

## Minutes of the Regulatory and Professional Policy Committee Meeting held in hybrid format in PSI House and online on 28 November 2024.

### Agenda Item A - Apologies

Name	Role	Present (Yes/No)
Mr Rory O'Donnell	Chair	Yes
Ms Gráinne Power		No - apologies
Ms Marie Louisa Power		Yes
Mr Peter Dennehy		Yes
Ms Dorothy Donovan		Yes
Mr Mark Jordan		Yes
Ms Geraldine Crowley		Yes
Dr Laura Sahm		Yes
Mr Richard Hammond S.C		Yes
<b>Members of PSI staff in attendance for part or all of the meeting included:</b>		
Ms Joanne Kissane	Registrar and Chief Officer	
Ms Cora O'Connell	Acting Head of Practitioner Assurance	
Ms Damhnait Gaughan	Head of Community Pharmacy Assurance	
Mr Garrett O'Donoghue	Registrant and Customer Relations Manager	
Ms Orla Carroll	Community Pharmacy Quality and Safety Manager	
Ms Laura Irwin	Community Pharmacy Quality and Safety Manager	
Mr Pádraig Corbett	Professional Standards Officer	
Ms Louise Hamra	Pharmacy Practice Officer	
Ms Andrea Boland	Professional Standards Coordinator	
Mr Ryan Duffy	Strategic Policy Officer	
Ms Elizabeth O'Halloran	Strategic Policy and Research Coordinator	
Ms Therese Anglim	Communication Project Executive	
The meeting commenced at 10 am.		

**Colour code: Red—for decision; Green—for discussion; Blue—for information**

### Agenda Item B – Declaration of Interests

#### Issue

Declaration of interests by Committee members.

#### Information

The Chair invited Committee members to declare any conflicts of interest regarding the items scheduled for discussion.

#### Decision Approved and/or Action Requested

No conflicts of interest were declared.

### Agenda Item C – Approval of meeting agenda

#### Issue

The Committee was asked if they were content to proceed with the meeting as per the agenda.

#### Information

The meeting agenda had been circulated in advance of the meeting.

#### Decision Approved and/or Action Requested

**Decision Approved:** The Committee approved the agenda on the proposal of Dr. Laura Sahm and seconded by Mr. Richard Hammond.

### Agenda Item D – Approval of Minutes – 12 September 2024 meeting

#### Issue

Approval of the minutes of the Regulatory and Professional Policy Committee meeting held on 12 September 2024.

#### Information

The Chair noted that the draft minutes of the previous Regulatory and Professional Policy Committee meeting had been circulated to Committee members in advance.

#### Decision Approved and/or Action Requested

**Decision Approved:** The Committee approved the minutes of the meeting held on 12 September on the proposal of Mr. Richard Hammond and seconded by Ms. Geraldine Crowley.

### Agenda Item E.1 – Amendment to the TCQR Implementation Policy

#### Issue

In advance of the meeting, the Committee was provided with a revised TCQR Implementation policy and legal opinion.

#### Information

The Committee discussed proposed amendments to the Third Country Qualification Recognition (TCQR) Implementation policy.

The Committee heard that the proposed revisions to the policy had been guided by legal engagement and advice.

The Committee discussed the draft amendments to the policy, including procurement and the wider legislative framework. The Committee heard that the Executive had commenced the market-sounding exercise with potential vendors as part of the procurement process for the examination required under Path B.

#### Decision Approved and/or Action Requested

##### **Decision Approved:**

The Committee approved the draft amendments to the Third Country Qualification Recognition (TCQR) Implementation policy and recommended the policy to Council for approval at the Council's next meeting on 12 December on the proposal of Mr. Richard Hammond, seconded by Ms. Marie Louisa Power.

### Agenda Item E.2 – Draft PSI Fees Rules to support the revised process for TCQR (Draft for Public Consultation)

#### Issue

In advance of the meeting, the Committee was provided with draft Fees Rules to support a revised TCQR process and legal opinion.

#### Information

The Committee discussed proposed amendments to the Pharmaceutical Society of Ireland (Fees) Rules 2014 to 2020 ('Fees Rules') intended to support the revised TCQR process.

