

Corporate Governance Framework

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1. Introduction

As the regulator of pharmacists and pharmacies, the Pharmaceutical Society of Ireland (PSI) must at all times act to protect and promote, the health, safety and wellbeing of patients and the public by ensuring that pharmacy services are delivered in a competent, professional and ethical manner and in an appropriate environment to the highest standards of quality, care and best practice.

Governance encompasses all processes, structures and procedures in place to ensure that persons and organisations charged with responsibilities by Government, shareholders, stakeholders or members, carry out those responsibilities to the highest standards. Governance obligations are reflected in legislation and in codes of practice, guidance and guidelines.

Good corporate governance is a key element in improving efficiency and accountability as well as enhancing openness and transparency and benefits organisations in taking informed, transparent decisions and managing risk.

1.1 Purpose and Scope of the Corporate Governance Framework

In accordance with the <u>Pharmacy Act 2007 (the Act)</u>, the PSI Council shall from time to time adopt and publish a governance framework. The Council of the PSI adopted its first Corporate Governance Framework in 2009.

This Corporate Governance Framework is intended as a guide for everyone who works for, and on behalf of, the PSI, as well as those we serve. It sets out the standards of conduct we expect from our employees and office holders, our values, and the governance systems and procedures, to which we seek to adhere. All PSI staff, Council and committee members have a role to play in ensuring the principles of good governance are adhered to, and that the PSI complies with the <u>Code of Practice for the Governance of State Bodies</u>.

2. Overview of the PSI

2.1 Governing Legislation



The key functions and powers of the PSI are set out in Sections 7, 8 and 9 of the Pharmacy Act 2007 and the Statutory Rules, which underpin it. The general governance responsibilities of the PSI are outlined in Schedule 1 to the Act, and the Registrar is responsible for ensuring compliance with these, subject to the direction of the Council. In addition, the Council also has powers conferred on it under Misuse of Drugs legislation, Medicinal Products legislation, Poisons legislation, Falsified Medicines Directive, Regulated Professions Health and Social Care Act Amendment Act 2020, Health Act, Animal Remedies legislation, Irish Medicines Board Act and European Union legislation.

Where any conflict appears to arise between this document and the legislation or the statutory instruments made under it, then the legislation takes precedence. Applicable legislation is available to download from the PSI's website.

2.2 Functions of the PSI

Our principal purpose as a regulator is to ensure patient safety and public protection. We are committed to carrying out our work independently, ethically, and transparently. The Pharmacy Act 2007, as amended, establishes the statutory role of the PSI as the pharmacy regulator. Under this legislation and all other applicable legal and public policy frameworks, the PSI must ensure that, on an ongoing basis, we:



operate prudent financial management practices and continue to steward all PSI funds so as to maximise the pool of financial resources available to deliver on our statutory functions.

Governance for State Bodies, which provides assurance that the PSI acts in accordance with

best practice in the management and governance of public bodies, and

2.3 Mission, Vision and Values

Our vision and mission are set out in the diagram below.

Our Mission

We protect the health, safety and wellbeing of patients and the public by taking timely and effective action to ensure that pharmacists in Ireland are competent and that pharmacies are operating to high standards of safety and reliability

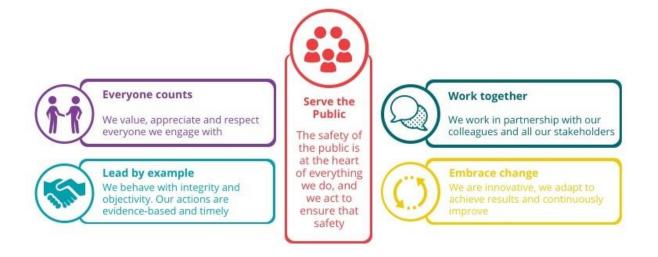
Assure trust in pharmacy through effective regulation

Our Vision

That the public has access to trusted pharmacy services and that the PSI makes a clear and demonstrable contribution to the availability and quality of those services

Values

Our values underpin how we will deliver on our mission. They guide our behaviour, the expectations we set ourselves, and the experience of others who engage with us.



3. Strategic Direction and Business Planning

3.1 Corporate Strategy

In accordance with the PSI Council Rules 2008 (as amended), the PSI is required to prepare and submit a strategy statement to the Minister for Health. The Registrar of the PSI is responsible for the preparation of a Corporate Strategy for adoption by the Council, publication and submission to the Minister for Health. The Corporate Strategy should cover a period of 3 to 5 years ahead and should set out appropriate objectives and goals and identify relevant indicators and targets against which performance can be clearly

measured. The Strategy should also be aligned to specific objectives in the Department of Health's Strategy and consistent with any Government policies for the reform and modernisation of the public service.

Process for setting strategy

The PSI Council approves the appointment, following an expression of interest process, of a Council subgroup to work with the Executive in driving the development of the next Corporate Strategy. The sub-group is made up of the President, Vice-President and no more than four other Council members. The sub-group meets jointly with PSI staff on the strategy project team, together with the Registrar and reports to Council on a regular basis throughout the strategy development process. There is also several opportunities and check points for the Council's collective input, discussion and assessment of the risk areas and strategic objectives during the development of the strategy.

The PSI's Corporate Strategy is prepared following consultation, within the PSI, and externally with our stakeholders. A copy of the draft Corporate Strategy is submitted to the Minister for Health at least 12 weeks in advance of finalisation and adoption by the Council to ensure that Council can consider the views of the Minister. Once approved by the PSI Council, the Corporate Strategy is submitted to the Minister for Health.

Progress against the Corporate Strategy is reviewed on a yearly basis to ensure that the objectives identified are being met, to reflect on achievements, to consider resources available, or any obstacles or risks to achieving the remaining objectives.

The Performance and Resources Committee advises the Council at a strategic level in relation to the delivery of its Corporate Strategy objectives, and on related developments pertaining to performance and resourcing of the organisation.

3.2 Business Planning

The Corporate Strategy sets out the high-level objectives and targets of the PSI over 3-5 years whereas the annual Service Plan explains how the PSI will carry out specific actions, which will deliver the objectives set out in the Corporate Strategy. The preparation and implementation of an annual Service Plan is central to guiding and monitoring progress at an organisational and individual level. The Service Plan is developed by the Executive with input from the Advisory Committees for consideration by Council. The Council of the PSI approves the annual Service Plan and budget in December of each year, and monitors performance by reference to the plan and budget on a quarterly basis at Council meetings.

The Registrar provides a detailed report to the Performance and Resources Committee and Council on a quarterly basis highlighting achievements against objectives and where any delays have occurred in the implementation of the Service Plan. The Performance and Resources Committee and the Regulatory and Professional Policy Committee monitor performance against the strategic objectives within their remit at each Committee meeting. The Executive Leadership Team reviews progress against Service Plan objectives on a bi-monthly basis.

