

Minutes of the Regulatory and Professional Policy Committee Meeting held online on Microsoft Teams at 10 am on 6 June 2024

Agenda Item A - Apologies

Name	Role	Present (Yes/No)
Mr Rory O'Donnell	Chair	Yes
Ms Gráinne Power		Yes
Ms Marie Louisa Power		Yes
Mr Peter Dennehy		Yes
Ms Dorothy Donovan		Yes
Mr Mark Jordan		Yes
Ms Geraldine Crowley		No -apologies
Dr Laura Sahm		Yes
Mr Richard Hammond S.C		No -apologies
<i>Members of PSI staff in attendance for part or all of the meeting included:</i>		
<i>Ms Joanne Kissane</i>	<i>Registrar and Chief Officer</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>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 Ciara Dooley</i>	<i>Regulatory Risk Coordinator</i>	
<i>Ms Louise Hamra</i>	<i>Pharmacy Practice Officer</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 Ms Dorothy Donovan and seconded by Mr Mark Jordan.

Agenda Item D – Approval of Minutes – 11 April 2024 meeting

Issue

Approval of the Minutes of the Regulatory and Professional Policy Committee meeting held on 11 April 2024.

Information

The Chair noted that the draft minutes of the Regulatory and Professional Policy Committee Meeting held on 11 April 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 11 April 2024 on the proposal of Mr Mark Jordan and seconded by Dorothy Donovan.

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

Issue

Approval of the amendments to the TCQR process and recommend to Council the removal of the mandatory adaptation period for TCQR applicants from the 2022 Third Country Qualification Recognition (TCQR) route.

Information

The Committee was briefed on the proposal to amend the Third Country Qualification Recognition (TCQR) process to remove the mandatory adaptation period for applicants. The Committee was informed that PSI conducted a comparative analysis of other Irish regulators who also have 'fast track' routes implemented, and those who use examination as a compensation measure for TCQR applicants.

The Committee heard that the proposed amendment to the route would remove the adaptation period, and further information was provided on the proposed examination structure. The examination will be used as a compensation measure to address any deficiencies that may be identified at the holistic assessment stage of the route. The examination will have two components: a Multiple-Choice Question (MCQ) exam and an Objective Structured Clinical Examination (OSCE) examination. The outcome of the holistic assessment will determine if one or both components will be required to address any identified deficiencies in an applicant's qualification.

The Committee was asked to approve the recommendation to remove the mandatory adaptation period from the revised TCQR process, which Council approved in 2022.

The Committee thanked the Executive for their work to date.

The Committee expressed positive feedback regarding the in-person exam element, highlighting its importance for managing risk. The Committee heard that the revised route would operate on a cost-recovery basis, with a fee associated with each stage.

The Committee discussed the operational elements of the revised route, including the incorporation of a review of its effectiveness once it is operational.

The Committee inquired about receiving further updates on the project. They were informed that there will be ongoing discussions about the TCQR process, with frequent updates of the project provided to the Committee at future RPP meetings and via the project health card.

The Committee discussed and agreed on the recommendation to remove the mandatory adaptation period from the TCQR policy, which Council approved in 2022.

Decision Approved and/or Action Requested

Decision Approved: The Committee approved the amendments to the TCQR process and recommended to Council the removal of the mandatory adaptation period for TCQR applicants on the proposal of Ms Dorothy Donovan and seconded by Mr Peter Dennehy.

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 and F.3 - Revised CPD Model for Pharmacists and Development of CPD Model for Pharmaceutical Assistants - Project Health Cards

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.2 - Revised CPD Model for Pharmaceutical Assistants - Consultation Draft:
CPD Themes to support continuing professional development of Pharmaceutical
Assistants***

Issue

Approval of the draft CPD themes to underpin the system of CPD for pharmaceutical assistants to progress to public consultation.

Information

Damnait Gaughan provided an update to the Committee.

