

Minutes of the Regulatory and Professional Policy Committee Meeting held in hybrid format at PSI House on 12 June 2025

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		No - apologies
Mr Mark Jordan		No - apologies
Ms Geraldine Crowley		Yes (joined 10.40 am)
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>Ms Damhnait Gaughan</i>	<i>Head of Community Pharmacy Assurance</i>	
<i>Ms Cora O'Connell</i>	<i>Acting Head of Practitioner Assurance</i>	
<i>Mr Dan Burns</i>	<i>Head of Strategic Policy, Research and Communication</i>	
<i>Ms Orla Carroll</i>	<i>Community Pharmacy Quality and Safety 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>Ms Louise Hamra</i>	<i>Pharmacy Practice Officer</i>	
<i>Mr Des Butler</i>	<i>Acting Manager, Fitness to Practise & Legal Affairs</i>	
<i>Ms Elizabeth O'Halloran</i>	<i>Strategic Policy and Research Coordinator</i>	
<i>Ms Emer Hannan</i>	<i>Authorised Officer</i>	
<i>Ms Carrie Reilly</i>	<i>Regulatory Executive</i>	
<i>Ms Jennifer Sullivan</i>	<i>Authorised Officer</i>	
<i>Mr Garrett O'Donoghue</i>	<i>Registrant & Customer Relations Manager</i>	
<i>The meeting commenced at 10 am.</i>		

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. Dr. Laura Sahm declared that she would abstain from voting on items F.1 and F.2 to avoid any conflict of interest.

Decision Approved and/or Action Requested

The Chair accepted Dr. Sahm's decision to abstain from voting on either item.

Agenda Item C – Agreement on the meeting agenda

Issue

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

Information

No changes were proposed to the meeting agenda as circulated.

Decision Approved and/or Action Requested

None.

Agenda Item D – Approval of Minutes – 12 May 2025 meeting

Issue

Approval of the minutes of the Regulatory and Professional Policy Committee meeting held on 12 May 2025.

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 previous meeting on the proposal of Mr. Richard Hammond and seconded by Ms. Marie Louisa Power.

Agenda Item E.1 - Approval of draft PSI (Education and training required to prescribe medicinal products in accordance with the common conditions and the continuation of contraception services) Rules 2025 (for public consultation)

Issue

The Committee was provided with memo and draft PSI rules in advance of the meeting.

Information

The Committee was asked to consider and discuss the draft rules, and subject to this consideration, advise the Council that the draft rules be approved for public consultation.

The Committee was provided with a short overview of the background and context of the draft rules, including the work of the Expert Taskforce and the Minister's approval of its recommendation to establish a Common Conditions Service (CCS). The Committee was also reminded that an additional service would be introduced in tandem, enabling pharmacists to prescribe by protocol for the continuation of contraception.

Committee heard that amendments introduced to the Pharmacy Act 2007 by the Health (Miscellaneous Provisions) Act 2024, require the PSI Council to make rules specifying the education and training which a registered pharmacist must receive to be enabled to prescribe medicinal products in accordance with regulations made under Section 32 (2)(l)(iv) of the Irish Medicines Board Act, 1995 (as amended).

The Committee was informed that very minor changes had been made to the draft rules by the legal drafter (Barrister-at-Law) since the rules had been provided to the Committee. The nature of these changes was explained to the Committee and involved the removal of the definition for the IIOP, and for the reference to the IIOP in the draft Rules to be brought in line with the wording of the proposed amendments to the PSI (Continuing Professional Development) Rules, which are with the Minister for consideration. The Committee were also reminded that there were several interdependent workstreams still being progressed by other member organisations of the Community Pharmacy Expansion Implementation Oversight Group (IOG) that could require minor updates to the rules. The Committee heard that pending approval of the rules for public consultation by PSI Council, a final draft of the rules would be brought to a future meeting of the Committee for consideration.

The Committee discussed the draft rules including the standard of education and training contained therein that a pharmacist must reach in order to prescribe as part of either service. The Committee sought further information on the length and content of the training modules and draft clinical protocols. The Committee heard that the training was designed to be not overly burdensome given that it builds on pharmacists' existing

knowledge and expertise, and in light of the detailed and supportive nature of the HSE clinical protocols.

The Committee sought clarity on whether the rules would allow for more conditions to be added to the service in time. It was confirmed by the Executive that this was the case.

Finally, the Committee sought further information on the secondary legislation underpinning the two services and how this would fit with the overall pharmacy legislative framework.

