requirements of the registration process will remain in place including professional and criminal fitness and language competence.

III. Students morale and drawing pharmacists to Ireland

Concerns over impact on students' morale when a high number of pharmacists enter the country and fill all vacancies while exams are postponed

Considerations over the ethical dilemma of drawing pharmacists from other countries to Ireland in a worldwide health emergency

PSI Response

This amendment to the Registration Rules is to provide limited flexibility to applicants from Third Countries for the duration of the COVID-19 pandemic. If these Rules are approved, it would allow third country applicants make an application through this process. There will be strict criteria to meet for an applicant to be successful in this process. If they are successful in this process, they would be eligible to apply to be entered on the PSI Register. The recruitment of pharmacists lies solely with pharmacy owners and pharmacist employers.

IV. Equal treatment of 3rd country applicants

How will equal treatment of 3rd country applicants be ensured before, during and after the period where the amendment will be in force

PSI Response

The criteria governing the application of this discretion will be applied informed by an evidence base relating to historical outcome of equivalence examinations, quality and accreditation system in home state and compliance with sectoral requirements specified in the Directive – these are independent of an individual.

V. Shortfall of Health Professionals and Vested Interests

Concerns over the reasoning behind the amendment “possible shortfall of health professionals” and whether there is documentation that this situation is at present occurring or will occur in the future

Concerns over whether vested interests are behind the proposed amendment

Nearly 60 % of responses rejected the claim that there will be a possible shortfall of health professionals (pharmacists) and approximately 15 % expressed concern over vested interests

PSI Response

The Pharmaceutical Society of Ireland (PSI) is a public body established in law to regulate pharmacists and pharmacies in Ireland, “having regard to the need to protect, maintain and promote the health and safety of the public”. It assures this in a number of ways including determining and applying the criteria for registration, and determining, approving and keeping under review programmes of education and training suitable to enable persons applying for registration to meet those criteria and pharmacists to comply with those codes

In the situation of the Covid-19 health emergency, the PSI is obliged to consider and mitigate possible risks for the health, safety and wellbeing of patients. The potential for either shortfall of health professionals, or shortfall of particular specialist skills in qualified professionals warrants consideration. It is noted that a high number of submissions in the consultation have stated that there is currently no shortfall of pharmacists and are predicting that this will not be the case during the Covid-19 health emergency. While the submission responses report no current shortage of pharmacists the PSI is mindful that this is an evolving and rapidly changing circumstance, and the requirement to be in a position to proactively and contemporaneously respond to system needs is vital.

This action is proposed in the context of the Health system strategy of anticipating and responding to the Covid pandemic in a proactive and agile manner to assure appropriate resources are in place to mitigate challenges to the health, safety and wellbeing of patients and the public.

VI. Knowledge of Irish Laws and the Irish Health System

Concerns that the candidates that will be approved will not have sufficient knowledge of Irish laws, the Irish health system and the daily practices of dispensing etc. in a pharmacy

Over 10 % of respondents expressed concern of whether candidates will have sufficient knowledge of Irish Laws and the Irish health system

PSI Response

The proposed amendments do not change the criteria for registration; it changes the process for recognition of qualification. At the point of registration an applicant will have to provide declarations stipulating that the pharmacist is aware of all legal, moral and ethical principles that govern the profession of a pharmacist and that (s)he will abide by the Code of Conduct as they pertain to Ireland.

It is the obligation of an individual employer to appraise an applicant's suitability for a particular position and to ensure that the necessary support, resources and supervision is in place for employees, whether they are newly graduated, from another EU-country or a third country.

VII. Consultation Process

Criticism that the consultation process was too short, that no email was sent to pharmacists on the register, and that replies could not be submitted anonymously

Nearly 15% of respondents expressed criticism of the consultation process

PSI Response

The Pharmacy Act prescribes under Section 11 that a draft set of Rules be published along with an invitation to comment thereon. This was done, and a notification issued via Twitter on the day of publication. The weekly update email to all registrants contained a notification regarding the consultation and an invitation to comment on the proposed Rules. PSI acknowledges that the time frame for comment was short but this was decided on by the Council in the context of the current emergency circumstances, and was in line with the process used in the preceding consultation.

Submissions were accepted whether received with a name attached or on an anonymous basis.

VIII. Alternative Suggestions instead of Amending Registration Rules

Suggestion that instead of the proposed amendment, the following actions could address the issue:

1. Move forward the PRE for 5th year students
2. Allow students that have fulfilled 6 months of the placement in the final year to register temporarily before sitting the PRE
3. Allow pharmacy technicians to perform tasks at present preserved for pharmacists

PSI Response

In accordance with the PSI (Education and Training) (Integrated Course) Rules 2014, a student can only undertake the PRE following successful completion of their undergraduate training. A student obtains a qualification appropriate for practice subsequent to completing training in a recognised HEI, with such training aligned to the provisions of the Professional Qualifications Directive in respect of sectoral requirements. The PSI is not aware that there are any plans to move this exam forward.