The PSI links its strategic and annual goals to the work of the PSI's Executive Leadership Team, and its staff, through the PSI's performance management and development process. This allows employees to see exactly how their individual work contributes to the corporate goals of the PSI.

3.3 Annual Report

The Annual Report outlines the main achievements and developments during the year to advance the PSI's objectives, as set out in its Statement of Strategy. The Annual Report and Financial Statements provide the information necessary for an assessment of the PSI's financial performance, financial position, business model and strategy. The Annual Report is submitted to the Minister for Health, by 31st of March each year, for approval and laying before the Houses of the Oireachtas.

4. External Stakeholders



4.1 Customer Charter

The PSI is committed to providing a professional, efficient, courteous and high-quality service to all our customers, in accordance with the 12 Principles of Quality Customer Service. We will treat all our customers equally and make every effort to ensure that the services we provide reflect their needs and expectations. The PSI has developed a Customer Charter to demonstrate our commitment to high quality customer service.

4.2 Stakeholder Engagement

Patient safety is at the heart of everything we do, and we are committed to consulting through a variety of means, and media, with all our stakeholders, including members of the public, Government, and the pharmacy profession, when we develop guidelines, or draft regulations. We seek out, listen to, and take account of our stakeholders' views, so that together we continue to build an effective regulatory framework, which protects patient safety, promotes public health, and drives best practice in pharmacy.

5. Structure of the PSI

5.1 Governance of the PSI

The PSI is a public body, which, by law, is independent in the exercise of its statutory functions. The PSI is self-funded through statutory fees levied on pharmacists and pharmacies. While independent, the PSI is also subject to public accountability requirements and, for these purposes, the PSI operates under the aegis of the Department of Health. In keeping with this principle, the PSI is required to report to the Minister for Health on various matters and to seek the consent of the Minister for Health in relation to, for example, the making of statutory Rules under the Pharmacy Act.

A 21-member Council governs the PSI. The Council is responsible for overseeing the delivery of the PSI functions in the public interest. This includes agreeing on the strategy for the PSI and ensuring that the strategic objectives are met.

The PSI Registrar (Chief Officer) is appointed under the Pharmacy Act and is responsible for leading the day-to-day work and operation of the organisation and seeing that the Council's strategy and decisions are implemented efficiently and effectively. The Registrar reports to the Council at each of its meetings on the organisation's activities and performance. All PSI staff are public servants and are recruited in accordance with public service recruitment principles. Staff numbers and grading are subject to oversight by the Department of Health.

5.2 PSI Council

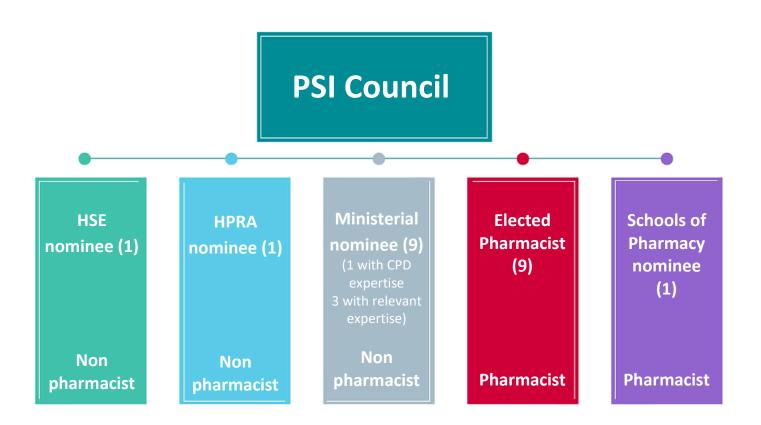
The PSI is governed by a Council which consists of 21 persons and the Minister for Health appoints each member in accordance with the provisions of the Pharmacy Act 2007 (Figure 1). The membership requirements of the Council are detailed in Part 3 of the Act and encompass a lay majority.

Removal of a Council Member from office

A Council member may be removed from office by the Minister for Health if:

- a) in the Minister's opinion, the member has become incapable through ill health, of performing their functions;
- b) the member has committed stated misbehaviour; or
- c) the removal of the member appears to the Minister to be necessary for the Council to perform its functions effectively.

Figure 1: Structure of the PSI Council



Resignation of a Council member

In the event that a Council member wishes to resign from the Council, they should write to the Minister for Health informing him/her of their resignation and send a copy of the letter to the President of the PSI Council. The President should notify the Council of the resignation.

Minister for Health & **Oireachtas Committees** The President and Council of the PSI **Audit and Risk** Internal Committee **Auditor** External **PSI Advisory Committees Auditor** Registrar(Chief Officer) **Chief Risk PSI Disciplinary** Officer Committees (statutory process) **Executive Leadership Team** Department of Health Acountable to **PSI Staff** Reports to Provides oversight of

Figure 2. Governance Framework of the PSI

5.3 Committees of the Council



The governance framework of the PSI, illustrated in figure 2, shows the reporting mechanisms in existence in the PSI. The Act allows for the establishment of Statutory Disciplinary Committees and Advisory Committees.

Disciplinary Committees

The Disciplinary Committees of the PSI are established under Part 6 of the <u>Pharmacy Act 2007</u>. They are the;

- 1. Preliminary Proceedings Committee
- 2. Professional Conduct Committee
- 3. Health Committee

These Committees are established in law and are referred to as Statutory Committees. Their function cannot be modified other than by a change to the law. The Council is responsible for appointing individuals to serve on Disciplinary Committees. Appointments to Disciplinary Committees are approved by Council, following nomination by the Special Purposes Committee. Nominations are made following an expression of interest process. Any resignation of Disciplinary Committee members should be notified to the Chair of the Committee, and the Council.

Advisory Committees

Separate to the Disciplinary Committees, the Council has established four Advisory Committees to advise it in relation to the performance of its functions. Council approves their terms of reference.

Currently the PSI's Advisory Committees are:

- 1. Special Purposes Committee: The role of the Special Purposes Committee is to provide advice to the President of the PSI Council on matters which may arise between scheduled meetings of Council. The Committee also makes recommendations to the Council for appointments to the PSI's Advisory and Disciplinary Committees. The Committee is also responsible for making recommendations to Council in relation to how the PSI Council governs its own business, in the area of fitness to practise regulatory functions e.g., standard operating procedures in relation to sanctions procedures and the Publications and Disclosure Policy. The Committee meets as and when required by the President.
- 2. Performance and Resources Committee: The role of the Performance and Resources Committee is to advise the Council in relation to the delivery of its strategic objectives, and the performance and resourcing of the organisation This will include the organisation's performance against the Service Plan, the organisation's development requirements (people, process, technology), resource optimisation and deployment, and delivery, as well as strategic financing.

