

Consultation Report on the PSI (Fees) (Amendment) Rules 2024



Contents

1.	Introduction
2.	Background
3.	Public Consultation
	3.1 Purpose of the Consultation
	3.2 About the Consultation
	3.3 Consultation Response
4.	Response to Online Survey
	4.1 Data Protection
	4.2 Are you contributing to this survey:
	4.3 Please indicate if you would like your name and/or organisation to be kept confidentia and excluded from the consultation report:
	4.4 The fee for the internal review stage (stage 1 in <i>Fees Rules 2024</i>) is €750. Do you think the fee for this is proportionate?
	4.5 The fee for the holistic assessment stage is €1500 (stage 2 of <i>Fees Rules 2024</i>). Do you think the fee for this stage is proportionate?
	4.6 The fee for the examination stage is €4000 (stage 4 of the <i>Fees Rules 2024</i>). Do you think the fee for this stage is proportionate?
	4.7 Do you have any other feedback on the <i>Pharmaceutical Society of Ireland (Fees)</i> (AMENDMENT) Rules 2024?
PS	SI Response
C	onclusionS
Δι	onendices 10

1. Introduction

This report summarises the feedback received during the 2024-2025 consultation process on the proposed Pharmaceutical Society of Ireland (Fees) (Amendment) Rules 2024 and includes the relevant outcomes of the online survey.

2. Background

Under the Pharmacy Act 2007 (the 'Act'), 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 Ireland or in another EU/EEA state and who hold a professional qualification recognised under the EC (Recognition of Professional Qualifications) Regulations 2017, are considered to 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. The process of applying for a *Certificate of Qualification Appropriate for Practice* is called the Third Country Qualification Recognition (TCQR) route. This is a prerequisite to applying for registration. Under this process, a non-EU/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 TCQR route has been in place since 2009. In 2017, the PSI initiated a review of the TCQR route, undertaking national and international benchmarking research on qualification recognition routes. Based on this work, a revised policy was drafted and amended following legal opinion, with such policy subsequently introduced by legislative amendment of the Registration Rules. In 2019, the PSI Council approved the revised policy for the TCQR route with the aim of strengthening and streamlining the recognition process. One of the key changes set out in the approved policy is the introduction of a holistic assessment of an applicant's qualification. A holistic assessment takes a broad view in assessing an applicant's qualification by considering aspects in addition to their pharmacy degree such as their relevant professional experience and the strength of the pharmacy regulatory system in place in the country where the applicant qualified.

The proposed <u>Pharmaceutical Society of Ireland (Fees) (Amendment) Rules 2024</u> were presented to the Council of the PSI at their meeting of 12 December 2024 and subsequently approved for public consultation. These amendments are necessary to update the fees associated with the TCQR process so that they may align with the revised process.

3. Public Consultation

3.1 Purpose of the Consultation

The PSI sought feedback as part of a public consultation on the proposed <u>Pharmaceutical</u> <u>Society of Ireland (Fees) (Amendment) Rules 2024</u> with particular attention to the proportionality¹ of each stage.

As outlined in the revised Fees Rules, each stage of the TCQR process will have an associated fee, providing a transparent set of fees for applicants. These fees have been determined based on the resources and external costs required to support each stage of the process. While the proposed fees are higher than those previously in place, they are grounded in the principle of cost recovery, whereby the costs of providing the service are borne by the service users.

Following the receipt of an application, the four stages² of the qualification recognition process are as follows:

- Internal Review for validity and eligibility
- Holistic assessment
- Examination
- Certification of qualification appropriate for practice

All applicants must complete the internal review and holistic assessment stages. Some applicants will be required to complete the examination stage. Applicants who have successfully completed all required stages of the TCQR process will be issued with a certificate by the PSI recognising their qualification as being a 'qualification appropriate for practice'. This certificate will enable the applicant to subsequently apply for registration as a pharmacist in Ireland.

This consultation was able to be completed either in a personal capacity or on behalf of an organisation, with respondents given the option to remain anonymous or request to be named in this report. A list of all individuals and organisations who asked to be named is provided in Appendix A.

The Directive was transposed into Irish law in August 2022 through Statutory Instrument 413/2022.