The Committee heard that on 22 June 2023, Council approved the Mazars Report for a Continuous Professional Development (CPD) Model for Pharmaceutical Assistants. This report recommended the use of CPD themes to underpin the new CPD system. The PSI has now developed draft CPD themes in consultation with the Pharmaceutical Assistants Association (PAA), which were now presented to the Regulatory and Professional Policy Committee for approval for public consultation.

The Committee expressed support for the themes, finding them descriptive and clear. Additionally, the Committee expressed satisfaction with the collaboration and engagement between the Executive and the Pharmaceutical Assistants Association.

Decision Approved and/or Action Requested

Decision Approved: The Committee approved draft CPD themes for pharmaceutical assistants to progress to the consultation stage on the proposal of Ms Maria Louisa Power Donovan and seconded by Dr Laura Sahm.

Agenda Item G.1 - IIOU Updates - Quarterly update on IIOU operations and developments

Issue

In advance of the meeting, a memo was circulated to the Committee.

Information

The Committee were updated on the activities of the Irish Institute of Pharmacy (IIOU) for Quarter 1 of 2024. It also includes relevant updates in relation to ePortfolio and Practice Review.

Decision Approved and/or Action Requested

The Committee noted the update.

Agenda Item G.2 - IIOB Updates - EPortfolio Review Policy 2024/2025

Issue

Approval of ePortfolio Review Policy for recommendation to Council at its meeting of 20 June.

Information

The Committee received an update on the oversight of the Continuing Professional Development (CPD) system for pharmacists in Ireland by the Irish Institute of Pharmacy (IIOB). This includes management of the ePortfolio Review process, governed by Rule 11(5) of the Pharmaceutical Society of Ireland (Continuing Professional Development) Rules 2015. The Committee heard that the ePortfolio Review Policy underwent an internal review on 23 May 2024, with no changes proposed.

The Regulatory and Professional Policy Committee is therefore requested to consider this policy for recommendation to Council at its meeting on 20 June.

Decision Approved and/or Action Requested

Decision Approved: The Committee approved the ePortfolio Review Policy for recommendation to Council at its meeting of 20 June on the proposal of Ms Dorothy Donovan and seconded by Mr Peter Dennehy.

Agenda Item H.1 – Expert Taskforce – Implementation of Recommendations to Support the Expansion of Pharmacist Roles - Revised Draft Guidelines to support Medicines Therapy Review, Counselling and Prescription Extension

Issue

Approval of revised Guidelines to support Medicines Therapy Review, Counselling and Prescription Extension to recommend these guidelines to Council for its approval at its meeting on 20 June 2024.

Information

Updated PSI Guidelines on Counselling and Medicine Therapy Review were approved for public consultation by the Regulatory and Professional Policy Committee at its April meeting. The purpose of the draft guidelines is to support pharmacists with the safe implementation of recent legislative changes to enable pharmacists to extend the validity of certain prescriptions.

The public consultation was open from 24 April to 15 May. PSI received 169 usable responses to the online survey and three additional responses by email. A focus group meeting was also conducted on 15 May with members of the PSI Pharmacist Panel. Feedback from the consultation and panel was incorporated into the guidelines.

The Committee welcomed the changes to the draft guidelines in response to the consultation, commenting on the enabling nature of the principles-based framework. The Committee highlighted that some respondents to the consultation had commented on the overall accessibility of language.

The Committee heard that PSI is working with the IOP to develop additional supports for pharmacists, such as webinars and case studies and that PSI is developing draft FAQs to provide further information to pharmacists.

Decision Approved and/or Action Requested

Decision Approved: The Committee recommended the draft revised Guidelines to support Medicines Therapy Review, Counselling and Prescription Extension to Council for approval at its meeting on 20 June on the proposal of Ms Marie Louisa Power and seconded by Dr Laura Sahm.