- 3. Regulatory and Professional Policy Committee: The role of the Regulatory and Professional Policy Committee is to advise the Council on its regulatory and professional policy functions, with regard to education, qualification recognition, registration (both pharmacists and pharmacies), pharmacy compliance and quality assessment, fitness-to-practise and continuing professional development (CPD) for the Profession.
- 4. <u>Audit and Risk Committee</u>: The PSI's Audit and Risk Committee maintains oversight, and ensures the integrity, of the PSI's governance, internal and external audits, and financial controls. It monitors such risks as the PSI may be exposed to, and the measures taken to mitigate those risks. As set out in the Code of Practice for the Governance of State Bodies, the Committee will report to Council, but may act independently of it, to ensure that the interests of the PSI's stakeholders are protected in relation to the PSI's business and financial reporting, and internal controls.

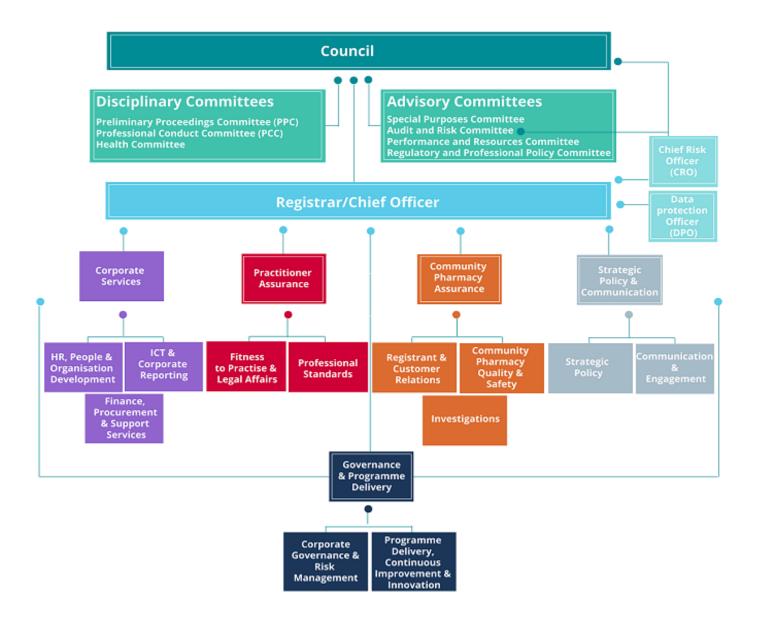
With the exception of the Audit and Risk Committee, the remaining Advisory Committees are directed by Council.

5.4 Organisational Structure

The organisational structure of the PSI is set out in figure 3.

We have five business areas that are made up of teams that reflect our main functions. Each business area is headed by a member of our Executive Leadership Team, which is led by the Registrar (Chief Officer).

Figure 3. Organisational Structure of the PSI



6. Council



6.1 Council's accountability

The PSI is a corporate body and, as such, has powers and duties under the <u>Pharmacy Act 2007</u>. These are exercised by the PSI as the legal entity, with the Council as governing body. The powers and responsibilities of the Council are exercised jointly by its members, each of whom has a statutory and fiduciary duty (i.e., the duty to act in good faith, and in the best interests of the PSI), in discharging them. Council is accountable to the Minister for Health, and the Oireachtas, for the overall performance of the organisation and for exercising its public responsibilities by ensuring it always acts within the context of the public benefit.

The Council provides strategic guidance to the PSI and monitors the activities and effectiveness of management. The Council is responsible for developing the capacity and leadership of PSI staff and is responsible for holding the Registrar to account for the effective performance of their responsibilities. The Council is accountable for its policy decisions, for the overall performance of the organisation, for ensuring that the necessary organisational and management framework is in place and has a fiduciary duty in relation to the PSI, Council's affairs, and finances.

Council members should act on a fully informed basis, in good faith, with due diligence and care, and in the best interest of the PSI, subject to the objectives set by Government. The Council has a key role in setting the ethical tone and culture of the PSI and should lead by example and ensure that good standards of governance and ethical behaviours permeate all levels of the organisation.

6.2 Collective and Individual Responsibilities of Council Members

Council is collectively responsible for all the PSI's policies and decisions. All Council members are afforded the opportunity to contribute to Council deliberations and are encouraged to provide constructive challenge. Once however, a decision has been approved, or voted on, all Council members are collectively responsible for that decision, even if they personally do not agree with it, abstained from voting or have voted against it. It follows that all Council members are bound by a decision of the Council made in good faith (whether a unanimous or majority decision) and may not obstruct or interfere with the promotion or execution of that decision. Excessive influence on Council decision-making by one or more individual members should be guarded against. Matters which are reserved for Council are outlined in Appendix A.

Individual responsibility requires Council members to ensure that they understand the matters that are put before them, have the courage to challenge, and be challenged and to give voice to their concerns. When they have done so, collective responsibility requires them to acknowledge the decision of the Council, and uphold it, irrespective of their personal views regarding the decision.

Council members must:

- 1. Be objective in their work on behalf of Council;
- 2. On appointment to the Council, furnish to the Registrar details relating to their employment and any business interests including shareholdings, professional

- relationships, etc., which could pose a conflict of interest, or materially influence the member, in relation to the performance of their functions as a member of Council of the PSI;
- 3. Inform the Registrar, of any new appointments they accept which may impinge on, or conflict with, their duties as a member of the Council of the PSI;
- 4. Work effectively with fellow Council members;
- 5. Support the Council's policies and views in a positive way to external audiences;
- 6. Not to disclose, without the consent of the Council, save in accordance with law, any information obtained by him, or her, while performing duties as a member of the Council, and after their term of office expires;
- 7. Treat papers marked for non-disclosure as confidential, not discuss them with others outside the Council of the PSI, not leave them unattended, and dispose of them appropriately, with due regard to the PSI's Data Protection Policy;
- 8. Not to misuse information gained in the course of their service for personal or political or material gain;
- 9. Support the integrity and probity of any proceedings taken under the Act and maintain public and professional confidence in these proceedings. Council members should not become personally involved in any proceedings e.g., act as character witnesses in fitness to practise proceedings or support applications for restoration; and
- 10. Council members may receive correspondence, from individual pharmacists, or members of the public. In responding to any matters raised by stakeholders, care must be taken to reflect the Council's policies accurately, particularly when dealing with sensitive and personal issues. All correspondence received should be forwarded to the Registrar's Office to be dealt with.

6.3 Effectiveness of Council

The Council should constantly review its own operation and seek to identify ways of improving its effectiveness including the identification of competency gaps and consider ways to address these gaps. Where the President believes specific competencies or skills are required, he/she should advise the Minister for Health when a vacancy on Council is due to arise.