The Committee heard that the proposed draft amending Fees Rules had been subject to legal scrutiny in drafting. The Committee discussed the draft amendments to both the policy and the rules, including fees. The Committee explored the process utilised in arriving at the proposed fees. It noted that the proposed fees are aligned with the principles of transparency and equity, as well as a non-subsidised cost recovery model, where applicants bear the costs directly associated with the services they utilise. After a

detailed discussion, which incorporated factors including cost recovery, inflation, anticipated increased demand for the service, sustainability, equity and the need to account for unforeseen or extraordinary costs, the Committee recommended increasing the proposed fee amount before submitting it for Council consideration.

#### **Decision Approved and/or Action Requested**

The Committee recommend that Council approve the Draft PSI Fees Rules to support the revised process for TCQR for public consultation at its December meeting on the proposal of Dr. Laura Sahm and seconded by Mr. Richard Hammond.

### **Agenda Item E.3 – Project Health Card update – Operationalisation of the Third Country Qualification Recognition Route**

#### **Issue**

The Committee was provided with the health card for the project.

#### **Information**

None.

#### **Decision Approved and/or Action Requested**

The Committee noted the project health card update.

### **Agenda Item F.1 – Consideration of proposed changes to PSI (Registration) and PSI (CPD) Rules (Drafts for Public Consultation)**

#### **Issue**

The Committee was provided with a presentation by Pádraig Corbett. The Committee was also provided with the current draft amendments to the Pharmaceutical Society of Ireland (Continuing Professional Development) and Pharmaceutical Society of Ireland (Registration) Rules in advance of the meeting.

#### **Information**

The Committee was asked to consider proposed changes to the Pharmaceutical Society of Ireland (Continuing Professional Development) and Pharmaceutical Society of Ireland (Registration) rules.

The Committee heard that the draft rules were developed to reflect the policy changes previously approved by the PSI Council in respect of the Continuing Professional Development (CPD) model for Pharmacists and the development and implementation of a CPD Model for Pharmaceutical Assistants.

The Committee was informed that a considerable preliminary consultation and engagement process had been carried out with key stakeholders, including the RPP Committee prior to further legal drafting, in advance of a wider public consultation on the proposed draft rules.

The Committee discussed the draft rules, seeking further information on how CPD changes would be communicated with registrants and whether consultation had included non-patient facing pharmacists. The Committee heard that non-patient facing pharmacists had been represented by PIER (Pharmacists in Industry, Education and Regulatory) as part of the PSI CPD review group, established by PSI to support the development of an evidence-based proposal to implement the recommendations contained within the Mazar's report. The Committee heard that the implementation proposal was approved by Council on 25 April 2024. The PSI also confirmed that members of the CPD review group would be contacted to support dissemination of key communications as part of the public consultation on the draft rules.

The Committee highlighted that the extenuating circumstances aspect of the CPD process could be more streamlined. Committee heard that although an extenuating circumstances application form is embedded within the new PSI website, supporting documentation must still be sent by email to the PSI. The PSI confirmed that they would endeavour to continue to streamline the process, in line with any potential functionality provided by the new website.

Finally, Committee discussed accessibility for pharmacists in understanding the changes to the CPD process, particularly in the context of legislative changes to the amended rules rather than an original statutory instrument. In the interests of time, it was agreed that rather than changing the draft amendments to the rules, an accessible document for pharmacists should be developed and that this may consist of a consolidated version of the rules or additional communication tools such as a video or FAQs, as part of the public consultation process.

#### **Decision Approved and/or Action Requested**

The Committee recommended that Council approve the draft Pharmaceutical Society of Ireland (Continuing Professional Development) and Pharmaceutical Society of Ireland (Registration) Rules for public consultation on the proposal of Ms. Dorothy Donovan and seconded by Mr. Mark Jordan.

#### **Agenda Item F.2 – Project Health Card update – Continuing Professional Development System for Pharmacists**

**Issue**

The Committee was provided with the health card for the project.

**Information**

None.

**Decision Approved and/or Action Requested**

The Committee noted the project health card update.

### **Agenda Item G.1 – Expert Taskforce - Progress update**

**Issue**

The Committee was provided with a presentation from Mr. Ryan Duffy on the PSI's progress in implementing the Expert Taskforce recommendations.