There are clear requirements in both national and EU legislation as to what are the “base” components in respect of the undergraduate training to be undertaken to obtain a qualification appropriate for practice. Registration as a pharmacist is subject to holding this qualification for practice and is aligned by design to assure that a graduate at the end of five years has the necessary, skills, competence and behaviours to practice as an independent practitioner involved in irreversible care and treatment of patients.

Pharmacy Technicians form part of the pharmacy team and play a valuable role in the delivery of pharmacy services under the governance structure defined in the Act, and the supervision of the pharmacist. Each individual superintendent will assess the role and function of the pharmacy team and assigned tasks on that basis and in line with the legislative obligations derived from the Act and Regulations.

IX. Suggestions to Assessment Process

Suggestions to the planned process for assessment during the period where the amendment will be in force:

1. Allow 3rd country applicants already in process to use the process
2. When the Covid-19 emergency is over, all pharmacists registered due to the amendment should sit the exams
3. A shortened adaptation period must remain as part of assessment
4. Some exam must remain as part of the assessment

PSI Response

The base premise associated with the potential exercise by the Council of the discretion proposed in the amendment, is that this will only occur in circumstances where the Council has absolutely no doubt that the applicant has received in a third country such training and education, passed such examinations and obtained such qualifications as are in the opinion of Council of a standard not lower than the standard of those necessary for practice in the State.

This requirement derives from the Pharmacy Act and cannot be compromised. The Act gives the Council the ability to require a Third Country Applicant to undertake examinations, but it does not make this an absolute requirement, and the proposed amendment is to facilitate the exercise of this discretion.

Where an applicant is currently having his/her qualification assessed through the TCQR process it is not envisaged that the flexibility could be applied, particularly in circumstances where an applicant has been assigned an adaptation period as this only arises when a doubt exists as to the standard of qualification held.

X. Clarifications

Clarification is asked on:

1. Can the process for how applications will be assessed be explained in more detail
2. Will applicants stay on the register when the Covid-19 emergency is over?
3. Is there a time limit for the validity of the amendment
4. What if the Covid-19 emergency is not declared over for a longer period of time
5. Will the amendment allow 3rd country applicants the same conditions for registration as EU-applicants

PSI Response

The base premise associated with the potential exercise by the Council of the discretion proposed in the amendment, is that this will only occur in circumstances where the Council has absolutely no doubt that the applicant has received in a third country such training and education, passed such examinations and obtained such qualifications as are in the opinion of Council of a standard not lower than the standard of those necessary for practice in the State. This requirement derives from the Pharmacy Act and cannot be compromised. The criteria governing the application of this discretion will be applied informed by an evidence base relating to historical outcome of equivalence examinations, quality and accreditation system in home state and compliance with sectoral requirements specified in the Professional Qualifications Directive, as amended.

Yes, the applicants will remain on the register when the Covid-19 emergency is over as the decision relating to qualification recognition is a stand alone decision.

The proposed amendment will only be in force for the duration of the COVID-19 pandemic and will be linked to the duration of application of Section 77 of the Act. If the Minister deems that the current date of 31 July 2020 this will be the timeline in which the amending rules will apply.

The process of registration is similar for national, EU/EEA and Third Country and will continue to remain so.

XI. Support for the amendment

The amendment is reasonable and pragmatic

There is at present a shortfall of pharmacists (in certain regions especially) and the amendment is welcomed to address this problem

Post Covid-19 there could be a shortfall of pharmacists and the amendment is welcomed to address this problem

Approximately 10 % of responses expressed support to the amendment

PSI Response

This is noted.

Conclusion

We have noted all responses with thanks. These are challenging and unprecedented times for everyone, and the PSI is grateful to all stakeholders who responded to the consultation under the very tight timeframe. The feedback and comments are provided to the Council of the PSI for consideration.

Appendices

- A List of targeted stakeholders
- B E-mail Responses from organisations to the Consultation
- C Proposed Rules to amend Pharmaceutical Society of Ireland (Registration) Rules 2008 as amended

Appendix A - List of targeted stakeholders

| | Stakeholder |
|----|---|
| 1 | Irish Pharmacy Union (IPU) |
| 2 | Pharmacists in Industry, Education and Regulatory (PIER) |
| 3 | Hospital Pharmacists Association of Ireland (HPAI) |
| 4 | Affiliation for Pharmacy Practice Experiential Learning (APPEL) |
| 5 | Irish Institute of Pharmacy (IIOP) |
| 6 | University College Cork (UCC) |
| 7 | Trinity College Dublin (TCD) |
| 8 | Royal College of Surgeons in Ireland (RCSI) |
| 9 | The Health and Social Care Regulator (CORU) |
| 10 | The Dental Council |
| 11 | Medical Council of Ireland (MCIRL) |
| 12 | Nursing and Midwifery Board of Ireland (NMBI) |

