

**Minutes of the Regulatory and Professional Policy Committee Meeting
held in hybrid format in PSI House and Microsoft Teams at 9 am on
11 April 2024**

Agenda Item A - Apologies

Name	Role	Present (Yes/No)
Mr Rory O'Donnell	Chair	Yes
Ms Gráinne Power		Yes
Ms Marie Louisa Power		No - apologies
Mr Peter Dennehy		No - apologies
Ms Dorothy Donovan		Yes
Mr Mark Jordan		Yes
Ms Geraldine Crowley		Yes
Dr Laura Sahm		Yes
Mr Richard Hammond S.C		Yes
Members of PSI staff in attendance for part or all of the meeting included:		
<i>Ms Joanne Kissane</i>	<i>Registrar and Chief Officer</i>	
<i>Mr John Bryan</i>	<i>Head of Community Pharmacy Assurance</i>	
<i>Ms Damhnait Gaughan</i>	<i>Head of Practitioner Assurance</i>	
<i>Mr Dan Burns</i>	<i>Head of Strategic Policy, Research and Communication</i>	
<i>Ms Cora O'Connell</i>	<i>Professional Standards Manager</i>	
<i>Ms Laura Irwin</i>	<i>Community Pharmacy Quality and Safety Manager</i>	
<i>Mr Pádraig Corbett</i>	<i>Professional Standards Officer</i>	
<i>Mr Shane McGlynn</i>	<i>Investigations Officer</i>	
<i>Ms Andrea Boland</i>	<i>Professional Standards Coordinator</i>	
<i>Ms Orla Carroll</i>	<i>Community Pharmacy Quality and Safety Manager</i>	
<i>Mr Ryan Duffy</i>	<i>Strategic Policy Officer</i>	
<i>Ms Elizabeth O'Halloran</i>	<i>Strategic Policy and Research Coordinator</i>	
<i>Ms Therese Anglim</i>	<i>Communication Project Executive</i>	

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

Agenda Item B – Declaration of Interests

Issue

Declaration of interests by members of the Committee.

Information

The Chair invited members of the Committee to declare any conflicts of interest regarding any of the items scheduled for discussion at the meeting before it commenced.

Decision Approved and/or Action Requested

The committee did not declare any conflicts of interest.

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 of the meeting on the proposal of Mr Richard Hammond S.C and seconded by Mr Mark Jordan.

Agenda Item D – Approval of Minutes – 21 February 2024 meeting

Issue

Approval of the Minutes of the Regulatory and Professional Policy Committee meeting held on 21 February 2024.

Information

The Chair noted that the draft minutes of the Regulatory and Professional Policy Committee Meeting held on 21 February had been circulated to Committee members in advance of the meeting.

Decision Approved and/or Action Requested

Decision Approved: The Committee approved the minutes of the meeting held on 30 November 2023 on the proposal of Mr Mark Jordan and seconded by Dr Laura Sahm.

Agenda Item E.1 - Update on operationalising the TCQR route process leading to registration as a pharmacist

Issue

The Committee was provided with a verbal update by John Bryan.

Information

The Committee was appraised of the necessity to reexamine the Third County Qualification Recognition (TCQR) process and, specifically, the requirement to amend the process adopted by Council in 2022.

The Committee discussed the proposed policy and its contextual basis, noting the absence of a third-party provider to support the delivery of the adaptation process and the risk-based approach recommended. The Committee discussed the proposed examination process and noted the clarifications provided.

The Committee expressed concerns about the rationale for the proposed changes to the process. Clarification was provided that the rationale for any change was predicated on adhering to the core mandate of public protection and patient safety.

The Committee sought further information and discussed in depth a number of aspects of the proposal, including;

- clarity on the examination format
- the approach of other regulatory bodies
- the availability of an appeals process within the proposed revised route
- the potential for conditional registration under the route incorporating a period of supervised practice
- applicable legislation and considerations of the Professional Qualifications Directive (PQD) absolute requirement to assure that competence and standard of the qualification are the determining factors for recognition.

A revised memo will be prepared for the RPP Committee's consideration at their meeting on 6 June 2024.

Decision Approved and/or Action Requested

The Committee noted the update.

Agenda Item E.2- Operationalisation of Third Country Qualification Recognition Route - Project Health Card Update

Issue

The Committee was provided with a project health card in advance of the meeting.

Information

None.

Decision Approved and/or Action Requested

The Committee noted the update.

Agenda Item F.1 - Revised CPD Model for Pharmacists - IOP Written Submission; Submitted in the context of the development of the CPD proposal and proposal for quality assurance

Issue

In advance of the meeting, the Committee received a memo from PSI and a written submission from the IOP, which had been submitted in the context of the development of the CPD proposal and proposal for quality assurance by PSI.