Decision Approved and/or Action Requested

Having considered the draft rules, the Committee recommended that Council at its meeting of 26 June approve the draft rules for public consultation on the proposal of Ms. Marie Louisa Power and seconded by Dr. Laura Sahm.

Agenda Item E.2 - Approval of Guidance for the Common Conditions Service and Renewal of Contraception

Issue

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

Information

The Committee was asked to consider the draft guidelines and approve them for public consultation.

The Committee heard that, similarly to the draft rules to enable the education and training of pharmacists to prescribe as part of the two services (Item E.1), the draft Guidelines were subject to minor changes until a number of key dependencies had been finalised by the Implementation Oversight Group (IOG), including secondary legislation and the HSE clinical protocols.

The Committee heard that the draft guidelines aimed to provide a principles-based framework to support both services to be safe and patient-centred.

The Committee discussed the draft guidelines, in particular where 'must' and 'should' are used throughout the draft guidelines. The Committee highlighted that these should align with the underpinning legislation. The Committee advised that antimicrobial stewardship be made more prominent in the draft guidelines. The Committee heard that antimicrobial stewardship would also be included in the training modules for the Common Conditions Service.

The Committee discussed other aspects of the draft Guidelines including staffing levels, the separation between prescribing and dispensing aspects of the service, a digital-first approach in relation to documentation, the requirements surrounding patient consent to use either service and patient consent to share healthcare information with another healthcare professional.

The Committee agreed to recommend that the draft guidance be recommended to Council for public consultation, pending minor amendments. The Executive agreed to review the Guidelines in light of the Committee's comments before issuing them to Council.

Decision Approved and/or Action Requested

The Committee recommended the draft guidelines to Council for approval for public consultation, subject to their amendment in light of Committee feedback, on the proposal of Mr. Peter Dennehy and seconded by Ms. Marie Louisa Power.

Agenda Item E.3 – Project Health Card update – Implementation of Taskforce recommendations

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 Continued Accreditation Reports (RCSI, TCD, UCC)

Issue

The Committee was provided with a memo and three final evaluation reports in advance of the meeting.

Information

The Committee was asked to consider the three evaluation reports submitted by the respective Accreditation Teams and to recommend to Council to approve the three evaluation reports for RCSI, TCD and UCC in addition to the recommendations of the Accreditation Teams to continue to grant its recognition and approval of the

Master's degree programmes in pharmacy provided by RCSI, TCD and UCC for a period of five years.

The Committee heard that Council had approved and recognised the continued accreditation of the five-year Master's degree programmes in pharmacy provided by RCSI, TCD and UCC for a period of five years in June 2020.

Committee heard that prior to the period of accreditation expiring for the three programmes in June 2025, the PSI had organised on-site visits to each of the three schools of pharmacy in February to review continued compliance with PSI accreditation standards. Following these visits, the accreditation teams are recommending that all three of the MPharm programmes be granted recognition and approval for a period of five years.

Decision Approved and/or Action Requested

Having considered the three evaluation reports submitted by the respective Accreditation Teams the Committee recommended that Council approve the three evaluation reports for RCSI, TCD and UCC, and approve the recommendations of the Accreditation Teams to continue to grant recognition and approval of the Master's degree programmes in pharmacy provided by RCSI, TCD and UCC for a period of five years on the proposal of Ms. Marie Louisa Power and seconded by Ms. Gráinne Power.

Agenda Item F.2 - Consideration of Conditions: University of Galway Accreditation

Issue

The Committee was provided with a memo, letter from the Chair of the Accreditation team and documents supplied by University of Galway in advance of the meeting.

Information

The Committee was asked to confirm to Council that it is satisfied that conditions one and two attached to the accreditation of the University of Galway's MPharm degree programme are met, further to its consideration of the letter from the Chair of the accreditation team and the evidence submitted by the University.

The Committee was reminded that in April PSI Council granted its recognition and approval of the MPharm degree programme to be provided by the University of Galway for a period of five years, subject to certain conditions and that the first two of these conditions were required to be met prior to the enrolment of students to the programme.

The Committee heard that the Chair of the accreditation team has considered the evidence provided by University of Galway and is satisfied that the two relevant conditions have now been met.