Good governance suggests that all governing bodies should periodically undertake an evaluation of their effectiveness. This is so as to ensure the organisation and the Council remains effective in implementing the legal, regulatory and governance obligations of the organisation. Council should embrace initiatives which will assist in improving its overall effectiveness. The evaluation process should incorporate a detailed analysis of the gender, diversity and skills mix within the Council, as required by the Annex to the Code of Practice for the Governance of State Bodies on Gender Balance, Diversity and Inclusion.

In line with the Code of Practice for the Governance of State Bodies, there is an expectation of 100% attendance at Council meetings and attendance will be evaluated when a member is due to be re-appointed. Attendance at Council meetings will also be reported on in the Annual Report.

6.4 Functions of Council and their delegation

The Council retains overall responsibility for the discharge of the key functions of the PSI as specified in the Pharmacy Act 2007. It must comply with all statutory regulations and legal obligations which apply to the PSI.

- The Council is accountable to the Minister for Health, and the Oireachtas, for the overall performance of the organisation, and to the public, for the discharge of its functions.
- The Council may delegate any of its functions to its Advisory Committees, or to the Registrar, or to any other employee of the PSI.
- Where the Council delegates a function, the Council remains the accountable body.
- The Council may revoke delegations previously made by it.
- The Registrar is accountable to the Council for the implementation of the Council's policies.
- The day-to-day management of the PSI is undertaken by the Registrar and the PSI's Executive Leadership Team

6.5 Failure of Council to perform a function

If the Council fails to perform any of its functions, the Minister for Health may direct it, in writing, to perform the function within a specified timeframe. If the Council does not comply with the direction, the Minister may, by order, remove from office, any, or all Council members, and perform the function him or herself.

6.6 Role of the President and Vice President

The Office of President of Council, and the Vice-President of Council, as specified in the <u>Pharmacy Act 2007</u>, can only be held by a pharmacist member of Council. The President, and the Vice-President when deputising for the President, must carry out the following functions:

- 1. Chair the meetings of Council and ensure that the Minutes of the meeting accurately record the decisions taken.
- 2. Agree, in consultation with the Registrar, the agenda for Council meetings.
- 3. Ensure that all meetings of the Council are conducted in accordance with the Pharmacy Act 2007, PSI (Council) Rules 2008 (S.I. No. 492 of 2008, as amended) and the Standing Orders of the Council.
- 4. Ensure that Council members understand their respective roles, and ensure Council works effectively.
- 5. Ensure the Council receives accurate, timely, and clear information.
- 6. Ensure, in conjunction with the Secretary to Council that there are good information flows between the Council and its Committees, and the Executive.
- 7. Chair meetings of the Special Purposes Committee when she/he judge it necessary to convene the Committee to advise them on matters.
- 8. Advise the Minister of any competency deficits on Council and ensure that candidates with specific skillsets which address those deficits, can be identified, and recruited through the State Boards appointments process.
- 9. Furnish a comprehensive report on the PSI to the Minister for Health in conjunction with the Annual Report and Financial Statements.
- 10. Report to the Minister for Health, and in the PSI's Annual Report, on the Statement of Internal Control, which should be reviewed by the External Auditors, to confirm that it reflects the PSI's compliance with paragraph 1.9 (iv) of the Code of Practice for the Governance of State Bodies, and is consistent with the information contained in audits of the PSI's Financial Statements.
- 11. When called upon, and in consultation with the Registrar, communicate the Council's strategy and policies.

- 12. Promote the work of the Council in the public arena.
- 13. To represent following consultation with the Registrar, the views of the Council at meetings with Ministers, Oireachtas Committees, leaders of other professional bodies; and
- 14. Represent the PSI at meetings with groups, agencies and organisations.

7. Advisory Committees of the Council

The agenda and Minutes of Advisory Committee meetings are published on the PSI's website following each Committee meeting.

7.1 Appointment to Advisory Committees of Council

In the interests of ensuring a broad representation of the Council on its individual Committees, Council members are required to sit on at least one Advisory Committee of the Council. Appointments to Advisory Committees are approved by Council, following nomination by the Special Purposes Committee. Nominations are made following an expression of interest process. Any resignation of Advisory Committee members should be notified to the Chair of the Committee, and the Council.

It is also open to the Council to nominate and appoint external non-Council members to Advisory Committees, should certain skillsets be required, and be unavailable from within the Council's own membership.

7.2 Period of Appointment to Advisory Committees and Rotation

The period of membership of an Advisory Committee is 2 years, as provided for in the Council Rules 2008, as amended. Committee members are eligible to be re-appointed for a further term of 2 years on that Committee. The Council considers it desirable that Council members rotate between Committees.

The exception to this is external members of the Audit and Risk Committee. In December 2020, Council made a decision that external members would be appointed for a term of 3 years, with an option to be reappointed for a further term of 3 years. This decision was made in consideration of the following:

- the establishment of an independent Audit and Risk Committee is set out separately in the Council Rules 2008, as amended, to the establishment of Advisory Committees, and therefore consideration was given to the applicability of Rules governing the period of membership of Advisory Committees to the Audit and Risk Committee;
- the role and function of the Audit and Risk Committee, unlike other Advisory Committees, is not directed by Council and is independent in nature;
- the valuable knowledge, expertise and independence external members bring to the Committee; and
- best practice guidance for Audit and Risk Committees, as provided for in the Code of Practice for the Governance of State Bodies, 2016, which recommends that first appointment to an Audit and Risk Committee should be for 3 years and renewed up to a maximum of 6 years in total.

7.3 Effectiveness of Advisory Committees of Council

The effectiveness of Advisory Committees and of individual Committee members will be reviewed on an annual basis, including the terms of reference. There is an expectation of 100% attendance at Advisory Committee meetings and attendance will be evaluated when a member is due to be re-appointed. Attendance at Advisory Committee meetings will also be reported on in the Annual Report.

7.4 Function of the Committee Chairperson

- 1. Chairs meetings of the Committee;
- 2. Manages the business of the Committee jointly with the Secretary to the Committee (Member of the Executive Leadership Team assigned to the Committee), including determining items that fall within the Committees remit, developing the work programme and forward planning of agendas;
- Submits any items for the agenda to the Secretary to the Committee not less than two weeks before the
 meeting and is responsible for approving the draft agenda, in advance of circulation to the wider
 Committee;
- 4. Manages time, ensuring adequate consideration, and completion, of all items on the agenda;
- 5. Ensures that clear and unambiguous decisions are taken by the Committee in accordance with its stated aims and objectives;
- 6. Encourages members of the Committee to take collective responsibility for what has been agreed;
- 7. Ensures participation of all Committee members and of the Executive;
- 8. Approves the draft Minutes of meetings and the Report to Council from the Committee, before their circulation to the wider Committee;
- 9. Monitors implementation of Committee decisions;
- 10. Provide to the Registrar copies of all agenda and Minutes of its meetings;
- 11. Deals with issues which arise between Committee meetings which require an urgent response in liaison with the Secretary;
- 12. Participates in meetings of the Special Purposes Committee;
- 13. Assists the Committee to review and assess its performance; and,
- 14. Gives an update on Committee activities to Council at every Council meeting and if they are not present at the Council meeting, nominates another Council member who sits on the Committee to give the update.

