

Consultation Report on the proposed rules to amend the PSI (Registration) Rules 2008

June 2023

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Introduction

This report summarises the feedback received during the public consultation (24 Feb – 19 Mar 2023) on the proposed Rules to amend the Pharmaceutical Society of Ireland (Registration) Rules 2008, as amended. It also includes the outcome of the online survey.

Background

The PSI proposed changes to the existing statutory rules which set out the procedures that apply in relation to the qualification recognition process for pharmacists who are awarded their pharmacy qualification in a non-EU/non-EEA country. This was proposed as part of an ongoing review of the existing Third Country Qualification Recognition (TCQR) process.

Under the Pharmacy Act 2007, an individual wishing to register to practise as a pharmacist in Ireland must, amongst other things, hold a 'qualification appropriate for practice'.

Pharmacists who qualified in a non-EU or non-EEA country (a third country) and wish to practise in Ireland must first have their qualification recognised as a 'qualification appropriate for practice', before they can apply to register with the PSI.

This process of applying for a Certificate of Qualification Appropriate for Practice, is called the Third Country Qualification Recognition (TCQR) route. This is a pre-requisite to be able to apply for registration.

Under this process, a non-EU or non-EEA qualified pharmacist may obtain a certificate recognising their qualification as appropriate for practice, provided they can show that the standard of their qualification is not lower than the standard of those necessary for practice in Ireland.

The existing TCQR route is a multi-stage process in place since 2009. The PSI has been reviewing the process with the intent of streamlining and simplifying our approach for applicants and to maximise benefits to patients and the wider public.

The PSI Council has agreed a revised policy approach and plan for implementing changes to the TCQR route. To give effect to the revised TCQR approach, the Council of the PSI has approved, for consultation, a draft set of rules to amend the PSI (Registration) Rules 2008. The amendments would change the existing rules to allow the PSI to implement a new approach to qualification recognition.

About the Consultation

The public consultation opened on 24 February 2023 and closed on 19 March 2023.

Participants could provide feedback via an online survey, by email, or by post.

PSI registrants and other relevant stakeholders were notified about the public consultation via email. The consultation was notified more broadly to the public on the PSI website, and through social media.

Response to the consultation

In total **n=414** responses were received to the public consultation.

Of these, 401 responses were received through the online survey and 13 responses were received via email.

Responses received via the online survey are anonymous. The online survey comprised of 9 questions, including a data protection question. Comment boxes were provided to allow respondents to give additional feedback.

Several significant themes have emerged as result of qualitative analysis of survey responses. This report identifies the main themes and provides further information to address the issues arising.

Response to the online survey

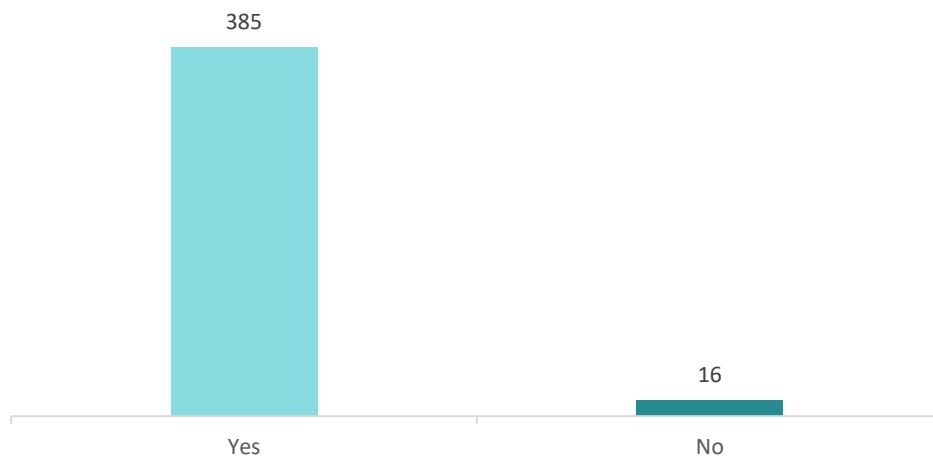
Prior to completing the survey, respondents were asked to review the draft Pharmaceutical Society of Ireland (Registration)(Amendment) Rules 2023.