Decision Approved and/or Action Requested

The Committee has confirmed to Council that it is satisfied that conditions one and two attached to the accreditation of the University of Galway's MPharm degree programme are met further to its consideration of the letter from the Chair of the accreditation team and the evidence submitted by the University on the proposal of Mr. Peter Dennehy and seconded by Ms. Gráinne Power.

Agenda Item F.3 – Project Health Card update – Accreditation of New and Existing MPharm programmes

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 – Operationalisation of Third Country Qualification Recognition (TCQR) Route update

Issue

The Committee was provided with a verbal update on the operationalisation of the Third Country Qualification Recognition (TCQR) Route.

Information

The Committee heard that progress is continuing on operationalising the remaining elements of the new TCQR route, including the panel of assessors, preparation for an external audit, and procurement for the examination component.

Decision Approved and/or Action Requested

The Committee noted the update.

Agenda Item G.2 - Consideration of proposed options regarding TCQR Fee Waiver Policy

Note

The Committee met in closed session to discuss the matter.

Agenda Item H.1 - Approval of draft report regarding updates to vaccination and emergency medicines training requirements for pharmacists

Issue

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

Information

The Committee was asked to consider the draft report and recommendations regarding updates to vaccination and emergency medicines training requirements for pharmacists, and subject to this consideration, advise the Council to approve the draft report and recommendations.

A short presentation was provided by Mr. Pádraig Corbett. The Committee heard that the review of vaccination and emergency medicines training had been informed by three main strands of research: a review of training requirements in four other countries, engagement with key stakeholder organisations and PPI involvement through the HPRPA Patient Forum and a survey of pharmacist registrants. The Committee heard an overview of the eight evidence-based recommendations in the report.

The Committee discussed the draft report and recommendations, commending the significant research and engagement that had been carried out by the project team. The Committee noted the additional complexities involved in vaccinating in a school-setting and highlighted the value of PSI reviewing vaccination guidance in tandem with significant developments or changes to relevant national vaccination programmes.

The Committee sought further information on emergency medicines training for pharmacists in comparison to emergency medicines training for other allied healthcare professionals. Finally, the Committee also welcomed the recommendation for PSI to engage with the Department of Health to consider how vaccination and emergency medicines training undertaken as part of MPharm programmes could be recognised.

Decision Approved and/or Action Requested

The Committee advised that Council at its meeting of 26 June approve the draft report and recommendations on the proposal of Mr. Richard Hammond and seconded by Dr. Laura Sahm.

Agenda Item I.1 - Approval of proposed RPB Registration Rules to conserve requirements of current rules (SI 495 of 2008) and to support a delineated operating model and revocation of current rules

Issue

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

Information

The Committee were asked to consider the proposed draft rules and recommend to Council that these draft rules be issued for public consultation.

The Committee heard that it is proposed that the current rules, the Pharmaceutical Society of Ireland (Retail Pharmacy Businesses) (Registration) Rules 2008 (SI 495 of 2008) be revoked and replaced by the Pharmaceutical Society of Ireland (Retail Pharmacy Businesses) (Registration) Rules 2025 incorporating the current legislative provisions and the legislative provisions to support the delineated model.

The Committee was reminded that following the recommendations of the PSI Workforce Intelligence Report, the PSI has been developing a 'delineated operating model' which intends to enable pharmacies who wish to delineate the pharmacy service from the retail part of the business to do so, thus facilitating a structured mechanism to assure pharmacists take required breaks and/or may leave the premises while allowing the retail part of the premises to stay open.

The Committee also heard that following Council's approval in April 2024, PSI submitted proposed amendments to the Regulation of Retail Pharmacy Businesses Regulations (SI 488 of 2008) to the Department to provide for implementation of the model. The Committee heard that the Department were supportive of the proposed changes and are working to progress the required legislative changes from their perspective and remit.

The Committee heard that legal advice received by PSI recommended that in addition to amendments to SI 488 of 2008, amendments to the PSI Registration Rules are required to provide for the implementation of a delineated operating model.

The Committee discussed the draft rules, including how the public would be informed that the model was in operation. The Committee heard that it was expected that pharmacies would reflect this under their opening hours information.

The Committee sought further clarification on the sale of General Sale Medicines (GSLs) in the absence of a pharmacist under the model. The Committee heard that PSI had sought extensive legal advice on the matter, and it had been confirmed that GSLs would not be permissible to be sold in the absence of a pharmacist under the model. The Committee reflected that this could be one potential barrier to the model's wider uptake but welcomed the draft rules in providing greater flexibility to pharmacies.