8. Key Roles and Functions of the Registrar (Chief Officer), Executive Leadership Team and Employees of the PSI



8.1 Appointment of the Registrar

The Council appoints the Registrar of the PSI, on terms and conditions approved by the Minister for Health and consented to by the Department of Public Expenditure NDP Delivery and Reform. The Registrar acts as the organisation's chief executive, and is also formally, Secretary to the Council, and Chief Officer of the PSI.

8.2 Appointment of an Acting Registrar

The Registrar may in their absence appoint a member of the Executive Leadership Team as Acting Registrar for a specified period of time.

8.3 Temporary vacancy in the Office of Registrar

If a temporary vacancy arises in the office of Registrar, the President of the Council must inform the Minister for Health immediately. The Council should then appoint, a suitable person to undertake the role, following an internal recruitment process, pending the outcome of a full competition process and inform the Minister for Health. A permanent appointment should be made as soon as possible following a competition under the auspices of the Public Appointments Service. The Council of the PSI should appoint a Registrar following a recommendation from the Public Appointments Service subject to the terms and conditions as the Minister for Health and the Department of Public Expenditure, NDP Delivery and Reform determines.

8.4 Specific functions, powers and obligations of the Registrar

All members of the Council have access to the Registrar for advice and guidance.

The Registrar is responsible for:

Performance and Planning

- 1. Arranging Council meetings in accordance with the Standing Orders of the Council and ensuring applicable rules and regulations are complied with;
- 2. Maintaining the Registers and managing and controlling the administration and business of the PSI and the Council;
- 3. Supporting the Council and the Advisory Committees;
- 4. Ensuring that an objective procedure for a review of the performance of the Council and of the Advisory Committees is in place and working effectively;
- 5. Ensuring that Council and Advisory Committee members are informed as to their legal and governance responsibilities and that they are familiar with the requirements of the Pharmacy Act 2007 and other applicable legislation in the performance of their functions;
- 6. Ensuring induction training for Council members on joining the Council and ongoing training annually;
- 7. Presenting the Council with strategic and operational plans for its review and approval;
- 8. Putting in place procedures and processes and providing appropriate advice and documentation, in a timely manner, to Council;
- 9. Ensuring systems, procedures and practices of the organisation are in place for evaluating the effectiveness of its operations. This includes the establishment of a performance management system which will assess the effectiveness/outcomes of major items of expenditure to ensure that they are focussed on clearly defined objectives and outcomes and provide reports to the Council;
- 10. The recruitment, direction and management of employees. All PSI employees report to and through the Registrar to Council and the Registrar is responsible for all staffing matters;

Report on Accounts

- 1. The preparation of the Annual Report and Financial Statements, which are submitted to the Council for adoption with a view to submission to the Minister for Health, 3 months after the end of each financial vear:
- 2. The probity, integrity, efficiency and cost-effectiveness of the general and financial management of the affairs of the PSI and shall be accountable to the Council in respect thereof;

Corporate Governance

- 1. Using their best endeavours to ensure compliance with all aspects of the Corporate Governance Framework, which includes their declaration of all relevant interests and they must make a declaration to the President of the PSI;
- 2. Ensuring that the governance responsibilities conferred upon the PSI are complied with;
- 3. Maintaining a register of Council, Advisory Committee and Disciplinary Committee members' interests, which should be updated on an annual basis. The register of interests for Council members is published on the PSI website, as agreed by Council;
- 4. Confirming to the Minister for Health that the PSI has put in place and complied with a Code of Conduct for Council members, Advisory Committee members and employees of the PSI;
- 5. Ensuring that the Council has sufficient information on risk identification, measurement and mitigation strategies;
- Notifying the President, if they become aware of any event, circumstance or conduct which might
 constitute a breach of the <u>Pharmacy Act 2007</u>, or any regulation or code of conduct made thereunder,
 or of this Corporate Governance Framework. Failure to do so may itself constitute a breach of good
 governance;
- 7. Ensuring information gained in the course of their employment as Registrar is not misused for personal gain or political purpose;

Reporting Requirements

- 1. The development and implementation of an annual Service Plan (containing proposals and financial and budgetary estimates for the delivery of the Service Plan) and a Corporate Strategy for adoption by Council, for publication and for submission to the Minister for Health;
- 2. Providing to the Council information in relation to any aspect of PSI's business as the Council may reasonably require;
- 3. Appearing before the Committees of the Oireachtas, when requested, and should inform the Secretary General of the Department of Health of such requests when received;

Communications

- 1. Putting in place effective internal and external communication structures to ensure policies and statutory responsibilities of Council are disseminated as appropriate;
- 2. Ensuring all media inquiries, correspondence, parliamentary questions, and questions from Oireachtas Committees and other Statutory Bodies, received by the PSI, are responded to, as appropriate;
- 3. Maintaining an effective working relationship with the Minister for Health, the Secretary General and relevant officers of the Department of Health;
- 4. Representing the PSI at international fora and events; and,
- 5. Acting as the principal point of contact for all communications intended for the PSI.

Seal of the PSI

The official Seal of the PSI is authenticated by the signature of two members of Council or the signature of a member of the Council, and an employee of the PSI authorised by the Council, to sign for that purpose. The Registrar is authorised by the Council to authenticate the Seal and is responsible for the safe custody of the official Seal.

The Registrar shall keep and maintain a permanent record of all occasions when the PSI executes a document under its Seal. Examples of documents on which the official Seal will go on include deeds, leases, warrants for Authorised Officers and decisions of Council for prosecutions. The Seal will be affixed in accordance with Section 6 of the Act.

8.5 Role of the Executive Leadership Team

The Registrar should assemble an Executive Leadership Team, which they should direct and instruct. The Executive Leadership Team should consist of the head of each of the business areas identified in Figure 3, Community Pharmacy Assurance, Practitioner Assurance, Strategic Policy and Communications, Corporate Services and Governance and Programme Delivery. Regular meetings are held between the Registrar and the Executive Leadership Team to discuss any matters arising in each business area and any matters that have been identified by the Advisory Committees, or Council.

