Minutes of the PSI Audit and Risk Committee meeting, which was convened in a hybrid manner, at 09.30 am on 13 March 2026.

Agenda Item 1 – Closed Session of the Committee

Issue
The Committee met in closed session with representatives from the external auditor, PKF Brenson Lawlor, and the internal auditor, Crowleys DFK, from 09.30 - 9.45 am

Agenda Item 2 - Attendees & Apologies

Name	Role	Present (Yes/No)
Ms Emily Kelly	Committee Chair	Yes
Dr Paula Barry Walsh	Committee Member	Yes
Mr Peter Dewhurst	Committee Member	Yes
Ms Ciara Lynch	Committee Member	Yes
Mr Leon O'Hagan	Committee Member	Yes
Dr Cyril Sullivan	Committee Member	Yes
Members of PSI staff & non-Committee external attendees included:		
Ms Joanne Kissane	Registrar & Chief Officer	
Ms Aoife Mellett	Head of Legal Affairs, Governance and Programme Delivery	
Mr Dan Burns	Head of Registration and Education	
Ms Damhnait Gaughan	Head of Community Pharmacy Assurance	
Dr Cheryl Stokes	Head of Corporate Services	
Mr Des Butler	Fitness to Practice and Legal Affairs Manager	
Ms Elaine Cronin	Finance Officer	
Ms Eileen Troy	Finance and Support Services Manager	
Ms Laura Irwin	Quality and Safety Manager	
Mr Shane McGlynn	Investigations Manager	
Mr Neil Wall	ICT Manager	
Ms Ruth Baily	Governance Executive	
Mr John Manning	PFK Brenson Lawlor (for part)	

Ms Fiona O'Sullivan	Crowley's DFK (for part)

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

Agenda Item 4

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

Information
Members of Committees of Council are subject to Section 9, Schedule 1, of the Pharmacy Act 2007 regarding disclosures of interest, as outlined in Appendix 1 of the meeting agenda.

Decision Approved and/or Action Requested
Decision Approved: No conflicts of interest were declared by any member of the Committee with regard to the items scheduled for discussion at the meeting.

Agenda Item 4

Issue
Request for Approval of the Minutes of the Audit and Risk Committee Meeting held on 26 November 2025

Information
The Chair noted that the draft Minutes of the Audit and Risk Committee meeting held on 26 November 2025 had been circulated to Committee members in advance of the meeting and that no amendments had been received.

Decision Approved and/or Action Requested
Decision Approved: The Committee approved the Minutes of the Audit and Risk Committee meeting, held on 26 November 2025, by consensus.

Agenda Item 5

Issue
Strategic and Operational Update

Information

The Committee was updated by the Registrar on the Strategic and Operational work that has taken place since the last meeting.

Core Funding Review: The Committee was informed that the Minister for Health has approved the draft PSI Fees Rules with no proposed amendments. It is anticipated that she will sign the Statutory Instrument in early April so that the fee increase will come into effect from 1 May.

Reform of the Act: The Committee was informed that work is ongoing concerning reform of the Pharmacy Act 2007, with an emphasis currently on the statutory Fitness to Practise process as contained in Part 6 of the Act, with a view to modernising that process and making it consistent with the processes employed at comparable regulatory bodies in Ireland.

Electronic Record Keeping: Draft Guidelines for recommendation to Council were approved by the Regulatory and Professional Policy Committee (RPP) at their meeting on 11 March 2026 to support the transition from paper-based records to electronic records. PSI is part of the Electronic Record Keeping Working Group, led by the Department of Health, along with HSE, the Irish Pharmacy Union, and other bodies.

Common Conditions Service (CCS): The service was formally launched by the Minister on 19 January 2026. It is designed to provide faster access to healthcare by enabling pharmacists to offer expanded treatment options for eight common conditions, including prescribing certain medicines where it is safe and appropriate to do so. Training has been delivered by the IIOP, and additional resources are available to pharmacists on both the PSI and IIOP websites. To date, the PSI has not received any statutory complaints or concerns in relation to this service.

Workforce Intelligence Report: The PSI Workforce Intelligence Report published in September 2023, provided a baseline view of the pharmacy workforce in Ireland. The Report provided recommendations to ensure the sustainability of the future pharmacy workforce. One of the short- term recommendations (1-2 years), proposed publishing guidelines on the expectations of pharmacy owners, superintendent pharmacists and supervising pharmacists in ensuring safe staffing levels, adequate staffing mix and appropriate rest periods in community pharmacy, with responsibility for this action assigned to the regulator. The draft guidelines were issued for public consultation to all pharmacists, pharmacies and pharmacy owners and the general public from January 2026 to February 2026. The responses to the public consultation have been analysed, and a public consultation report has been prepared and circulated to the RPP Committee.
The RPP Committee considered and approved the public consultation report and draft PSI Guidelines on Safe Staffing and recommended them to Council for their consideration on the 26 March.