The Committee stressed the importance of pharmacists being enabled to take breaks, from both a patient safety and workforce perspective. The Committee noted that the delineation model was only one method to provide lunch breaks for pharmacists and that pharmacies could also choose to close for lunch.

Decision Approved and/or Action Requested

The Committee recommended that Council approve the draft rules for public consultation at its 26 June meeting on the proposal of Dr. Laura Sahm and seconded by Ms. Gráinne Power.

Agenda Item I.2 - Approval in principle of Draft PSI Guidance on the Operation of a Retail Pharmacy Business using a Delineation Model

Issue

The Committee was provided with the draft guidance in advance of the meeting.

Information

The Committee were asked to consider the draft guidance and to recommend it to Council for approval in principle, subject to any changes necessitated by the final approved Registration Rules.

The Committee was reminded that at Council's meeting in April 2024, PSI Council requested that principles-based guidance be developed to support pharmacy owners and those in other governance positions to implement the delineated operating model, if they wished.

The Committee heard that the draft guidance was principles-based and intended to describe how a delineated pharmacy should be structured and how it should operate. The Committee heard that the guidance was for approval in principle at this point, as it may be subject to additional changes depending on finalised legislative amendments.

Decision Approved and/or Action Requested

The Committee recommended that Council approve in principle the draft guidance, subject to any changes necessitated by the final approved Registration Rules on the proposal of Dr. Laura Sahm and seconded by Ms. Gráinne Power.

Agenda Item J.1 - Consideration and Approval of PSI Position Paper on Regulation and Potential Regulatory Gaps in Hospital Pharmacy

Issue

The Committee was provided with a memo and the draft position paper in advance of the meeting.

Information

The Committee was asked to consider the draft position paper and advise the Council to approve the position paper for submission to the Department of Health.

A short presentation was provided by Ms. Orla Carroll. The Committee heard that PSI has committed in both its current and previous corporate strategies to clarify PSI's role in relation to hospital pharmacy regulation. The Committee heard that the PSI has undertaken a series of research and stakeholder engagement projects since 2018, which are reported in the position paper, to better understand the regulation of hospital pharmacy activity, and clarify any potential gaps. The Committee heard a summary of the key issues identified in the position paper and the proposed next steps.

The Committee then discussed the draft position paper, commending it as a strong document that highlights the key issues, particularly between the remits of the PSI and HIQA. The Committee emphasised the need for greater clarity on the regulation of hospital pharmacy due to the patient safety risks identified as well as the desirability for policy direction from the Department of Health in this regard.

The Committee sought further information on how the PSI would continue to raise the key patient safety issues identified in the position paper with the stakeholders involved, in particular, the Department. The Committee heard PSI would continue to engage on the matter with the Department and other key stakeholders and that the paper would be also shared with HIQA, the HPRA and HPAI. The Committee noted that the item was represented on the PSI Corporate Risk Register. It was suggested that a risk matrix could also be produced in future, in addition to the paper to further emphasise the identified risks.

Decision Approved and/or Action Requested

The Committee recommended that Council approve the position paper at its meeting of 26 June 2025 for submission to the Department of Health on the proposal of Mr. Richard Hammond and seconded by Mr. Peter Dennehy.

Agenda Item K.1 – Review of the Fitness to Practise complaints process update

Issue

The Committee was provided with a verbal update on the review of PSI's Fitness to Practise complaints process.

Information

The Committee heard that progress was continuing on the project, which aims to make recommendations by the end of the year. The Committee heard that an Expression of Interest (EOI) process had been carried out to establish an advisory group for the project comprising members of PSI Council and that there had been a good response to the EOI. The Committee also heard that a mapping exercise of the complaints process had been carried out and that engagement with stakeholders was progressing.

Decision Approved and/or Action Requested

The Committee noted the update.

Agenda Item K.2 – Project Health Card update – Review of the Fitness to Practise complaints process

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 L.1 - Approval of Draft PSI guidance to support transparency of medicines pricing and fees for pharmacy services

Issue

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

Information

The Committee was asked to consider the draft guidance and subject to its consideration and/or any proposed changes recommend to the Council that the draft guidance be approved for issue for public consultation.

The Committee was reminded that in April, the Minister for Health formally requested that the PSI develop guidance aimed at improving patient access to information on the fees they pay in respect of dispensed products and services provided by community pharmacies.