**Information**

The Committee heard that the PSI continues to contribute to the work of the Community Pharmacy Expansion Implementation Oversight Group (IOG), which was established by the Minister for Health to oversee the introduction of a common conditions service in community pharmacies, including contraceptive prescribing by pharmacists to extend or continue a prescription for contraception.

The Department of Health chairs the Implementation Oversight Group, whose members include PSI, HSE, HPRA, IPU, practising pharmacists, and a patient and public advocate.

The Committee was informed that while PSI contributes to all of the six workstreams identified and overseen by the IOG, the PSI is leading the second workstream, 'Education and training for pharmacists and regulatory matters,' which will see the delivery of necessary training and development. PSI is currently progressing a draft specification for pharmacist training for a common conditions service.

**Decision Approved and/or Action Requested**

The update was noted by the Committee.

### **Agenda Item G.2 – Project Health Card update – Expert Taskforce**

**Issue**

The Committee was provided with the health card for the project.

**Information**

None.

**Decision Approved and/or Action Requested**

The Committee noted the project health card update.

**Agenda Item H.1 – Hospital Pharmacy Regulation – Progress update**

**Issue**

The Committee was provided with a verbal update on the project.

**Information**

The Committee heard that following the Committee's consideration of the draft Position paper on the regulation of hospital pharmacy in June, work is continuing in revising the document, including engagement with HIQA in November.

The Committee heard that the next steps of the project will involve engagement with the HPRA to inform further revision of the draft paper and that once the relevant updates have been completed, the revised paper will be brought before the Committee for review.

**Decision Approved and/or Action Requested**

The update was noted by the Committee.

**Agenda Item I.1 – Advance reform of the Pharmacy Act – Progress update**

**Issue**

The Committee was provided with a presentation by Ryan Duffy, updating the Committee on the Advance Reform of the Pharmacy Act project.

**Information**

The Committee was reminded that since 2018, the PSI has been engaging with the Department of Health on advancing reform of the Pharmacy Act 2007 and that as part of this engagement, a position paper outlining the key challenges and weaknesses in the Act was developed and submitted to the Department in 2022.

The Committee heard that in November, following recent discussions with the Department of Health, the PSI submitted an action plan to the Department that identifies a subset of high-priority proposed legislative changes outlined in our position paper that

are at a relatively low level of complexity, and which we believe could be actioned within a short timeframe.

The proposed changes that are being sought in the short term relate to the Fitness to Practise process, including the role of the PSI Council in the process, along with a request to provide powers to the PSI to introduce outcomes-focused regulatory standards.

The Committee discussed the update on the project, highlighting that the project was an important piece of work for the PSI. The Committee enquired whether there had been any coordination with other regulators who might be seeking similar amendments.

The Committee heard that PSI was aware of the work of other regulators in this space being undertaken currently and that the Registrar had written to the Department with this in mind, highlighting the potential read across between PSI's action plan and amendments other regulators might be seeking to their fitness to practise processes.

#### **Decision Approved and/or Action Requested**

The update was noted by the Committee.

### **Agenda Item I.2 – Project Health Card update – Advance reform of the Pharmacy Act**

#### **Issue**

The Committee was provided with the health card for the project.

#### **Information**

None.

#### **Decision Approved and/or Action Requested**

The Committee noted the project health card update.

### **Agenda Item J.1 – Update on accreditation processes for the MPharm programme**

#### **Issue**

The Committee was provided with a verbal update on the accreditation process for the MPharm programme.

#### **Information**

The Committee heard that an accreditation visit to a potential new School of Pharmacy had been carried out and that an accreditation report was currently being drafted.

The Committee were also informed that an additional five accreditation visits had been scheduled for early 2025 and that accreditation teams were being established to carry out



those visits. The proposed nominees' names were currently being sent to the respective schools with a view to confirming that no conflicts arose. The Committee was made aware that the proposed accreditation teams are expected to go before Council at its December meeting for approval and that all team members have been proposed through the EOI process, as detailed to the Committee earlier in 2024.

#### Decision Approved and/or Action Requested

The update was noted by the Committee.

### Agenda Item K – Open Disclosure project update

#### Issue

The Committee was provided with a presentation from Cora O'Connell and Louise Hamra updating the Committee on PSI's progress on the Open Disclosure project.