8.6 Role of PSI employees

Employees of the PSI are informed of the standards of behaviour required of public servants and of the particular standards that apply to the work of PSI. Regular briefing sessions are held to remind staff of the key requirements as regards values, behaviours, conduct and compliance requirements etc. This Governance Framework will be publicised within the PSI and used as a basis to ensure an appropriate culture is in place within the PSI. The Registrar should ensure that all employees understand their responsibilities for contributing to a sound and effective governance culture, grounded in public service values.

Codes of Conduct, Ethics in Public Office,Disclosure of Interests and Protected Disclosures



9.1 Code of Conduct for Council and Advisory Committee Members of the PSI

For the PSI to command the confidence of the public it is necessary that the Council, as its governing body, should adopt and comply with appropriate standards of conduct. The Council has approved a <u>Code of Conduct for Council and Advisory Committee members.</u>

In discussions at meetings, in decision-making and in communications, Council and Committee members are expected to observe the highest standards of impartiality, integrity and objectivity. So long as they continue to serve on the Council or Committee, members cannot, by their actions or behaviour, divest themselves of their role. If a Council or Committee member becomes aware of matters regarding another member that might be of

concern or might affect their ability to perform their duties as a Council or Committee member, they should seek the advice of the President, Chair of the Committee or the Registrar.

Council members and Advisory Committee members on assuming office will be asked to sign an acknowledgement that they have received and read the Code of Conduct and that they agree to abide by the principles set out therein. On an annual basis, Council and Committee members will be required to re-confirm their commitment to the principles set down in the Code of Conduct.

9.2 Breaches of Conduct identified by Council or Advisory Committee Members

Where individual Council or Advisory Committee members become aware of any event, circumstance or conduct which might constitute a breach of the code of conduct made thereunder or of this Corporate Governance Framework, they are required to bring this to the attention of the President, or Chairperson of the relevant Advisory Committee. Failure to do so may itself constitute a breach of good governance. The Council has approved a Resolution procedure for possible breaches of the Code of Conduct for Council and Advisory Committee members.

9.3 Code of Conduct for Employees of the PSI

Each employee, upon appointment, will be given a copy of the Corporate Governance Framework and must agree to honour what is outlined in it in relation to the functions and duties of the PSI and ensure that in doing their job they are acting at all times in the public interest. Employees will also be provided with the Conduct for Employees of the PSI and asked to sign an acknowledgement that they understand and agree to be bound by the principles set out therein.

9.4 Breaches of conduct identified by employees of the PSI

Where an employee becomes aware of any event, circumstance or conduct which might constitute a breach of the Act or any regulation or Code of Conduct made thereunder or of this Corporate Governance Framework they are required to bring this to the attention of the Registrar. Failure to do so may itself constitute a breach of good governance.

9.5 Disclosure of Interests

Council and Committee Members

To avoid conflicts of interest each Council or Committee member must furnish to the Registrar details of their employment, and all other business interests including shareholdings, which could be perceived as posing a conflict of interest or could materially influence their functions as a member of the Council or a Committee of the PSI.

To ensure compliance, PSI Council members, Advisory Committee members, Disciplinary Committee members and PSI employees are required to provide the PSI with details of employment they are engaged in, in addition to

their work for the PSI, and/or other business interests, including shareholdings, if they believe they could lead to a conflict of interest, or could materially influence the functions carried out on behalf of the PSI.

The interests of relatives, as defined in Schedule 1, paragraph 9, of the Pharmacy Act, i.e. a spouse, a partner or individuals who are not married to each other but who are cohabiting as partners or a parent, brother, sister, child or spouse/partner of a child of the person, should also be declared, where relevant.

Each Council and Committee member of the PSI is responsible for ensuring that any change to their interests which could be perceived as influencing their work with the PSI, is notified to the Registrar in order that the PSI Register of Interests can be amended.

The guiding principle when declaring interests, is that matters need only be declared which in the perception of others, might be seen to give material or other advantage to the Council or Committee member, or her/his close family members, or business or professional associates either directly or indirectly.

The Standing Orders of Council and of the Advisory Committees of Council also provide that each member should declare any conflict of interest with regard to a particular agenda item at the beginning of a meeting. The member must then absent themselves from the meeting or that part of the meeting during which the matter is being discussed. In the event of a member not appreciating at the beginning of a discussion that an interest exists; the member shall declare such an interest as soon as they become aware of it. In any case of doubt, the member should openly declare the possibility of interest.

If a Council or Committee member, the Registrar or employees of the PSI believe that another member present has a direct or indirect interest in an item for discussion and that interest has not been declared, they should inform the chairperson. If a member of the Council or Committee is asked to leave for the duration of the relevant item when it is being discussed at the meeting, then they will not be counted for the purpose of determining a quorum for the duration of that section of the meeting. The disclosure should also be recorded in the Minutes.

If the Chairperson discloses an interest, then the Deputy/Acting Chairperson should chair the meeting or in their absence, the meeting shall choose another member to chair it for the purposes of the determination. Council and Committee members should, in cases where they receive documents relating to their interests or of those connected them, return the documents to the Registrar at the earliest opportunity.

Employees of the PSI

To avoid conflicts of interest, each PSI employee furnishes to the Human Resources Unit, details of their business interests including shareholdings which could be perceived as materially influencing their functions as an employee of the PSI.

The interests of relatives, as defined in Schedule 1, paragraph 9, of the Pharmacy Act, i.e. a spouse, a partner or individuals who are not married to each other but who are cohabiting as partners or a parent, brother, sister, child or spouse/partner of a child of the person, should also be declared, where relevant.

Each employee of the PSI is responsible for ensuring that any changes to their interests are notified to the Human Resources Team. A Register of Interests declared by PSI employees, is maintained by the Head of Corporate Governance and Programme Delivery

9.6 Gifts and Hospitality

The PSI maintains a Register of Gifts for its staff and office holders. The purpose of the register is to enable members of Council and Committees, and PSI employees to make a declaration of any gifts or hospitality that could or could be thought to adversely influence the performance of their duties.

Hospitality provided by a commercial, representative or other organisation may be construed as an attempt by the organisation to gain influence or favours, and all PSI office holders and employees should avoid any conduct which could give rise to suspicions of this kind and are required to comply with the Gifts and Hospitality Policy of the PSI.

9.7 Ethics in Public Office Act, 1995 and 2001

Council

In addition to their obligations under Schedule 1 paragraph 9 of the Pharmacy Act 2007 to declare their interests to the Council, Council members are also bound by the Ethics in Public Office Act 1995 and the Standards in Public Office Act 2001. Each member of Council is required to comply with their obligations to prepare and furnish an annual statement of disclosure. In January of each year, Council members are sent a reminder regarding their duty to disclose interests for the previous year.