Information

Damhnait Gaughan provided an update to the Committee on the discussion paper, which had been provided by the IOP. The Committee was tasked with considering and discussing the IOP written submission, particularly in the context of considering the draft proposal for the CPD Model for Pharmacists following the Mazars Report. The committee noted the contents of the discussion document and the memo.

The Committee noted the alignment of many aspects of the IOP document with the current trajectory being proposed by PSI in the CPD and quality assurance proposal papers. It noted that other elements of the IOP document were outside of the current focus on the mechanisms for CPD assurance for pharmacists. In particular, the Committee discussed the matter of leadership within the pharmacy profession. Background context was provided, including past efforts towards establishing a leadership body, issues identified during the IOP contract review in 2017/2018, and PSI's accountability for workforce planning. It was clarified that the leadership body issue is separate from the CPD report and requires careful consideration of feasibility and funding. It was noted that the matter of a leadership body is raised as one of the action points in the PSI Workforce Intelligence Report.

PSI's engagement with IOP was discussed, including bi-annual strategic meetings and frequent engagement between the Registrar & Chief Officer and the IOP Executive Director. It was suggested that the next bi-annual strategy meeting be brought forward to discuss matters raised in the IOP written submission. The PSI Executive expressed readiness to align with the Committee's recommended approach.

Decision Approved and/or Action Requested

The Committee noted the update.

Agenda Item F.2 - Revised CPD Model for Pharmacists - Proposal for CPD model for pharmacists following on from the Mazars Report 'Review of the Continuing Professional Development (CPD) Model for Pharmacists in Ireland (2023)'

Issue

Approval of proposal for CPD model for pharmacists following on from the Mazars Report 'Review of the Continuing Professional Development (CPD) Model for Pharmacists in Ireland (2023)'. A presentation was delivered during this agenda item.

Information

Pádraig Corbett updated the Committee on the ongoing work regarding the development of a proposal for the CPD Model for Pharmacists, following on from the Mazars Report 'Review of the CPD Model for Pharmacists in Ireland (2023)'.

The Committee was asked to consider a draft implementation proposal for the CPD Model for Pharmacists and decide if it was satisfied to advise the Council that the draft proposal be approved at its meeting on 25 April 2024.

The purpose of this implementation proposal is to further inform and elaborate on the PSI Council's consideration on the scope of the revised CPD model for pharmacists and to provide an evidence-based framework to implement the recommendations contained within the Mazars report.

The Committee sought further information and discussed a number of aspects of the proposal, including;

- the potential value, merits, insights and learnings from the recently suspended Practice Review, and whether these could be used in any other way. Department of Health (DOH) awareness of the ongoing work and proposed changes.

Decision Approved and/or Action Requested

Decision Approved: The Committee is recommending that the Proposal for a CPD Model for Pharmacists following on from the Mazars Report 'Review of the Continuing Professional Development (CPD) Model for Pharmacists in Ireland (2023)', be approved by Council at its meeting of 25 April, on the proposal of Mr Richard Hammond S.C and seconded by Dr Laura Sahm.

Agenda Item F.3 - Revised CPD Model for Pharmacists - Approval of Proposal paper for Systems for Quality Assurance of Continuing Professional Development Training Programmes and Activities for Pharmacists

Issue

Approval of proposal paper for Systems for Quality Assurance of Continuing Professional Development Training Programmes and Activities for Pharmacists. A presentation was delivered during this agenda item.

Information

Cora O'Connell provided an update to the Committee on the ongoing work regarding the Systems for Quality Assurance of Continuing Professional Development (CPD) Training Programmes and Activities for Pharmacists.

The Committee was asked to consider a proposal paper reviewing the Systems for Quality Assurance of such Training Programmes and Activities for Pharmacists, which proposed a future direction for quality assurance.

It was explained how the Executive initiated this review with a view to improving and rationalising the current accreditation system. This project involved benchmarking, stakeholder engagement, and review of alternative quality assurance systems.

The Committee heard that the proposed system requires legislative change and aims to provide greater flexibility and agility through the development of a Council-approved quality assurance policy for CPD programmes and activities.

Decision Approved and/or Action Requested

Decision Approved: The Committee is recommending the proposal paper for Systems for Quality Assurance of Continuing Professional Development Training Programmes and Activities for Pharmacists to be approved by Council at its next meeting on 25 April, on the proposal of Mr Richard Hammond S.C and seconded by Ms Gráinne Power.