Appendix B - E-mail Responses from organisations to the Consultation

| Organisation | Response |
|---|---|
| Irish Pharmacy Union (IPU) | Darragh and I have reviewed the proposed amendment and consider it to be pragmatic and reasonable. |
| Irish Institute of Pharmacy (IIOP) | On behalf of Catriona Bradley, I would like to thank you for inviting our feedback on the draft Rules, as amended. Having reviewed the proposed amendment in the current context of the Covid 19 public health emergency, we feel that the proposal is reasonable and have no further feedback to contribute. |
| The Health and Social Care Regulator (CORU) | I unfortunately missed the deadline because yesterday, Monday 4 May, was a public holiday. However I am happy to confirm a positive response to the proposal. I hope my response will be of assistance in any event, |

Appendix C – Consultation Draft of Proposed Rules to amend
Pharmaceutical Society of Ireland (Registration) Rules 2008 as
amended



STATUTORY INSTRUMENTS.

S.I. No. [•] of 2020



PHARMACEUTICAL SOCIETY OF IRELAND (REGISTRATION) (AMENDMENT) RULES 2020

S.I. No. of 2020

PHARMACEUTICAL SOCIETY OF IRELAND (REGISTRATION) (AMENDMENT)
RULES 2020

The Council of the Pharmaceutical Society of Ireland, in exercise of the powers conferred on the said Society by section 11 of the Pharmacy Act 2007 (No. 20 of 2007) (as adapted by the Health and Children (Alteration of Name of Department and Title of Minister) Order 2011 (S.I. No. 219 of 2011)), with the consent of the Minister for Health, hereby makes the following rules:

1. (1) These Rules may be cited as the Pharmaceutical Society of Ireland (Registration) (Amendment) Rules 2020.

(2) The Principal Rules, Rule 15 of the Pharmaceutical Society of Ireland (Continuing Professional Development) Rules 2015 (S.I. No. 553 of 2015), the Rules of 2017 and these Rules may be cited together as the Pharmaceutical Society of Ireland (Registration) Rules 2008 to 2020 and shall be construed together as one.

2. In these Rules—

“Principal Rules” means the Pharmaceutical Society of Ireland (Registration) Rules 2008 (S.I. No. 494 of 2008);

“Rules of 2017” means the Pharmaceutical Society of Ireland (Registration) (Amendment) Rules 2017 (S.I. No. 100 of 2017).

3. Rule 3(1) (as amended by Rule 3 of the Rules of 2017) of the Principal Rules is amended by substituting for the definition of “Act” the following:

“‘Act’ means the Pharmacy Act 2007 (No. 20 of 2007), as amended by the European Communities (Recognition of Professional Qualifications relating to the Profession of Pharmacist) (No. 2) Regulations 2008 (S.I. No. 489 of 2008), the Civil Partnership and Certain Rights and Obligations of Cohabitants Act 2010 (No. 24 of 2010), the Health (Pricing and Supply of Medical Goods) Act 2013 (No. 14 of 2013), the Health Identifiers Act 2014 (No. 15 of 2014), the European Union (Amendment of the Pharmacy Act 2007) Regulations 2015 (S.I. No. 86 of 2015), the Professional Qualifications Regulations, the Data Protection Act 2018 (No. 7 of 2018) and the Emergency Measures in the Public Interest (Covid-19) Act 2020 (No. 2 of 2020);”.

4. Rule 18 of the Principal Rules is amended—

(a) by inserting after paragraph (2) the following paragraph:

“(2A) Notwithstanding paragraph (2), until the date specified for the purpose of section 77(6) of the Act (whether in that provision or by order of the Minister under section 77(7)), the Council may consider an application under this Rule otherwise than by requiring the applicant to undergo the measures referred to in paragraph (2).”, and

(b) in paragraph (3), by inserting “or has had his or her qualification recognised in accordance with paragraph (2A),” after “set out in paragraph (2),”.

I, SIMON HARRIS, Minister for Health, consent to the making of the foregoing Rules.

L.S. GIVEN under my Official Seal,
[DATE] [MONTH] 2020.

SIMON HARRIS,
Minister for Health.

L.S. GIVEN under the Official Seal of the Council of the
Pharmaceutical Society of Ireland,
[DATE] [MONTH] 2020.

JOANNE KISSANE,
President.

NIALL BYRNE,
Registrar.

EXPLANATORY NOTE

(This note is not part of the Instrument and does not purport to be a legal interpretation)

These Rules amend the Pharmaceutical Society of Ireland (Registration) Rules 2008.

These Rules may be cited as the Pharmaceutical Society of Ireland (Registration) (Amendment) Rules 2020.