
Agenda Item E.1, F.2,F.3, H.1, I.1a,I.1b, I.1c, J.1 and J.2

Report on material decisions of the Regulatory and Professional Policy Committee

From: Rory O'Donnell, Chair of the Regulatory and Professional Policy Committee

The Regulatory and Professional Policy Committee met on Thursday, 11 April 2024, at 9am. The meeting was held in a hybrid format in PSI House and online via MS Teams.

The agenda items below refer to the matters before Council for decision.

The full agenda for the Committee meeting can be found in Annex 1. This highlights the additional items discussed and items that were for information only.

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

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 in 2022. The Committee discussed the proposed policy and its contextual basis, also noting the absence of a third-party provider to support the delivery of the process and the risk-based approach. 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 made 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
- approach of other regulatory bodies
- Confirming 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 of the 6th June.

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)'

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 in depth a number of aspects of the proposal, including;

- the potential value of extracting functionality from the recently suspended Practice Review events for the Third Country Qualification Route,
- potential insights and learnings from the Practice Review events for future reference,
- Department of Health (DOH) awareness of the ongoing work and proposed changes.

The Committee is recommending that the draft implementation proposal for the CPD Model for Pharmacists in Ireland, tabled to support the recommendations contained in the previously approved Mazars Report 'Review of the Continuing Professional Development (CPD) Model for Pharmacists in Ireland (2023)', be approved by the Council.

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

The Committee was asked to consider a proposal paper reviewing the Systems for Quality Assurance of Continuing Professional Development Training Programmes and Activities for Pharmacists, which proposed a future direction for the quality assurance of CPD training programmes for pharmacists.

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 proposal paper based on these findings, aimed to provide a future direction for CPD quality assurance. The proposed system aims for greater flexibility and agility, with the development of a quality assurance policy for CPD programmes and activities delivered through the IIOP. In addition, in circumstances where formal approval of CPD training is required to facilitate the delivery of additional pharmacy services, it is proposed that the Registrar/Council, as appropriate, should determine the relevant policy and pathway for its consideration and approval, based on risk and the specific programming outputs and needs.

The Committee is recommending this draft proposal paper to Council for approval at its meeting on 25 April 2024.

Agenda Item H.1 - Emerging Risks to Future Pharmacy Workforce - 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.

The Committee is recommending that the draft Workforce Survey Analysis Report be approved by Council at its meeting on 25 April 2024.

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.

The Committee was briefed on the concerns raised in the PSI Workforce Intelligence Report 2023, particularly the frequent absence of protected time for rest periods/lunch breaks due to legislative requirements mandating pharmacist presence at all times 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 stringent security measures for medicine storage.

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 also discussed the proposed two-hour per daytime limit, and heard its purpose was to provide for pharmacist rest breaks.

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

The Committee is recommending to Council that the proposed amendments be submitted to the Department of Health for their consideration and approval, along with the guidance document to support the proposed amendments.

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

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 judgement, it is safe and appropriate. 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, followed by revisions based on feedback and submission for Committee and Council approval in June. 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.

The Committee has approved the draft updated Guidelines to support Medicines Therapy Review, Counselling, and Prescription Extension for public consultation.



**Agenda for PSI Regulatory and Professional Policy Committee
held on 11 April 2024 at 9am.**

The meeting will be in hybrid format held at PSI House and on Microsoft Teams.

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

Agenda Notation: * = document provided in advance;

** = will be presented in slide deck at meeting;

*** = verbal update

Indicative time	Item and descriptor		Presenter
9.00	A	Apologies	Chair
9.02	B	Declaration of Interests (See appendix A below)	Chair
9.03	C	Approval of Meeting Agenda*	Chair
9.04	D	Approval of Minutes – 21 February 2024 meeting*	Chair
9.05	E	Operationalisation of Third Country Qualification Recognition Route	J Bryan
	E.1	Update on operationalising the TCQR route process leading to registration as a pharmacist*	
	E.2	Project Health Card Update*	
9.30	F	Revised CPD Model for Pharmacists	
	F.1	IOP Written Submission; Submitted in the context of the development of the CPD proposal and proposal for quality assurance*	D Gaughan C O'Connell P Corbett
	F.2	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)'*.	D Gaughan C O'Connell A Boland
			D Gaughan