Employees of the PSI

In addition to their obligations under Schedule 1 paragraph 10 of the Pharmacy Act 2007, to declare their interests to the Council, some senior employees are also bound by the Ethics in Public Office Act 1995 and the Standards in Public Office Act 2001. Each person holding a designated senior position, as defined in the legislation, or prescribed by the organisation by nature of the person's role, is required to comply with their obligations to prepare and furnish an annual statement of disclosure. In January of each year, these employees will be sent a reminder regarding their duty to disclose interests. Designated senior employees should forward their annual statement to the President of the Council.

9.8 Protected Disclosure

The Protected Disclosures Acts (2014 and 2022) enables workers, as defined in the legislation, to raise a concern regarding perceived wrongdoing in the PSI, and ensures they are safeguarded against any reprisal by the PSI arising from their disclosure. The PSI is committed to addressing concerns relating to wrongdoing in the workplace, and to provide the necessary support for staff who raise concern regarding wrongdoing at the PSI. The PSI has in place <u>protected disclosure policies</u>, which have been circulated to all staff. We also publish an annual Protected Disclosures Report on our website, detailing protected disclosures received.

9.9 Non-compliance with statutory obligations

If a Council member finds evidence that there is non-compliance with any statutory obligations that apply to the PSI, they should immediately bring this to the attention of the President with a view to having the matter rectified. In line with the Code of Practice for the Governance of State Bodies the matter should also be brought to the attention of the Minister for Health by the President indicating (i) the consequence of such non-compliance and (ii) the steps that have been or will be taken to rectify the matter. It is the responsibility of Council members to ensure that matters are addressed and the concerns of Council members that cannot be resolved, should be formally recorded in the Minutes of the Council meeting.

9.10 Conflict Resolution

The Council of the PSI is committed to reaching a prompt and fair resolution in any disputes, conflicts or disagreements that may arise from time to time and has developed a Conflict Resolution Procedure for Council and Advisory Committee Members.

10. Meetings and Procedures of the PSI Council



10.1 Standing Orders of Council

Schedule 1 of the Pharmacy Act 2007, the PSI (Council) Rules 2008, S.I. 492 of 2008, as amended, and the Civil Law and Criminal Law (Miscellaneous Provisions) Act 2020, respectively, set out the terms under which meetings of Council are convened, which must be a minimum of 4 times a year.

In exceptional circumstances a decision of Council may be required between Council meetings. In this instance the views of Council members may be sought by email, phone or videoconference.

Agenda

The agenda of a Council meeting shall be prepared by the Registrar, in consultation with the President or where the office of President is vacant, the Vice-President. Policy matters arising from Advisory Committee meetings are presented to Council for discussion and decision. The public meeting agenda will contain an item called "Any Other Business" during which, a Council member may table an item for discussion at the meeting. Council members should give due consideration to the item's relevance, to the role and function of Council, and the public nature of the meeting, before requesting a matter be tabled for discussion under this item. It will be for the President to decide whether or not the discussion may proceed at the meeting. The Standing Orders of Council set down the procedures to be followed in relation to "Any Other Business".

10.2 Public Access to Meetings of Council

Public meetings of Council are open to the public to the attend unless the business under consideration concerns:

- 1. Information relating to a registrant, former registrant, or applicant for registration;
- 2. Information relating to an employee or office holder, former employee or applicant for any post or office;
- 3. The terms of, or expenditure under, a tender or contract for the purchase or supply of goods or services or the acquisition or disposal of property;
- 4. Negotiations or consultation concerning labour relations between the Council and its employees;
- 5. Any issue relating to legal proceedings;
- 6. Action being taken to prevent or detect crime or to prosecute offenders;
- 7. Position Papers to be used in negotiations or in making submissions to outside bodies;
- 8. The PSI's Corporate Risk Register;
- 9. Information given to Council in confidence; and,
- 10. Any other matter which, in the opinion of the President is confidential or the public disclosure of which would prejudice the effective discharge of Council's functions.

The public attend meetings of Council as observers and only at the public part of the Council meeting. Private business of Council, as above, is conducted in private. Each Council meeting will have a public and private session denoted by a public and private agenda. The public agenda will be available to view on the PSI's website www.psi.ie. The private agenda will remain confidential.

The Council may also hold closed sessions. The holding of a closed session during the Council meeting provides an opportunity for informal discussions between Council members, without members of the PSI Executive, or other persons present. The purpose of the closed session is to facilitate Council members to reflect on meeting arrangements and processes, to develop their knowledge and understanding of their role and thereby assist them in the performance of their role, to enhance relationships and communications among Council members, to increase meeting efficiency, to consider working relationships, and to provide a forum for Council to manage its own performance and conduct. Closed sessions are governed by the Closed Session's Policy, approved by Council.

10.3 Designation of items as confidential

The Registrar, following consultation with the President of the Council, may determine that an item for discussion is confidential. Inclusion on a confidential agenda does not necessarily mean that the paper or Minute is protected from disclosure, under the Freedom of Information Act 2014, or within due legal process.

Council and Committee members should not retain documentation obtained during their terms of office and should return such documentation to the Registrar, or otherwise indicate to the Registrar that all such documentation in their possession has been disposed of in an appropriate manner.

Members of Council and Advisory Committees should bear in mind that they do not have absolute privilege during the course of Council and Committee meetings and discussions during meetings should be kept to the business of Council and Committees.

10.4 Prohibition of unauthorised disclosure of confidential information

A person who recklessly and/or intentionally discloses confidential information, which they obtained as a member of Council, or one of its Advisory Committees, as an advisor or consultant to the PSI, or to the Council or one of its Committees, or as an employee of the PSI, may be guilty of a criminal offence. It may also result in disciplinary action being taken against that person by the PSI, should their contract of employment with the PSI, be subject to the PSI's Code of Conduct for its employees. Confidential information includes information declared by the Council on the advice of the Registrar to be confidential, or proposals of a commercial nature or tenders submitted to the Council.

10.5 Publishing of Council proceedings

The agenda and minutes of Council public meetings and the Registrar's Report are published on the PSI's website following each public Council meeting.

10.6 Access to information by Council Members

In carrying out the functions and duties of the PSI, the Council requires information relevant to such functions and duties and the implementation thereof. The management and employees of the PSI are responsible for all executive matters and implementation of Council policy under the direction of the Registrar. In general Council members should avoid getting into the executive running of the organisation and informational matters relating to it. Council members should discuss with the President and Registrar the management of Council business so that there are sufficient and appropriate levels of information and reporting available to them.

10.7 Professional Advice

Council members in the furtherance of their duties may take independent professional advice, if necessary, at the reasonable expense of the PSI where it is judged to be necessary to discharge their responsibilities as Council members. The Council has approved formal procedures for this process.

10.8 Reimbursement and Expenses

Members of Council and Advisory Committees are entitled to reimbursement for expenditure on travel and expenses incurred on PSI business and for costs of accommodation and subsistence within rates determined by the Department of Public Expenditure, NDP Delivery and Reform as set out in the PSI's Travel and Subsistence Policy.