#### Information

The Committee heard that the new Patient Safety (Notifiable Incidents and Open Disclosure) Act 2023 has recently commenced, which requires mandatory open disclosure processes in specific, rare, but very serious circumstances.

The Committee also heard that in addition to the new Act, a new National Open Disclosure Framework has been developed by the Department of Health to help manage the requirements surrounding patient safety incidents or adverse events outside of those explicitly prescribed for in the legislation. The framework means that all pharmacies will need to show evidence of open disclosure in their policies and procedures.

The Committee was reminded that PSI has obligations under the new framework, including supporting pharmacists to embed open disclosure into their practice, approving CPD courses, ensuring open disclosure is included in all pharmacy programmes and submitting an annual report to the Department of Health.

The Committee sought clarity on whether the HSE had training on open disclosure that could be accessed by pharmacists. The Committee heard that this training was being highlighted to pharmacists in the interim, but that the HSE's training is quite broad and that pharmacy-specific training would better support pharmacists and pharmacies in meeting their open disclosure requirements.

#### Decision Approved and/or Action Requested

The update was noted by the Committee.

### Agenda Item L.1 – Emerging Risks to Future Pharmacy Workforce update

### Issue

The Committee was provided with a presentation from Cora O’Connell and Louise Hamra highlighting some initial data from the State of the Register Survey 2024.

### Information

The Committee heard that the State of the Register Survey had been emailed to all registered pharmacists on 4 September and that the survey, which closed on 30 September, had received a positive response rate.

The Committee was informed that the survey sought further quantitative information to enhance the data PSI already holds on its registers, including additional information on demographics, areas of practice, location of practice and staffing and that the purpose of this enhanced data was to better assess the picture of pharmacy both in Ireland and for the pharmacist workforce as part of the wider EU health system.

While analysis and modelling are still ongoing, the Committee was presented with some highlights from the initial survey data. The Committee commended PSI on the work, highlighting the usefulness of the data in informing the regulatory work of PSI. The Committee requested that a copy of the slides be shared with the Committee following the meeting.

The final survey report is expected to be completed in early 2025.

### Decision Approved and/or Action Requested

The update was noted by the Committee.

## Agenda Item M.1 – Quarterly update on IOP operations and developments

### Issue

The Committee was provided with a memo and the Quarterly Update on IOP Operations and Developments before the meeting.

### Information

None.

### Decision Approved and/or Action Requested

The update was noted by the Committee.

## Agenda Item M.2 – Draft IOP Annual Workplan 2025

#### Issue

The Committee was provided with the draft IOP Annual Work Plan 2025 in advance of the meeting.

#### Information

The Committee considered the draft IOP Annual Workplan 2025, having heard that as part of the development of the draft workplan, PSI had carried out a prioritisation exercise following engagement with registrants and a number of other key stakeholders.

#### Decision Approved and/or Action Requested

The Committee recommended that the draft IOP Annual Workplan 2025 be approved by Council at its December meeting on the proposal of Mr. Mark Jordan and seconded by Ms. Marie Louisa Power.

### Agenda Item M.3 – Suspension of Practice Review 2025

#### Issue

The Committee was provided with a memo in advance of the meeting.

#### Information

The Committee considered the implications of continuing to suspend Practice Review for 2025 while work is progressed on approval of the required changes to both the Pharmaceutical Society of Ireland (Continuing Professional Development) Rules and the Pharmaceutical Society of Ireland (Registration) Rules.

As outlined in Agenda Item F.1 above, these draft changes are intended to operationalise Council-approved changes to the CPD model for pharmacists and the development and implementation of a CPD model for pharmaceutical assistants.

The Committee was reminded that in January, PSI Council decided to suspend Practice Review for 2024 pending further review, in line with recommendations of the review of the CPD model for pharmacists.

#### Decision Approved and/or Action Requested

The Committee decided to advise Council that Practice Review should continue to be suspended for 2025, pending implementation of the necessary changes to the Pharmaceutical Society of Ireland (Continuing Professional Development) and Pharmaceutical Society of Ireland (Registration) Rules on the proposal of Dr. Laura Sahm and seconded by Ms. Dorothy Donovan.

### Agenda Item N.1 – iNAP2

### Issue

The Committee was provided with a verbal update on the project.