A total of 401 total survey responses were received to the online survey. 16 responses were removed as the relevant data protection requirements were not agreed. Therefore, 385 survey responses were reviewed.

Survey Question 1: Data Protection question

Answered	401
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Respondents were asked whether they are happy to proceed with the survey, having been informed about relevant data protection terms and policies.

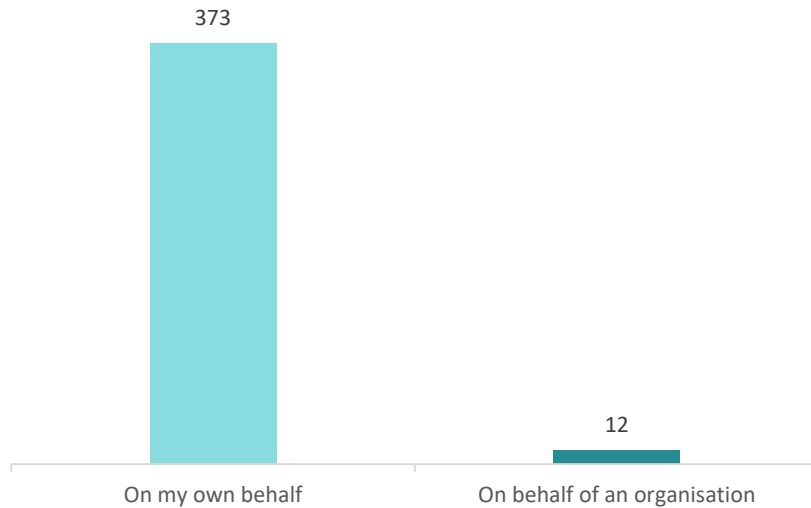


All respondents wishing to partake in the survey were required to answer this question. By answering 'no' the respondent was blocked from continuing the survey and referred to the PSI Public Consultation webpage for further information on alternative ways to provide feedback.

16 participants did not agree to the data protection terms, and were not able to proceed with the online survey. Those responses were deleted.

Survey Question 2: Are you responding on your own behalf or on behalf of an organisation?

Answered	385
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97% of respondents indicated that they were responding on their own behalf and 3% of respondents indicated that they were responding on behalf of an organisation.

Survey Question 3: If you indicated that you are responding on behalf of an organisation, please specify what organisation.

Answered	10
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Respondents who indicated they were providing feedback on behalf of an organisation were given the option to indicate which organisation they were responding on behalf of.

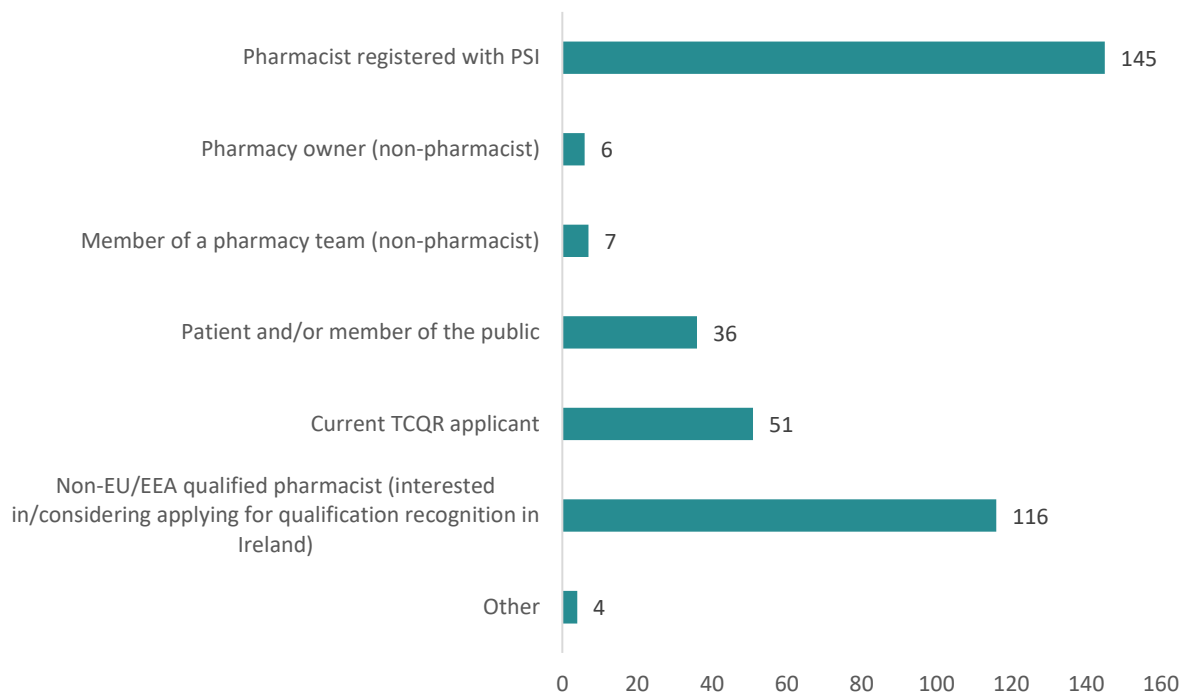
Ten respondents elected to identify an organisation they were responding on behalf of. Those included:

- Daly's pharmacy
- ThePharmacistPanel.com
- Pharmacy
- Active Life Pharmacy
- Pharmacists Facebook Group
- Saudi Commission for Health Specialties
- CORU, the Health and Social Care Professionals Council
- Irish Institute of Pharmacy (IIOP)
- FRS Recruitment
- Egyptian Pharmacists Group

Survey Question 4: Which best describes you? (You may select one option only)

Answered	365
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Respondents were provided with a number of categories to describe themselves and invited to select the category that best applies to them, as an optional step. The breakdown of responses is as follows:



Of the respondents who provided an answer to Question 4:

- 39% of respondents declared as pharmacists registered with PSI
- 32% of respondents indicated that they are a Non-EU/EEA qualified pharmacist, interested in or considering applying for qualification recognition in Ireland
- 14% of respondents declared as current TCQR applicants
- 10% of respondents indicated that they are a patient and/or a member of the public
- 1.5% of respondents declared as pharmacy owners (non-pharmacist)
- 1.5% of respondents indicated that they are a member of a pharmacy team (non-pharmacist)
- 1% of respondents selected 'Other'

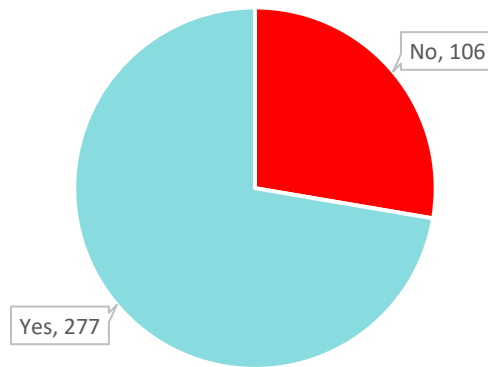
Of the four respondents who indicated 'Other', participants self-declared as a pharmacy student, pharmacist recruiter, a Pre-Reg Pharmacist and an individual who finished the TCQR process but is not yet registered with PSI.

Survey Question 5: Do you agree with the proposed PSI (Registration)(Amendment) Rules 2023?

Answered	383
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Participants were asked whether they agree with the proposed rule changes, having considered the draft PSI (Registration)(Amendment) Rules 2023.

The breakdown of responses is as follows:



Of the respondents who provided an answer to Question 5:

- 72% indicated that they agree with the proposed rule changes
- 28% indicated that they do not agree with the proposed rule changes

A comment box was provided (in the form of question 6: Please add any additional comments if you wish). There were **148** comments submitted. A number of substantial themes were identified within the responses, which are described in the *Thematic Discussion* section of this report.

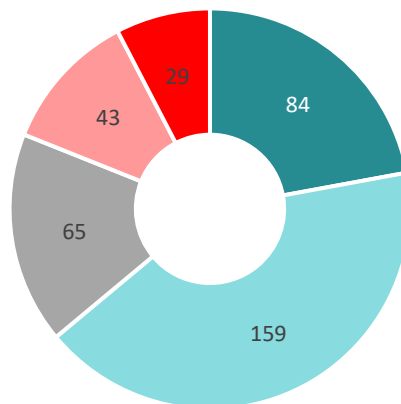
Survey Question 7: Do you agree that the proposed PSI (Registration)(Amendment) Rules 2023 are clear?