¹ <u>Directive 2018/958 of the European Parliament and Council</u> – on a proportionality test before adoption of new regulation of professions – establishes rules for proportionality assessments to be conducted by EU countries before the adoption of new professional regulations or the amendment of existing regulations. The aim of the Directive is to:

[•] prevent undue restrictions on access to or the pursuit of professional activities; and

[•] ensure transparency and the proper functioning of the EU internal market.

² Note that Regulation 19(5) of the Pharmaceutical Society of Ireland (Registration) Rules 2008 to 2023 provides that there are five stages to the revised TCQR route, as applicable. As per the Council approval in June 2024, the TCQR process was amended from a five-stage to a four-stage process as the mandatory adaptation period was removed. Therefore, this consultation document only refers to the four stages currently applicable.

3.2 About the Consultation

The public consultation opened to all pharmacists, pharmaceutical assistants, pharmacy owners, and members of the public on 13 December 2024 and closed on 6 January 2025. At the time of the public consultation, there were 7731 pharmacists, 177 pharmaceutical assistants, and 1989 pharmacy owners registered with the PSI, in addition to the 12 stakeholders who were all initially made aware of the consultation through email on 13 December 2024.

The consultation was made available under the 'Public Consultations' section of the PSI website and featured in the PSI December Newsletter issued on 18 December 2024.

3.3 Consultation Response

299 responses were received via the online survey. Additionally, one response was received via email. This email included comments that fell outside the scope of the consultation and, therefore, only areas that fell within the scope of the consultation were considered. The relevant portion has been considered and included in line with other feedback in <u>Section 4.7</u>

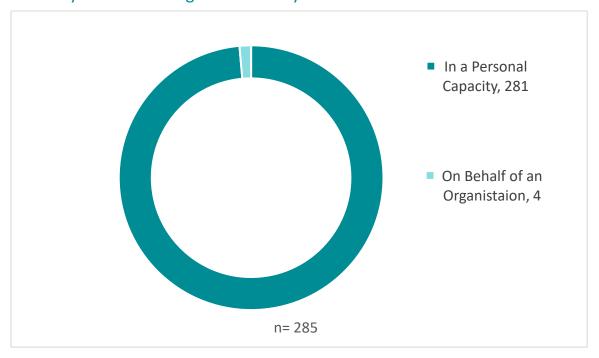
Fourteen respondents indicated that they did not agree to the PSI data protection statement and, therefore, were restricted from completing the survey. Therefore, 285 survey responses were reviewed. Information about the responses and the response rate for each question included in the online survey is provided below.

4. Response to Online Survey

4.1 Data Protection

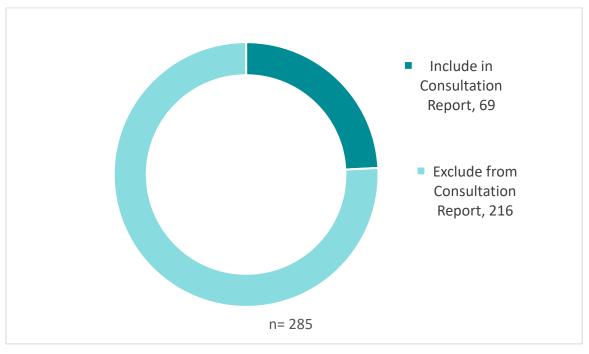
285 out of the 299 respondents confirmed they consented to providing their answers to the questions in the survey. Fourteen respondents did not and, therefore, could not progress to the rest of the questions.

4.2 Are you contributing to this survey:



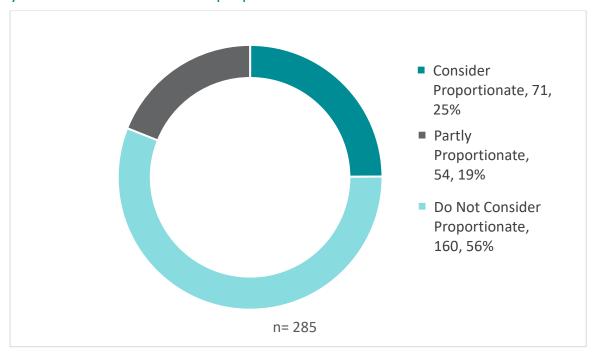
Respondents were given the option to respond in a personal capacity or on behalf of an organisation. The 1% who responded on behalf of an organisation were asked to specify which organisation.