Implement our ICT strategy 2024-2027: A vendor has been selected to conduct the Data Maturity Assessment, which will evaluate key areas including governance, quality, architecture, security, and analytics. This assessment is scheduled for completion in the

first half of the year. Subsequently, a Data Strategy will be developed in the second half of the year, leveraging insights from the assessment to establish an organisation-wide blueprint for managing, governing, securing, and maximising the value of data. The objective is to align people, processes, and technology to position data as a strategic asset. **Business Transformation Project (BTP):** The Committee was advised that the procurement for the next phase of the BTP is due to commence. No funds have been drawn down yet, and any funds will have to be approved by the Performance and Resource Committee and the Council.

Decision Approved and/or Action Requested
Decision Approved: There were no actions arising from this agenda item.

Agenda Item 6

Issue
Request for Approval of the PSI's 2025 year-end financial statements. (a) Financial Statements 2025. (b) External Audit Management Letter.

Information
The Committee reviewed the draft financial statements for the year ended 2025. The Committee was given a high-level update on the financial statements and was advised that an unqualified (clean) audit opinion was provided by the external auditors. There was a matter of emphasis reported in the Financial Statements, concerning the Pharmaceutical Society of Ireland Superannuation Scheme 2016. The Committee was advised that the PSI operates two pension schemes, the Single Public Service Pension Scheme where employee and employer contributions are remitted to DPER on a monthly basis, and the ultimate financing of benefit payments is dealt with in section 44(1)(b) of the 2012 Act, which states that the payments will be met from funds provided by the Oireachtas. The second pension, The Pharmaceutical Society of Ireland Superannuation Scheme 2016, is the older, pre-existing scheme where the fund is temporarily reported as an asset and corresponding liability on the PSI balance sheet, pending transfer to the Department of Health (DoH). Following an external actuarial valuation under FRS 102 rules, the valuation at 31 December 2025 reports a net scheme asset to the value of 1.6 million. PSI has been in correspondence for some time with the DoH in relation to this pension scheme. The pension is regularly discussed at the Governance meetings as an item of concern and was discussed at the most recent governance meeting. , and There has been previous correspondence from the President and the Chair of the Audit and Risk Committee to the DoH last year. PSI has also researched the matter and been in contact with similar organisations. Some organisations have transferred their pension contributions in full,

and others are transferring contributions on a quarterly basis. At present, there appears to be no coherent pathway to finalise the issue. The Committee agreed to write to the Department again to escalate the issue further and seek timelines from the Department for a resolution On the financial statements, the Committee was advised that the deficit for the year is €1.4 million. The original planned deficit was budgeted to be €3 million, in Q2 the deficit was forecast to be €2 million, and in Q3 it was forecast at €1.6 million. The reserves now stand at €10.4 million, excluding the revaluation reserve, and the presentation of the reserves in the financial statements has been updated to align with the recent Reserves Policy update. It was noted that PSI House was revalued in 2023, and that the building value may see a downward adjustment of 12% due to the current rental market, but the advice received was that a full revaluation report was not required at this time. The Committee was advised that an additional grant allocation of €700,000 was awarded by the Department in 2025 to support various activities carried out by the PSI, including NIS2 compliance; training programmes for common conditions and continuation of contraception; and the development of an Advanced Practice Framework. €146,729 was drawn down from this funding allocation during the period. The Committee was advised that further funding of €1.438 million has been allocated from the DoH in 2026 for the IIOP, NIS2, Common Conditions, Reform of the Act and staffing for roles related to the expansion of pharmacy practice, and these funds can be drawn down as needed. The Committee discussed the Statement of Internal Controls and agreed on updated wording. The Committee received more detailed information and assurances regarding the organisation's bank reconciliation processes and noted the improvement and controls currently in place. The Committee asked whether there was an SOP for bank reconciliations and the Executive confirmed that there was.

Decision Approved and/or Action Requested
Decision Approved: Following discussion, the Committee agreed to approve the PSI's 2025 year-end Financial Statements and the External Audit Management Letter by consensus.

Agenda Item 7

Issue
Request for Approval of PSI Annual Report 2025. (a) Statement of Internal Control. (b) Report of the Audit & Risk Committee. (c) Risk Report: Principal Risk and Uncertainties.