Agenda Item H.2, H.3 and H.4 - Expert Taskforce – Implementation of Recommendations to Support the Expansion of Pharmacist Roles - Public Consultation Report, Revised Draft Guidelines to support Medicines Therapy Review, Counselling and Prescription Extension and Project Health Card update

Issue

In advance of the meeting, a memo, public consultation report and the project health card were circulated to the Committee.

Information

None.

Decision Approved and/or Action Requested

The Committee noted the update.

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

Issue

The Committee were provided with a verbal update from Dan Burns.

Information

None.

Decision Approved and/or Action Requested

The Committee noted the update.

Agenda Item I.2 - Advance reform of the Pharmacy Act – Project Health Card

Issue

Approval of an amendment to Advance reform of the Pharmacy Act Project Health card.

Information

The Committee heard about a change in approach to this project. Due to competing priorities, particularly the review and reform of fitness to practise structures and processes and the expansion of pharmacist roles for full prescribing, the research stage of this project will not continue as planned. Instead, resources will be redirected to focus on these priority areas. Additionally, ongoing research on the use of regulatory tools by the HRB will help inform this project.

The Committee broadly agreed with and supported this change in direction.

Decision Approved and/or Action Requested

Decision Approved: The Committee approved the amendment to Advance the reform of the Pharmacy Act Project Health card on the proposal of Mr Peter Dennehy and seconded by Ms Dorothy Donovan.

Agenda Item J.1 - Hospital Pharmacy Regulation Position paper on Hospital Pharmacy Regulation

Issue

In advance of the meeting, the position paper and a memo were circulated to the Committee.

Information

The Committee heard that the Executive does not have regulatory authority over hospital pharmacy activities such as supplying medicines to in-patients or wards or providing clinical services at ward level, but does regulate all registered pharmacists regardless of their place of practice. There is a recognised need for clarification of PSI's role in hospital pharmacy regulation due to potential regulatory gaps.

The Executive's corporate strategies and annual work plans since 2018 have included projects focusing on engagement with the hospital pharmacy sector, benchmarking with other jurisdictions, and mapping the Executive's legislative framework in relation to hospital pharmacy. The findings indicate limitations in the Executive's regulatory function for hospital pharmacies registered as retail pharmacy businesses, a lack of clear delineation of regulatory responsibilities among regulators (PSI, HPRA, HIQA), and potential risks to patients due to insufficient regulation.

The Executive has drafted a Position Paper on Regulation and Regulatory Gaps in Hospital Pharmacy, with recommendations including:

1. Seeking updates from the Department on proposals for a hospital licensing system.
2. Collaborative work to examine the remits of relevant regulators and the potential benefit of a single lead regulator.
3. Establishing a definition of pharmacy services within hospital settings.
4. Considering legislative reviews to ensure comprehensive regulation of hospital pharmacy activities.

The Committee heard that this draft Position Paper was presented for discussion at this meeting, with further work planned and a revised draft to be presented in September. The Committee acknowledged the significance of this work and discussed the paper in detail.

The Committee recommended that other regulators, such as the HPRA and HIQA, should be consulted prior to the paper being presented to the Committee at their September meeting.

Decision Approved and/or Action Requested

The Committee noted the update.

Agenda Item K – 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 L – Project Health Cards

Issue

The Committee was provided with an update by Dan Burns.

Information

The Committee noted the following project health cards:

- Implementation of Policy Developments Relating to Pharmacy
- Patient Safety and Quality Initiatives

Decision Approved, and/or Action Requested

The Committee noted the updates.

Agenda Item L - AOB

Issue

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

Information

The Committee discussed their selected in-person meeting date for the year, scheduled for Thursday, 28 November. The Chair noted that the date was not unanimously agreed upon by all members and inquired whether a fully in-person meeting would be feasible on that date. The Committee decided to make every effort to attend in person but also to accommodate a hybrid meeting format.

Decision Approved, and/or Action Requested

None.

The meeting concluded at 12.11 pm

Signed by:

Chair

Date