4.3 Please indicate if you would like your name and/or organisation to be kept confidential and excluded from the consultation report:



Of the 285 respondents, 68 people and 1 organisation shared their names and indicated they wished for their name to be included in this consultation report. This list can be found in Appendix A.

4.4 The fee for the internal review stage (stage 1 in *Fees Rules 2024*) is €750. Do you think the fee for this is proportionate?

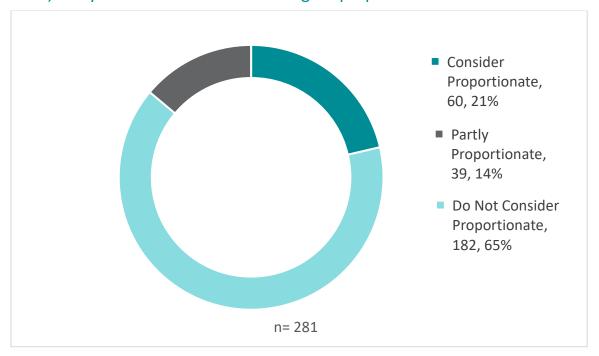


56% of respondents did not consider the internal review stage fee of €750 to be proportionate, whereas 44% considered it to be partly or fully proportionate.

Respondents were invited to provide a brief rationale for their answer with 112 individuals opting to do so. Approximately 30% of the submitted comments were outside the scope of the consultation and, therefore, could not be considered. The remaining comments were reviewed, revealing that the majority expressed concerns about the fee being too high or disproportionate. Conversely, around 10% of the respondents considered the fee to be proportionate and approximately 20% suggested that the fee should be higher.

All comments are available upon request.

4.5 The fee for the holistic assessment stage is €1500 (stage 2 of *Fees Rules 2024*). Do you think the fee for this stage is proportionate?

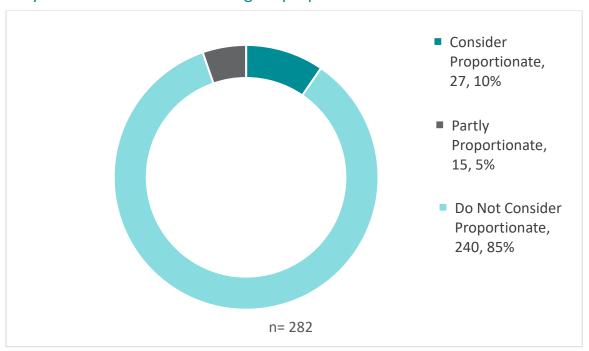


65% of respondents did not consider the holistic assessment stage fee of €1500 to be proportionate whereas 35% considered it to be partly or fully proportionate.

Respondents were encouraged to provide a brief rationale for their answer with 111 individuals opting to do so. Approximately 25% of the submitted comments were outside the scope of the consultation and, therefore, could not be considered. The remaining comments were reviewed, revealing that the majority expressed concerns about the fee to being too high or disproportionate. Conversely, around 20% of the respondents considered the fee to be proportionate and approximately 5% suggested that the fee should be higher.

All comments are available upon request.

4.6 The fee for the examination stage is €4000 (stage 4 of the *Fees Rules 2024*). Do you think the fee for this stage is proportionate?



85% of respondents did not consider the examination stage fee of €4000 to be proportionate whereas 15% considered it to be partly or fully proportionate.

Respondents were able to provide a brief rationale for their answer with 131 individuals opting to do so. Approximately 25% of the submitted comments were outside the scope of the consultation and, therefore, could not be considered. The remaining comments were reviewed, revealing that the majority expressed concerns about the fee to being too high or disproportionate. Conversely, around 10% of the respondents considered the fee to be proportionate or suggested the fee should be higher.

All comments are available upon request.

4.7 Do you have any other feedback on the *Pharmaceutical Society of Ireland* (Fees) (AMENDMENT) Rules 2024?

129 respondents provided feedback in this section and one response was received via email in addition to the survey. Approximately 35% of the comments did not contain commentary within the scope of the consultation and therefore could not be considered. The email response also included comments outside the scope of the consultation so these could not be considered however the relevant portion has been considered and included in-line with other feedback in this section. Most comments echoed previous section comments whereby they expressed finding the fees too high/disproportionate and expressed how this would be a substantial barrier for many pharmacists seeking qualification recognition.

All comments are available upon request.