Answered	380
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Having considered the draft PSI (Registration)(Amendment) Rules 2023, participants were asked whether they agree that the proposed amendment rules are clear.

The breakdown of responses is as follows:

■ Strongly agree
 ■ Agree
 ■ Neither agree nor disagree
 ■ Disagree
 ■ Strongly disagree



Of the respondents who provided an answer to Question 7:

- 64% of respondents indicated they ‘agree’ or ‘strongly agree’ that the proposed amendment rules are clear
- 17% of respondents indicated that they neither agree nor disagree that the proposed amendment rules are clear
- 18% of respondents indicated that they ‘disagree’ or ‘strongly disagree’ that the proposed amendment rules are clear

A comment box was provided (in the form of question 8: Please add any additional comments if you wish). There were **93** comments submitted. A number of substantial themes were identified within the responses, which are described in the *Thematic Discussion* section of this report.

Survey Question 9: Is there any other feedback that you would like to provide on the proposed statutory rule changes?

Answered	125
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A comment box was provided for this question to allow respondents to submit free text responses. A number of substantial themes were identified within the responses, which are described in the *Thematic Discussion* section of this report.

Email Responses to the Consultation

Thirteen responses to the public consultation were received via email. Five responses were received on behalf of organisations. The remaining eight submissions were received from individuals submitting feedback on their own behalf.

A number of substantial themes were identified within the email submissions, which are described in the *Thematic Discussion* section of this report.

Discussion

Of the 385 individuals who provided feedback via the online survey, the vast majority chose to indicate their background. The largest category of respondents were pharmacists registered with PSI, which constituted 39% of respondents. This was closely followed by Non-EU/EEA qualified pharmacists who are interested in or are considering applying for qualification recognition in Ireland. This group constituted 32% of survey respondents.

The majority of respondents indicated that they agree with the proposed rule changes, with 72% of responses in favour of the proposed changes. Further analysis of responses by background indicates significant variations in perspectives among different demographic groups:

- Of those who declared as pharmacists registered with PSI, only 42% agreed with the proposed rule changes, with remaining 58% indicating they are against the proposed Amendment Rules. Similar response was observed among non-pharmacist members of the pharmacy team, with 43% of respondents within this group agreeing with the proposed rule changes. However, the small sample size for this group is noted (n=7), raising the possibility that this viewpoint may not be reflective of the entire demographic.
- Of those who indicated they are pharmacists who qualified in a Non-EU/EEA country and are interested in or are considering applying for qualification recognition in Ireland, 95% stated they agree with the proposed rule changes. Only 5% of respondents within this group disagreed with the proposed Amendment Rules.
- Current TCQR applicants and patients/members of the public also tended to agree with the proposed rule changes, with over 90% of respondents within those groups agreeing with the proposed Amendment Rules.
- The respondents who identified themselves as pharmacy owners generally expressed agreement with the proposed rule modifications, with 83% indicating their approval of the Amendment Rules. However, as for other non-pharmacist members of the pharmacy team, it should be noted that the sample size for this group is small (n=6), so this perspective may not be representative of the entire population of pharmacy owners.

There was overall agreement among respondents that the proposed Amendment Rules are clear, with 67% of survey respondents indicating they 'agree' or 'strongly agree' that the proposed Amendment Rules are clear. Some variations in perspectives were again noted across different groups, as illustrated in table 1 below:

Table 1. Breakdown of responses to Survey Question 7 by population group.

	Net disagree	Net neutral	Net agree
Pharmacists registered with PSI	38%	23%	39%
Non-EU/EEA qualified pharmacist (interested in/considering applying for qualification recognition in Ireland)	6%	11%	83%
Current TCQR applicant	6%	18%	76%
Patient and/or member of the public	8%	11%	81%
Member of a pharmacy team (non-pharmacist)	-	50%	50%
Pharmacy owner (non-pharmacist)	33%	-	67%

Pharmacists registered with PSI and non-pharmacist members of the pharmacy team were more likely to view the proposed Amendment Rules as unclear. This is in contrast with the viewpoints of Non-EU/EEA qualified pharmacists, current TCQR applicants and patients and/or members of the public, who tended to agree that the proposed Amendment Rules are clear.