	F.3	Proposal paper for Systems for Quality Assurance of Continuing Professional Development Training Programmes and Activities for Pharmacists*	C O'Connell P Corbett
	F.4	Project Health Card Update*	D Gaughan C O'Connell P Corbett
10.00	G	Development of CPD Model for Pharmaceutical Assistants	D Gaughan C O'Connell A Boland
	G.1	Proposal for CPD themes to underpin model of CPD for Pharmaceutical Assistants Update on progress on the development of a CPD Model for Pharmaceutical Assistants***	
	G.2	Project Health Card Update*	
10.20	H	Emerging Risks to Future Pharmacy Workforce	D Gaughan C O'Connell A Boland
	H.1	Draft Workforce Survey Analysis Report 2023*	
	H.2	Project Health card update*	
10.40	I	Patient Safety and Quality Initiatives	J Bryan
	I.1a	Memo re proposed approval of a delineated model for Retail Pharmacy Businesses and proposed amendments to the Regulation of Retail Pharmacy Businesses Regulations (SI 488 of 2008)*	
	I.1b	Proposed amendments to the Regulation of Retail Pharmacy Businesses Regulations (SI 488 of 2008)*	
	I.1c	Draft PSI Guidance on the Operation of a Retail Pharmacy Business using a Delineation Model*	
11.00	J	Expert Taskforce – Implementation of Recommendations to Support the Expansion of Pharmacist Roles	D Burns
	J.1	Memo re consideration of draft updated Guidelines to support Medicines Therapy Review, Counselling, and Prescription Extension*	J Bryan/O Carroll
	J.2	Draft updated Guidelines to support Medicines Therapy Review, Counselling, and Prescription Extension*	J Bryan/O Carroll
	J.3	Project Health Card update*	D Burns
11.50	K	2024 Work Plan Projects – Project Health Cards	
	K.1	Implementation of Policy Developments Relating to Pharmacy*	D Burns
	K.2	Patient Safety and Quality Initiatives*	J Bryan

	K.3	Advance reform of the Pharmacy Act*	D Burns
12.10	L	AOB -Meeting close- Next meeting date: 6 June 2024	

We anticipate the meeting should end at approximately 12.15pm – Rory O'Donnell, Chair of the Regulatory and Professional Policy Committee.

APPENDIX

Pharmacy Act 2007 Schedule 1, Section 9: Disclosure of certain interests

9. (1) In this paragraph— “connected relative”, in relation to a person, means a spouse, a man and woman who are not married to each other but are cohabiting as husband and wife, parent, brother, sister, child or spouse of a child of the person;

“meeting” means a meeting of the Council or of a committee of the Council;

“member” includes a member of a committee of the Council;

“specified matter” means—

- (a) an arrangement to which the Council is a party or a proposed such arrangement, or
- (b) a contract or other agreement with the Council or a proposed such contract or agreement.

(2) A member present at a meeting where a specified matter arises who, otherwise than in his or her capacity as a member, has an interest in that matter—

- (a) shall at the meeting, disclose that fact and the extent of the interest,
- (b) may not influence or seek to influence a decision to be made in relation to the matter,
- (c) shall absent himself or herself from the meeting or that part of the meeting during which the matter is being discussed,
- (d) may not vote on a decision relating to the matter, and
- (e) may not take part in any further deliberation of the Council or any of its committees relating to the matter.

(3) For the purposes of this paragraph, but without prejudice to the generality of *subparagraph (2)*, a member shall be regarded as having an interest in a matter if a connected relative of that member or a nominee of either of them has such an interest.

(4) The disclosure shall be recorded in the minutes of the meeting and, for as long as the specified matter is being dealt with by the meeting, the member making the disclosure may not be counted for the purposes of determining the presence of a quorum for the meeting.

(5) The question of whether a member’s course of conduct, is or would be a contravention of *subparagraph (2)* shall be determined by the chair, whose decision shall be final, and the particulars

of the determination shall be recorded in the minutes of the meeting.

(6) Where the member referred to in *subparagraph (4)* is the chair, the meeting shall choose another member to chair it for the purposes of the determination.

(7) If satisfied that a member has contravened *subparagraph (2)*, the Minister may remove the member from office and that person is then disqualified from office.