PSI Response

The PSI acknowledges the feedback provided during the consultation process regarding the proposed fee structure for the recognition of pharmacy qualifications obtained outside the EU/EEA. The feedback received reflects a range of sentiments, with some respondents perceiving the proposed fees as disproportionately high, others expressing neutrality, and a portion indicating that the fees may be too low. It is noteworthy, however, that no respondent presented economically substantiated arguments to justify either a reduction or an increase in the proposed fees.

The PSI recognises that the adjustment to fees may appear significant given that the qualification recognition fees have remained unchanged since 2009. Nonetheless, the proposed fees are aligned with the principles of transparency, equity, and a non-subsidised cost-recovery model, ensuring that applicants bear the costs directly associated with the services they utilise.

The revised process introduced the removal of a mandatory adaptation period, which inherently required an applicant to be resident in the State. This adjustment eliminates a significant "hidden cost" previously borne by the applicant, thereby reducing the overall financial burden despite the increase in upfront fees.

The determination of the proposed fees has been informed by analysis and experience of the operational resources and external costs required to administer each stage of the revised process. This revised process offers a more holistic and inclusive approach to recognising pharmacy qualifications from outside Ireland and the wider EU/EEA, and ensures that the process remains efficient, inclusive, and reflective of the resources expended.

While the proposed fees are higher than those previously in place, it is essential to emphasise that they are not designed to create an undue financial barrier for applicants. Rather, the fees are structured to cover the operational costs of each stage of the qualification recognition process. This approach safeguards the sustainability of the system while providing a robust pathway to qualification recognition that remains equitable and accessible to all eligible applicants.

The PSI remains steadfast in its commitment to upholding a transparent, efficient, and fair process for the recognition of pharmacy qualifications for applicants from outside Ireland and the wider EU/EEA. By adopting a non-subsidised, cost-recovery model, the PSI ensures that all applicants are treated equitably while safeguarding the long-term viability of the qualification recognition system.

Conclusion

We have noted all responses with thanks. The feedback provided has been considered by the PSI Council in their consideration of the proposed Pharmaceutical Society of Ireland (Fees) (Amendment) Rules 2024.

Appendices

A – List of named respondents

B – Proposed *Pharmaceutical Society of Ireland (Fees) (Amendment) Rules 2024* as issued for public consultation

Appendix A

The following 68 people and 1 organisation shared their names and indicated they wished for their name to be included in this consultation report:

- Abdalla
- Adarsh Syla Kumar, HPRA
- Adeel
- Adekunbi
- Afifa sadiq
- Afifa Saghir
- Ahmed Farrag
- Ahmed Nashat
- Ali
- Ali shan
- Almigdad abdulrahman haggag
- ALTHAF ALIKHAN
- Angelito Eldho
- Anju Susanna Alex
- Areeba Mateen
- Aswathy Rajan
- Dhruva Teja Thurlapati
- Divya Tresa thomas
- Dr, Dehane Said
- Eatemad Ibrahim
- Emile Calitz
- Eyad emad hamdy mostafa
- Fatima Qureshi
- Hasan fawad
- Hassan Eltayeb Osman Ahmed
- Hina Shahbaz
- Iman
- Irish Pharmacy Union,

Sinead Mc Cool - Head of Professional Services (acting)

- Jamyung Park
- Javed Saleem Bin Sina Pharmacy Abu Dhabi
- Jodri Helmand
- Maab Elhadi ahmed Mohammed
- Mahmoud Gomaa
- Marva

- Michelle Ohagan
- Mohammed moiz
- Muhammad Ahmed Khan
- Ngabo
- Niamh Galvin
- Nimrah Faroog
- Nuseba
- Odimegwu ujunwa Concillia
- Omerwasila
- Perihan amr abdallah elsayed elmorsy
- Qaneeta Haseeb
- Qasim
- Ragda Ibrahim
- Rania Ezaldeen
- Richard Churchward
- Rimsha Khan
- Saddaf
- Safa Mohammed
- SAMI UL HAQ
- Samreen Hameed
- Shabana sarwar
- Shadia Elabbassi
- Shahzad Ahmad
- Shahzad Ullah
- Shankar lal
- Sissi Nemer
- Soha Elgaili
- Soumya George
- Sulaiman Abdussalam Adeshina
- TAHZEEBA RIAZ from BIOLIFE
- Wafa Wafa
- Wajahat
- Wilson George
- Yes
- Zain Ashfaq