Thematic discussion

While the feedback received on the proposed PSI (Registration)(Amendment) Rules 2023 was overall in favour of the proposed rule changes, several significant themes emerged from the free text survey responses and email submissions. The themes, and the PSI response, are discussed below.

1. Feedback on the proposed five stages of the revised TCQR route

33.91% of respondents provided comments regarding the various stages of the proposed revised TCQR route. Submissions set out several concerns and mixed views on the proposed approach, including:

- ***Concerns over the lack of clarity/insufficient detail provided on the proposed five stages of the revised TCQR route.***

This is the view which arose most frequently under this theme, with respondents calling on further clarification to be provided on various aspects of the revised TCQR route. In particular, submissions sought further detail and information regarding:

- the criteria for the holistic assessment at Stage 2 of the revised route and the requirements which must be met by an individual to proceed via path A,
- the proposed timeframe for recognition of qualification under the revised route,
- proposed duration, structure, and purpose of adaptation placements at Stage 3,
- the format, content, and number of exams an applicant will be required to undertake,
- proposed fees.

- ***Concerns over the implementation of path A under the revised process/removal of the requirement to undergo an adaptation placement and exam under path A.***

A number of respondents were of the view that the removal of the requirement to sit an exam for path A applicants poses a risk to patient safety. Submissions questioned whether the holistic assessment at Stage 2 is sufficient to determine whether an individual possesses the required qualifications, competencies, and skills as those which are necessary to practice as a pharmacist in Ireland. A number of respondents viewed the adaptation placement for all those new to pharmacy practice in Ireland as a critical step in ensuring patient safety and quality of care.

- ***Views on the eligibility to apply for qualification recognition under the revised TCQR process.***

Several respondents expressed the view that the criteria which determine the eligibility of an individual to apply for qualification recognition should be broadened. Respondents highlighted that under the current TCQR process pharmacists who received their pharmacy qualification in certain countries are not eligible to apply for qualification recognition in Ireland due to the structure of their primary qualification and pre-registration practical training.

- ***Views on the format and subject matter of the exam.***

Several submissions recommended that the exam at Stage 4 of the revised route should cover the topic of pharmacy and medicines legislation. Some respondents were also of the

view that the exam should be in the form of an Objective Structured Clinical Examination (OSCE), focusing on clinical pharmacy practice.

Other issues and views expressed in the submissions that related to this theme included:

- Proposed TCQR process is overly lenient
- More adaptation placements should take place in a hospital setting
- Proposed TCQR process is too complicated and onerous on the applicant
- Consideration should be given to those applicants with a refugee status, especially concerning the challenges they may face in submitting the required documentation
- Concerns regarding how the PSI will verify the authenticity and legitimacy of the qualifications and documentation submitted by applicants
- Transition of current TCQR applicants into the new process should be facilitated
- There should be an online platform for submitting and processing applications
- Priority should be given to those applicants who are already in Ireland when assessing applications and progressing through the process
- Applicants' post-graduation experience should be considered when assessing applications
- Concerns over the removal of the Equivalence Exam, and the potential negative impact of this on patient safety

PSI Response

While the subject of this public consultation was limited to the draft PSI (Registration)(Amendment) Rules 2023, the PSI welcomes the feedback and comments on the proposed five stages of the revised TCQR route.

The PSI acknowledges that the information on the proposed implementation of the revised TCQR route provided as background to this public consultation was high level and limited in detail.

As the implementation of the revised TCQR route progresses and individual stages of the process are being developed and tested, many details continue to remain subject to change. The issues and concerns raised regarding the revised route as part of this consultation will be taken into account by PSI during the implementation of the revised TCQR process.

To ensure that the proposed implementation of the revised TCQR policy is examined and reviewed from different perspectives, and that potential risks are identified and managed, the PSI has engaged a number of experts to join an Advisory Group dedicated to this project. The PSI will consult with the Advisory Group on the issues and concerns raised as part of this consultation, and we will continue to engage with the Advisory Group as needed throughout the implementation of the revised process to ensure its robustness and fairness. It is intended that only those applicants who have clearly demonstrated that they received in a third country such training and education, passed such examinations and obtained qualifications of a standard not lower than the standard necessary for practice in the State, will be eligible to progress through the revised route via path A.