Agenda Item F.4 - Revised CPD Model for Pharmacists - Project Health Card

Issue

The Committee was provided with a project health card in advance of the meeting.

Information

None.

Decision Approved and/or Action Requested

The Committee noted the update.

Agenda Item G.1 – Development of CPD Model for Pharmaceutical Assistants – Proposal for CPD themes to underpin the model of CPD for Pharmaceutical Assistants. Update on progress on the development of a CPD Model for Pharmaceutical Assistants

Issue

Cora O'Connell gave the Committee a verbal update on the development of the CPD model for the Pharmaceutical Assistants project.

Information

The Committee heard that a meeting took place with the Chairperson and Secretary of the Pharmaceutical Assistants Association on 26 October 2023 to discuss the report on the Development of a Continuing Professional Development (CPD) Model for Pharmaceutical Assistants, which was approved by Council at their meeting on 22 June 2023. It was advised that this meeting was very positive.

The Committee was also provided with an update on a workshop that took place on 15 February 2024 in PSI House with pharmaceutical assistants and members of the Pharmaceutical Assistants Association (PAA), in which disparate views were expressed. Further to that workshop, the PSI has had positive engagement with the PAA, and the project is progressing to deliver CPD 'themes to underpin the new system of CPD for pharmaceutical assistants. The Committee heard that the work would continue with a consultation with all registered pharmaceutical assistants regarding the CPD themes in the coming months.

The Committee commended the Executive on the project's progress to date.

Decision Approved and/or Action Requested

The Committee noted the update.

Agenda Item G.2 - Development of CPD Model for Pharmaceutical Assistants
- Project Health Card

Issue

The Committee was provided with a project health card in advance of the meeting.

Information

None.

Decision Approved and/or Action Requested

The Committee noted the update.

Agenda Item H.1 - Draft Workforce Survey Analysis Report 2023

Issue

Approval of Draft Workforce Survey Analysis Report 2023. A presentation was delivered during the agenda item.

Information

Cora O'Connell provided an update to the Committee on the Draft Workforce Survey Analysis Report 2023.

The Committee heard that the "Emerging Risks to the Future Pharmacy Workforce" project was initiated in 2022 to assess risks to the pharmacy workforce. In furtherance of this work, the Council approved and published the PSI Workforce Intelligence Report and Pharmacy Workforce Survey Analysis Report.

Grant Thornton was commissioned in October 2023 to deliver a second Workforce Survey Analysis report. The aim was to build on the 2022 report and identify any risks to the continued availability of the patient-facing pharmacist workforce in Ireland. The draft report covers themes including role identification, work conditions, and career progression, and where possible, comparisons are made to the 2022 findings. The Committee heard that if approved, this report will serve as a tool to inform the ongoing efforts of the Workforce Implementation Group.

The Committee discussed the report. It queried the optimum frequency for conducting this report and acknowledged its sentiment-based nature and data limitations. The Committee recognised the value of the work.

Decision Approved and/or Action Requested

Decision Approved: The Committee is recommending that the draft Workforce Survey Analysis Report 2023 be approved by Council at its next meeting on 25 April on the proposal of Mr Richard Hammond S.C and seconded by Ms Gráinne Power.

Agenda Item H.2 – Emerging Risks to Future Pharmacy Workforce – Project Health Card Update

Issue

The Committee was provided with a project health card in advance of the meeting.

Information

None.

Decision Approved and/or Action Requested

The Committee noted the update.

Agenda Item I.1a, 1.1b, I.1c - Patient Safety and Quality Initiatives - Proposed approval of a delineated model for Retail Pharmacy Businesses, proposed amendments to the Regulation of Retail Pharmacy Businesses Regulations (SI 488 of 2008) and draft PSI Guidance on the Operation of a Retail Pharmacy Business using a Delineation Model

Issue

Approval of proposed delineated model for Retail Pharmacy Businesses and proposed amendments to the Regulation of Retail Pharmacy Businesses Regulations (SI 488 of 2008)

Information

Shane McGlynn provided the Committee with an update on the agenda items I.1a, I.1b, and I.1c.

The Committee was briefed on the concerns raised in the PSI Workforce Intelligence Report 2023, particularly the absence of protected time for rest periods/lunch breaks due to legislative requirements mandating a pharmacist presence when a pharmacy is open to patients and the public.

To address this issue, the PSI is developing a 'delineated operating model' to separate pharmacy services from retail operations. This model would enable pharmacists to take breaks while keeping the retail area open, with necessary security measures to restrict medicines access.