Information
(a) The Committee discussed the Statement of Internal Control and agreed on updated wording. (b) Subject to the inclusion of an additional sentence to reflect that the activities outlined in the report were primarily overseen by the previous Chair, the Committee agreed the Report of the Audit and Risk Committee. (c) The Committee approved the Risk Report: Principal Risk and Uncertainties.

Decision Approved and/or Action Requested
Decision: Following discussion, the Committee agreed on the Approval of the PSI Annual Report 2025, the Statement of Internal Control, the Report of the Audit & Risk Committee and the Risk Report: Principal Risk and Uncertainties by consensus.

Agenda Item 8

Issue
Update on the Implementation of Internal Audit Recommendations.

Information
The Committee reviewed the consolidated Internal Audit Recommendations. It was noted that the document contains seven low and two medium classification recommendations. Since the last Committee meeting in November 2025, two low classification recommendations—relating to the updated Financial Policies and Procedures and the reconciliation of registration fees—have been completed. The Committee was also advised that two additional low classification recommendations, arising from the 2025 audit, have now been incorporated into the consolidated list. The first of these relates to the PSI's IT policy, specifically the inclusion of a policy statement covering relevant PSI personnel and the accessing of PSI related documents on personal devices. This recommendation is expected to be completed in Q3 2026. The second recommendation concerns the PSI undertaking an external review of its Risk Management Framework, with completion expected in Q4 2026. The Committee was further advised that a Periodic Critical Review, to be carried out on behalf of the Department of Health, is scheduled to take place in either 2026 or 2027, with the exact timing yet to be agreed. The Institute of Public Administration (IPA) delivered a presentation to Council at its training and development day on 5 March 2026 regarding Periodic Critical Reviews and will also present to all PSI staff at the April Anchor Day.

Decision Approved and/or Action Requested
The Committee noted the update on the Implementation of Internal Audit Recommendations.

Agenda Item 9

Issue
Review of the PSI Corporate Risk Register. Review of the Community Pharmacy Assurance Risk Register.

Information
Corporate Risk Register The Committee reviewed the PSI Corporate Risk Registrar. A query was raised regarding the risk rating assigned to the risk concerning business performance and continuity in the event of a cyber-attack. Following a brief discussion, the Committee agreed that the current rating remains appropriate. The Committee noted the ongoing work on the project to reform the Pharmacy Act 2007, with current efforts focused on the reform of the statutory complaints process under Part 6 of the Act. An update was provided on the Third Country Qualification Recognition (TCQR) process, including the number of applicants at each stage. The duration of the process and the various routes were discussed, and the Committee was updated on the procurement of an exam provider. The Committee was further informed that two internal assessors have been appointed to support the timely progression of applications and are expected to be in post by the end of April. **Community Pharmacy Assurance Risk Register** The Committee was advised that two new risks have been added since the last review. These relate to the proposed designation of the PSI as the competent authority for the NIS2 Directive as it applies to the pharmacy sector, and to any potential impacts derived from proposed forthcoming legislative changes to facilitate Electronic Record Keeping in RPB's. In relation to Electronic Record Keeping, the Committee noted the emerging risk that, as legislative change moves towards enabling electronic record keeping within pharmacies, there may be a consequential impact on the PSI's inspection and enforcement activities. Specifically, there is a risk that inspection and investigation procedures, as well as the associated offences framework, may not appropriately evolve in parallel with the regulatory changes and the resulting shifts in pharmacy operations and service delivery. This misalignment could potentially affect the PSI's ability to effectively hold registrants to account.

The Committee was advised that although the PSI has not yet been formally designated as the competent authority under NIS2, it is likely that this designation will follow once the relevant legislation is published. The Committee discussed the changing and emerging landscape for pharmacy practice in light of the forthcoming Electronic Record Keeping provisions. It was further informed that work is ongoing to update the PSI's inspection and monitoring processes to ensure they remain fit for purpose.

Decision Approved, and/or Action Requested
The Committee noted the PSI Corporate Risk Register and Community Pharmacy Assurance Risk Register.

Agenda Item 10

Issue
Q1 Cyber Security Report

Information
The Committee was updated on the Q1 Cyber Security Report. The Committee was advised that the recent vulnerability test found six issues, two high, two medium and two low. One of the high issues had already been fully mitigated, and all of the other issues will be mitigated by Ecko shortly. A follow-up vulnerability test will be carried out in Q2, and it should validate the work carried out to amend all of the original issues. The Committee was informed that the report also provides a general overview of wider IT security developments occurring outside the PSI. The importance of maintaining awareness of evolving cyber-threat activity and the tactics of malicious actors was highlighted as a key factor in safeguarding the organisation. The Committee was further advised that a tabletop exercise will be undertaken in the near future to assess the organisation's readiness to respond to issues such as fire or flood. The Committee asked if Co-Pilot was widely used across the business. The Committee was advised that all users have access to Co-Pilot and usage is monitored monthly, with about 95% of the organisation using it. The Committee was also advised that there is an AI policy in place and Co-Pilot is the only AI product allowed unless a written business case is submitted to the IT manager and Data Protection Officer for specific usage.