The suggestions regarding the content and format of the exam are noted by PSI. It is our intention to engage with a panel of experts in pharmacy education and assessment to ensure that the exam's format and subject matter are appropriate. It is also intended that applicants will receive necessary training and exposure to the practice of pharmacy during their adaptation placements.

The comments regarding broadening of the criteria which determine the eligibility of an individual to apply for qualification recognition are noted. It is envisaged that the new process will provide the opportunity for Non-EU/EEA pharmacists who were previously denied access due to their primary qualification not meeting the directive minimum standard, to apply for recognition by adopting the holistic assessment of qualification. The assessment is intended to take into account, amongst other aspects, an applicant's work experience and CPD activities, and allow for applicants to address any

deficiencies in their primary qualification (instead of being immediately denied access) ultimately resulting in a more transparent and fair process.

2. Pharmacy workforce issues

One of the themes that emerged from the feedback pertained to the workforce issues affecting the pharmacy profession at present, with 15.32% of respondents providing comments under this theme. A number of concerns and mixed views were expressed, including:

- ***Concerns regarding the purpose behind the initiation of the TCQR route review and the implementation of amendment rules.***
Many respondents questioned the motivation behind the review of the TCQR route. Some raised concern that the review of the TCQR process is being carried out by PSI as a direct response to the perceived shortage of pharmacists in Ireland. Some respondents were of the view that the decision to review the TCQR route may have been influenced by pharmacy owners or pharmacy businesses. Respondents were of the view that there is no shortage of pharmacists in Ireland but that traditional roles have become unattractive, causing pharmacists to seek alternative career paths, and in turn resulting in a perceived workforce shortage. Unsatisfactory working conditions in community pharmacy (including the lack of protected lunch breaks), lack of career progression, administrative burden and increasing workloads were highlighted as some of the issues currently affecting the pharmacist workforce. Submissions stated that ‘increasing the number of pharmacists’ via this route is a short-term solution. Respondents were of the view that it would be more appropriate for PSI to take steps to address some of the issues that are known to affect the sector in order to improve retention of pharmacists in patient-facing roles.
- ***The view that a more streamlined TCQR process will relieve some of the workforce pressures.***
In contrast to the views described above, a similar number of submissions welcomed the effort to introduce a revised streamlined TCQR route. Respondents anticipate that the new process will attract more pharmacists to Ireland and reduce the barriers currently faced by those seeking qualification recognition in Ireland. Respondents expect that this will alleviate the workforce pressures that have been caused by perceived shortages in the sector.
- ***Concerns that increasing the number of pharmacists in Ireland will further exacerbate problems facing the sector.***
A number of submissions expressed concern that the introduction of a revised TCQR route may result in a substantial influx of pharmacists into Ireland. Respondents were of the view that this potential increase in the number of pharmacists may intensify competition for positions, thereby exacerbating the already challenging working conditions in community pharmacy and lowering pay rates. Respondents believed that this will result in roles in community pharmacy becoming less attractive to pharmacists in Ireland, leading an increasing number of pharmacists to seek alternative career paths.

PSI response

Under the Pharmacy Act 2007 (the ‘Act’), persons are entitled to be registered as a pharmacist in Ireland if they meet a number of criteria. This entitlement derives from the Act and cannot be compromised. The TCQR route is the process under which PSI Council verifies that an individual meets the required criteria as set out in the Act and holds a ‘qualification appropriate for practice’. This is a pre-requisite to be able to apply for registration.

The existing TCQR route has been in place since 2009. The review of the current process was initiated by PSI in 2017, as the current route is resource-intensive and lengthy. This action was proposed in the context of process improvement, as opportunities were identified to make it more efficient, transparent, and sustainable. As a public interest regulator, the PSI ensures to maintain an appropriate distance from the commercial interests of pharmacy owners and pharmacy businesses.