The Committee heard that the draft guidance had been developed under the stewardship of a PSI cross-unit defined purpose Pricing Transparency Working Group and had been informed by engagement with a number of key stakeholders including the patient sub-group of the Community Pharmacy Expansion Implementation Oversight Group, telephone interviews with patients, an online workshop with the PSI Pharmacist Panel, and meetings with the Irish Pharmacy Union, Pharmacy Software Vendors and the Competition and Consumer Protection Commission.

The Committee discussed the draft guidance, suggesting some minor edits for improved clarity of language, and noting that overall, the guidance effectively addressed the Ministerial request. The Executive confirmed that the guidance would be amended as requested by the Committee prior to the PSI Council June meeting.

Decision Approved and/or Action Requested

The Committee recommended that Council approve the draft guidance for public consultation, subject to some minor amendments, on the proposal of Mr. Richard Hammond and seconded by Ms. Gráinne Power.

Agenda Item M.1 – Exempt Medicinal Products and review of PSI Guidance

Issue

The Committee was provided with a memo and Regulatory Review Paper in advance of the meeting.

Information

The Committee was asked to review the Regulatory Review Paper and consider the proposed recommendations, with a view to engaging in further discussion at the meeting.

The Committee was reminded that a review of the existing regulatory framework governing the sale and supply of exempt medicinal products by pharmacists had been recently undertaken to identify any potential opportunities to streamline supports, such as practice guidance updates, clarification of requirements and opportunities for learning.

The Committee heard that the review aimed to ensure pharmacists have access to relevant, accurate and up to date information to facilitate compliance with legislation and

relevant guidance to safeguard patient and public safety and that it had identified three recommendations.

The Committee discussed the review paper, noting the professional experience that the sale and supply of exempt medicinal products had increased significantly in recent years. The Committee sought clarification on a number of aspects of the draft guidance within the review paper and suggested minor edits. The Executive welcomed the minor edits and also highlighted that the draft guidance in the paper was indicative, rather than finalised. The Committee advised that PSI also engage with the Department on the matter prior to finalising and publishing the paper.

Decision Approved and/or Action Requested

None.

Agenda Item N.1 – Revised PSI Inspection and enforcement policy update

Issue

The Committee was provided with a verbal update on the revised PSI Inspection and enforcement policy.

Information

The Committee heard the Executive had recently completed an update of PSI's Inspection and enforcement policy to better align with the process that is currently in place.

The Committee was informed that a more extensive 'root and branch' review and discussion was being undertaken on future inspection and enforcement policy, considering aspects in more detail, including analysis of similar policies nationally and internationally and patient expectations on inspection frequency.

Decision Approved and/or Action Requested

The Committee noted the update.

Agenda Item O.1 - Approval of IIOP ePortfolio Review Policy

Issue

The Committee was provided with a memo and draft IIOP ePortfolio Review Policy in advance of the meeting.

Information

The Committee was asked to consider and discuss the draft policy, and subject to this consideration, advise the Council that it be approved at its next meeting.

The Committee heard that no substantive changes had been made to the ePortfolio Review Policy for the 2025/2026 year. The Committee noted that any changes to the policy following the recent independent review of the CPD system for pharmacists are expected to not be in place until 2027 as they would require significant changes to operational and ICT infrastructure.

Decision Approved and/or Action Requested

Having considered and discussed the draft ePortfolio Review Policy, the Committee advised that Council approve the policy its meeting of 26 June on the proposal of Ms. Marie Louisa Power and seconded by Mr. Peter Dennehy.

Agenda Item O.2 – Quarterly update on IOP operations and developments

Issue

The Committee was provided in advance of the meeting with a memo and the quarterly update from the IOP on its operations and developments.

Information

None.

Decision Approved and/or Action Requested

The Committee noted the update.

Agenda Item P – 2025 Work Plan Projects – Project Health Card updates

Issue

Project health cards were provided to the Committee in advance of the meeting.

Information

The Committee noted the following project health cards:

- Propose and implement policy changes agreed with the Department of Health that relate to pharmacists and pharmacy services
- Regulatory response to digital health
- Update on patient and public involvement in our work
- Advance reform of the Pharmacy Act
- Implementation of the recommendations of the Workforce Intelligence Report.

Decision Approved and/or Action Requested

The Committee noted the project health cards.

Agenda Item Q – Any other business

Issue

No other business was discussed.

Information

None.

Decision Approved and/or Action Requested
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None.

The meeting concluded at 12.30 pm.

Signed by:

Chair

Date