### Information

The Committee was reminded that the PSI has obligations to take a number of actions under iNAP2, the second national action plan to combat antimicrobial resistance across both human and animal health.

The Committee heard that in response to a request from the National Patient Safety Office in August, PSI provided a progress update on our actions under iNAP2 and that the purpose of the update was to inform the development of iNAP3.

The Committee also heard that PSI had carried out a number of communications actions in October and November to highlight European Antibiotics Awareness Day and World AMR Awareness Week.

### Decision Approved and/or Action Requested

The update was noted by the Committee.

## Agenda Item O – Patient and public involvement in our work

### Issue

The Committee was provided with a presentation by Ryan Duffy, who updated the Committee on the project.

### Information

The Committee heard that the PSI aims to increase patient and public involvement in our regulatory work and that a number of actions have been taken in this regard.

The Committee was informed that PSI has been engaging with our HPRA colleagues in relation to the potential of PSI leading a session with the HPRA patient forum during 2025.

The Committee also heard that in October, PSI sought expressions of interest from experienced researchers to partner with the PSI for a HRB Applied Partnership Award (APA) application and that an experienced researcher from RCSI had been selected through an external evaluation panel. The deadline for the APA award application is in December.

The Committee discussed the project and its funding, emphasising that the project was an important piece of work related to both PSI's vision and strategy.

#### Decision Approved and/or Action Requested

The update was noted by the Committee.

### Agenda Item P – 2024 Work Plan Projects – Project Health Cards

#### Issue

The Committee was provided with an update on the remaining projects in its 2024 Committee Workplan. The health cards were provided to the Committee in advance of the meeting.

#### Information

The Committee noted the following project health cards:

- Implementation of Policy Developments Relating to Pharmacy.
- Development of CPD Model for Pharmaceutical Assistants.
- Patient Safety and Quality Initiatives.

#### Decision Approved and/or Action Requested

The project health card updates were noted by the Committee.

### Agenda Item Q – Service Planning

#### Issue

The Committee was provided with the draft PSI Service Plan 2025 and draft budgetary documentation for 2025 in advance of the meeting.

#### Information

The Committee heard an update from the Registrar on the draft service plan and draft budgetary documentation for 2025.

The Committee was informed that each of the advisory committees of Council had received both the draft Service Plan and draft budgetary documentation for discussion and consideration in advance of the PSI Council December meeting.

The Committee discussed the draft Service Plan and associated budget, in particular costs associated with the TCQR process and a planned Core Funding Review for 2025.

#### Decision Approved and/or Action Requested

The update was noted by Committee.

### Agenda Item R – Annual Committee performance review

#### Issue

The Committee received a link to an online survey in advance of the meeting which is intended to facilitate the Committee to carry out its annual performance review.

#### Information

The Chair asked Committee members to complete the annual performance review if they had not done so already.

#### Decision Approved and/or Action Requested

The Committee noted the update.

### Agenda Item S – Terms of reference

#### Issue

The Committee was provided with draft revised Terms of reference for the RPP Committee in advance of the meeting.

#### Information

None.

#### Decision Approved and/or Action Requested

**Decision Approved:** The Committee approved the terms of reference on the proposal of Ms. Marie Louisa Power and seconded by Ms. Geraldine Crowley.

### Agenda Item T – Proposed meeting dates 2025 and AOB

#### Issue

The Committee was provided with proposed meeting dates for 2025 in advance of the meeting.

#### Information

The Committee discussed the prospect of holding one to two Committee meetings in person during 2025. Further consideration is to be given to identifying which particular meeting(s) would be most suitable to have in-person.

The Committee also discussed the use of ShareFile only for Committee documentation, in place of email attachments and the use of Microsoft Co-Pilot to assist in note-taking for

Committee meetings, which would require the temporary recording of Committee meetings.

The Committee was broadly supportive of both measures; however, some Committee members highlighted challenges in using ShareFile. It was noted that the measures would be used on a trial basis in early 2025.

#### **Decision Approved and/or Action Requested**

The Committee approved the meeting dates for 2025 on the proposal of Dr. Laura Sahm and seconded by Mr. Mark Jordan.

**The meeting concluded at 12:52 pm.**

**Signed by:**

\_\_\_\_\_  
**Chair**

\_\_\_\_\_  
**Date**