The PSI is aware of the challenges being experienced by the pharmacy sector and of the increasing risk to the continued availability of a pharmacist workforce, with the concern being that the issue may be exacerbated into the future. In response, separately to the revision of the TCQR route, the PSI is undertaking the 'Emerging Risks to the Future Pharmacy Workforce' project. Feedback from the profession and other data gathered as part of this project will inform the final Workforce Intelligence Report, which will contain a set of recommendations to support the strategic planning of the pharmacy workforce into the future. This report will be published by the PSI later this year.

3. Concerns over the standard of pharmacy practice, patient safety and English language competency

12.06% of respondents provided comments under this theme. Several submissions expressed concerns about the possibility of individuals who do not meet the minimum standards of training and competence being granted qualification recognition in Ireland as a result of the proposed Amendment Rules and revised TCQR process. Respondents were of the view that any effort to simplify the existing qualification recognition process may have a negative effect on the overall standard of pharmacy practice in Ireland and undermine public confidence in the profession.

A number of submissions queried whether English language proficiency would be evaluated as part of the revised TCQR process, emphasizing that a sufficient level of English language competency should be mandatory for all applicants to ensure patient safety and quality of care.

PSI Response

These concerns are noted by PSI. The principal function of the PSI is to ensure patient safety and public protection. As a public interest regulator, we work to assure the public that pharmacists are always working to high standards of practice and that the public can trust in the professionalism of pharmacists wherever they encounter the profession. The PSI will consult with the dedicated Advisory Group on the issues and concerns raised as part of this consultation. As we work to implement the revised TCQR process, we will continue to engage with external stakeholders, as well as the Advisory group, to ensure the robustness and fairness of the TCQR route.

We acknowledge the comments regarding the need to ensure English language proficiency. While there is no legislative basis for the introduction of English language assessment during the qualification recognition process, language competence requirements apply to all qualified pharmacists who have completed their training outside of Ireland and who are seeking registration with the PSI. Although TCQR applicants are not required to demonstrate their English language competence until after their qualification has been recognised and they are ready to apply for registration, as part of the revised process the PSI will provide all TCQR applicants with the necessary information to assist them in having an informed understanding of these requirements prior to applying.

4. Difficulties in obtaining work visas to complete adaptation placements

8.04% of respondents provided comments under this theme. Several submissions stressed the challenges faced by applicants under the current TCQR process in securing work permits or visas to complete an adaptation placement. Submissions highlighted that current work or study visa options are not available to non-EEA pharmacists as they do not meet the required criteria. Respondents queried whether any assistance will be provided to applicants in obtaining the required work permits/visas under the revised process.

PSI Response

The PSI is aware that in some cases, TCQR applicants may face challenges in securing a working permit or visa to undertake an adaptation placement as part of the TCQR route. Although pharmacists are currently on the Critical Skills Occupations List, our understanding is that this extends only to registered pharmacists, not individuals undergoing qualification recognition or the registration process.

The PSI is actively engaging through the Department of Health with the Department of Enterprise, Trade and Employment to agree a solution to this issue. The PSI will endeavour, as part of the revised TCQR route to inform potential applicants that they should be familiar with any working permit or visa requirements that may apply to them prior to submitting a TCQR application.

5. Other

Other feedback and views that arose to a lesser extent across the responses received included:

- The review of the TCQR route is welcome and should be expedited
- The PSI Registration Rules and the TCQR process should be reviewed regularly to ensure they are fit for purpose
- The route to registration for Non-EU/EEA applicants should not be more onerous than it is for EU qualified pharmacists
- Concerns over the waiting period for the Equivalence Exam under the current TCQR process
- PSI should consider establishing a mutual recognition agreement with certain non-EU/EEA countries, where the education, training and qualifications for pharmacists are deemed equivalent to those in Ireland.

PSI Response

These comments are noted and will be considered as part of the on-going implementation of the revised TCQR route.

Next steps

We have noted all responses with thanks. The feedback and comments will be provided to the Council of the PSI for its consideration and will inform any further amendments to the TCQR route.

The issues and concerns regarding the proposed implementation of the revised TCQR route raised as part of this consultation will be considered by PSI as part of its on-going implementation.

At a later date, we will need to make changes to the PSI's statutory fees rules, in order to align them with the revised TCQR route. We will seek feedback through a separate consultation process on the proposed changes to the fees.