Decision Approved and/or Action Requested
Decision Approved: The Committee noted the Q1 Cyber Security Report

Agenda Item 11

Issue
Report from PSI Health and Safety Officer on the management of any major incidents, near misses, and lessons learned, and acted upon.

Information
The Committee was advised that there had been no major incidents or near misses since the last meeting.

Decision Approved and/or Action Requested
Decision Approved: The Committee noted the report from the Health and Safety Officer

Agenda Item 12

Issue
Report from the PSI Data Protection Officer on the management of any data breaches.

Information
The Committee was informed that there had been one data breach notifiable to the Data Protection Commission since the Committee meeting last November. That involved correspondence relating to a statutory fitness to practise complaint being sent via email to a solicitor who was not involved in the matter, in error. Once the breach was discovered, the matter was rectified. The relevant data subjects were contacted and informed that they could make a complaint to the Data Protection Commission. The Data Protection Commission was also formally notified of the breach. Separately, six registration certificates have been lost in the post since the last meeting. These have been logged as data incidents.

Decision Approved and/or Action Requested
Decision Approved: The Update from the Data Protection Officer was noted by the Committee.

Agenda Item 13

Issue
Self-evaluation of Audit and Risk Committee - Outputs of Self-Evaluation survey December 2025.

Information

The Committee reviewed the Self Evaluation of the Audit and Risk Committee and the Outputs of the December 2025 Self Evaluation Survey. The Committee noted that it continues to operate effectively and commented positively on the quality of the papers presented. It also identified two key areas to monitor closely: NIS2 and the accreditation of new schools. The Committee was advised that ongoing monitoring of the new school is continuing. The conditions set out as part of the approval process are under active review, a letter has recently been issued to the new schools, and site visits will proceed as scheduled.

Decision Approved and/or Action Requested
Decision Approved: The Committee noted the Self-evaluation of Audit and Risk Committee - Outputs of Self-Evaluation survey December 2025.

Agenda Item 14

Issue
Report from the PSI Freedom of Information Officer on the management of freedom of information requests received.

Information
The Committee was updated regarding Freedom of Information (FOI) requests received by the PSI since the last meeting. There have been five FOI requests in total since the meeting in November, relevant to topics such as the TCQR process and Pricing Transparency. All of the requests have been processed, aside from one, which is currently under review.

Decision Approved and/or Action Requested
Decision Approved: The Committee noted the update from the FOI Officer.

Agenda Item 15

Issue
PSI Protected Disclosure Report 2025.

Information
The Committee was updated on the PSI Protected Disclosure Report for 2025. PSI is obliged to publish the number of protected disclosures received annually. In 2025, the Committee was informed that the PSI received one internal protected disclosure and two external protected disclosures, and all have been processed.

Decision Approved and/or Action Requested
Decision Approved: The Committee noted the PSI Protected Disclosure Report for 2025.

Agenda Item 16

Issue
Items for Inclusion in the ARC Report to Council, in addition to those for formal approval

Information
The Committee noted that the red, approval items will be included in the report to Council. No additional items were added to the report for inclusion.

Decision Approved and/or Action Requested
Decision Approved: The Committee noted the items for inclusion in the Committee report to Council.

Agenda Item 17

Issue
AOB

Information
The Committee asked whether the CPD contract with the RCSI for the IIOP remained in place. The Committee was advised that the contract had been extended to 31 March, and that a further extension to 30 June had since been agreed. These extensions have been notified to the Performance and Resources Committee. The long term contract is currently being finalised and is expected to be in place by the end of June. The Committee was further advised that work is ongoing to ensure all necessary arrangements are in place for registrants to begin annual CPD reporting from 2027. Communication and support activities will commence in April 2026, accompanied by training and workshops.

Decision Approved and/or Action Requested
Decision Approved: None.

Agenda Item 18

Issue
Closed session with the Fitness to Practise and Legal Affairs Manager and the Head of Registration and Education.

Information
The Committee met in closed session with the Head of Registration and Education and the Fitness to Practise and Legal Affairs Manager.

Decision Approved and/or Action Requested
Decision Approved: None.

The meeting finished at 12:25

Signed:

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Chair **Date**