The Committee heard implementing this model requires legislative amendments to the Regulation of Retail Pharmacy Businesses Regulations 2008 (SI 488 of 2008) and the Pharmaceutical Society of Ireland (Retail Pharmacy Businesses) (Registration) Rules 2008 (SI 495 of 2008).

The Committee reviewed proposed amendments to SI 488 and discussed the draft guidance. The Committee raised queries regarding structural aspects required in the guidance, with clarification provided on the requirement for using lockable metal shutters. The Committee discussed the proposed two-hour per day time limit and heard that the purpose of implementing a delineated model was to facilitate pharmacist rest breaks and that the proposed time limit would accommodate such breaks.

The Committee highlighted the need for further examination of the amendments and guidance by the Department of Health, advising against overly prescriptive measures. The Executive outlined that the next steps include submitting the Statutory Instrument (SI 488 of 2008) draft amendments and draft guidance to the Department of Health for consideration.

Decision Approved and/or Action Requested

Decision Approved: The Committee is recommending submitting the draft amendments to the Department of Health for their consideration and approval, along with the draft guidance document to support the proposed amendments on the proposal of Mr Mark Jordan and seconded by Ms Gráinne Power.

[Agenda Item J.1 and J.2 - Expert Taskforce - Draft updated Guidelines to support Medicines Therapy Review, Counselling, and Prescription Extension](#)

Issue

Approval of draft updated Guidelines to support Medicines Therapy Review, Counselling, and Prescription Extension

Information

Dan Burns and Orla Carroll provided the Committee with an update.

The Committee was briefed on the establishment of the Expert Taskforce in July 2023 by the Minister for Health, Stephen Donnelly, aimed at exploring the expansion of pharmacists' roles in Ireland. The Taskforce's first recommendation, published November 2023, enables pharmacists to extend certain prescriptions from six to twelve months, where, in their professional judgment, it is safe and appropriate to do so. This resulted in

legislative amendments introduced on 1 March 2024, with pharmacists being enabled to extend prescriptions six months thereafter (i.e., from 1 September 2024).

The PSI Expansion of Pharmacy Services Working Group, in consultation with external stakeholders, identified the need for statutory guidelines to ensure compliance with the regulatory changes. Version 4 of the Guidelines on Counselling, Medicines Therapy Review, and Prescription Extension were updated accordingly, adopting a principles-based approach.

The draft Guidelines will now undergo public consultation, with revisions made based on feedback from the consultation. They will be submitted to the RPP Committee for their consideration and approval in June. If approved by the RPP Committee, the draft Guidelines will be considered by the Council at their June meeting. The Committee commended the Executive's work on the guidelines and stressed the importance of continuous communication to ensure awareness and understanding of these legislative changes within the profession.

Decision Approved and/or Action Requested

Decision Approved: The Committee is approving the draft Guidelines that will be published for public consultation, along with the guidance document to support the proposed amendments on the proposal Mr Richard of and seconded by Mr Mark Jordan.

Agenda Item J.3 – Expert Taskforce – Implementation of Recommendations to Support the Expansion of Pharmacist Roles – Project Health Card Update

Issue

The Committee was provided with a project health card in advance of the meeting.

Information

None.

Decision Approved and/or Action Requested

The Committee noted the update.

Agenda Item K – Project Health Cards

Issue

The Committee was provided with an update by Dan Burns and John Byran.

Information

The Committee noted the following project health cards:

- Implementation of Policy Developments Relating to Pharmacy
- Patient Safety and Quality Initiatives
- Advance reform of the Pharmacy Act

The Committee briefly discussed the health card: Implementation of Policy Development Relating to Pharmacy. A discussion followed on the planned introduction on a permanent basis of legislation to allow for emergency supply of controlled drugs by pharmacists and the potential risk this introduces to overuse of these medicines. The Committee noted the benefit of being able to dispense emergency supplies of controlled drugs in certain circumstances to meet urgent patient needs, as was provided for during the COVID-19 pandemic. The Committee agreed that a balance between patient safety and appropriate and rational use of controlled drugs was important.

Decision Approved, and/or Action Requested

The Committee noted the update.

Agenda Item L - AOB

Issue

The Chair asked if there was any other business to be raised.

Information

The Committee discussed the timeline for the Code of Conduct review, noting that the last review occurred in 2019 and that a review is due.

The Chair brought up the possibility of holding an in-person meeting for the Committee in 2024. There was consensus among the Committee members that an in-person meeting would be beneficial.

Further discussions revolved around the logistics of scheduling the in-person meeting, with the idea of conducting a poll to determine the most convenient time for everyone.

Decision Approved, and/or Action Requested

None.

The meeting concluded at 11.51am.

Signed by:

Chair

Date