The PSI adheres to the guidelines covering payment of fees to the Chairpersons and Directors of State Bodies. The Annual Report of the PSI includes a schedule of the fees and aggregate expenses paid to Council Members.

11. Assurance, Audit and Compliance Arrangements



Council and its Committees approve programmes of action, set deadlines, review

priorities, and are kept informed of progress. It is the responsibility of the Registrar to decide the extent of the internal control system based on current best practice and the responsibility of the Council to ensure that the internal control system is effective.

Internal control systems should include a number of sub-systems, including internal financial, operational and compliance controls, internal audit, Audit and Risk Committee and risk management strategies. The Council should review the effectiveness of these systems annually. The following are ways in which Council monitors progress:

11.1 Business and Financial Reporting

The PSI prepares a Corporate Strategy spanning between 3 to 5 years and on an annual basis, a Service Plan which sets out how the Corporate Strategy will be implemented. This is monitored by Council through the receipt of updates from the Registrar, and the Chairs of the Advisory Committees, at Council meetings.

The Registrar is responsible for the preparation of the Annual Report and Financial Statements in accordance with relevant accounting standards which are submitted to the Council for approval, for onward submission to the Minister of Health. The Financial Statements are subject to external audit by External Auditors who are appointed by the Council.

11.2 Assurance Framework

The PSI's assurance framework is a means of identifying and mapping the main sources of assurance for the organisation and contains four lines of defence. The first line refers to business operations responsible for ensuring the risk and controls are managed as part of day-to-day activities. This encapsulates the work of the various departments or units within the PSI and in particular, the duties and responsibilities of individual staff members within each of these.

The second line of defence includes management, oversight, and supervision by Heads of Business Areas. This line may also be supported by external consultants, who may undertake reviews in conjunction with line managers, give related advice and carry out independent reviews on behalf of the management of the various Business Areas.

The third line of defence refers to functions which are independent of the first and second line and give independent assurance. Internal audit activities are part of the third line.

The fourth line of defence refers to external auditors, or those with a specific legal, or regulatory remit, such as the Data Protection Commission, the Health and Safety Authority, or the Office of the Ombudsman, to independently review, or investigate if they deem it necessary, activities within the organisation, which fall within their specific regulatory scope.

Table 1. Four Lines of Defence-Key Components within the PSI

First Line Business Operations (Control Frameworks and Day to Day Controls)	Second Line Risk and Compliance (Management and Supervision)	Third Line Independent Audit (Assurance Process)	Fourth Line External Audit (Assurance Process)
Strategy / Service Planning	Oversight and Management Roles (risk, finance, registration, inspection, education, other activity)	Internal Audit and Assurance Systems	External Audit Systems
IT Computer Systems (Finance / HR / Registration)	Quality Control / Exception Reporting	Review undertaken by external bodies; reviews commissioned by PSI	Independent review
Protocols, Policies, Procedures	Authorisation and Approval Arrangements	External Accreditation Bodies / Peer Reviews	
Job Descriptions /Roles and Responsibilities	Performance Management Systems		
Appropriate Knowledge / Skills / Competency / Experience	Committee, Council and Executive Leadership Team Reporting		
Team based / Unit Working	Monitoring / Review of Service Plan Deliverables		

Figure 4. Pharmaceutical Society of Ireland Assurance Framework

Central Guidance

Ethics Legislative
Framework, Corporate
Governance Framework and
Risk Management
Guidelines, Public Spending
Code, Guidance from the
Department of Health etc.

Registrar (Chief Officer) and PSI Council

Minister/ Oireachtas

Audit and Risk Committee

Provides independent assurance on the adequacy and effectiveness of the governance arrangements, including risk management and the control environment

Executive Leadership Team

Receive / Provide reports on performance and risk management to inform key decisions.

Key Sources of Information

Internal Audit

Independent opinion on the adequacy of, and compliance with, internal control.

Risk Management

Outcomes from risk assessment as documented in Corporate and Unit Risk Registers and quarterly report from the Chief Risk Officer. Executive Leadership Team monitoring of risk registers. Formal review of Corporate Risk Register by PSI Council.

Internal Management

Day-to-day
management of
services. Financial
Management, Service
Plan, Corporate
Strategy, Performance
Reporting, Corporate
Governance
Framework, processes
and procedures.
Customer Charter and
complaints processes.
Quality assurance etc.

Other (Internal)

Business Process
Improvement Strategic
Projects, External
Benchmarking etc.
Service Level
Agreement obligations /
MOUs etc.

Other (External)

Reviews/Audits, Health and Safety Reports; Ombudsman; Information Comm., Data Protection Commissioner, etc.

External Audit

Independent scrutiny of the effectiveness of the financial control environment including financial reporting, internal control, risk management and Value for Money. Control improvements highlighted in auditor reports.

Procurement

Provision of oversight and reporting role on compliance with legislation.

11.3 Internal Audit

The purpose of internal audit is to ensure that the PSI's operations are conducted according to the highest standards by providing an independent, objective assurance function and by advising best practice. The Internal Auditors, approved by Council, examine, and evaluate, the adequacy and effectiveness of the PSI's governance, risk management, and system of internal controls as well as the quality of performance in carrying out assigned responsibilities to achieve the PSI's stated goals and objectives.

The scope of the internal audit includes:

- Evaluating risk exposure relating to the achievement of the PSI's strategic objectives.
- Evaluating the reliability and integrity of information and the means used to identify, measure, classify, and report such information.
- Evaluating the systems established to ensure compliance with policies, plans, procedures, laws, and regulations which could have a significant impact on the PSI.
- Evaluating the means of safeguarding assets and, as appropriate, verifying the existence of such assets.
- Evaluating the effectiveness and efficiency with which resources are employed.
- Evaluating operations or programmes to ascertain whether results are consistent with established objectives and goals and whether the operations or programmes are being carried out as planned.
- Monitoring and evaluating governance processes.
- Monitoring and evaluating the effectiveness of the PSI's risk management processes.
- Performing consulting and advisory services related to governance, risk management and control as appropriate for the PSI.
- Reporting significant risk exposures and control issues, including fraud risks, governance issues, and other matters needed or requested by the Council, Audit and Risk Committee or management.
- Evaluating specific operations at the request of the Council, Audit and Risk Committee or management, as appropriate.
- Ensuring that value-for-money auditing receives adequate attention.
- Ensuring confidentiality of all information and records accessed in the course of its work.

11.4 The Audit and Risk Committee

The PSI's Audit and Risk Committee acts independently to maintain oversight, and ensure the integrity, of the PSI's governance, internal audit, external audit, and financial controls and monitor such risks as the PSI may be exposed to, and the measures taken to mitigate those risks. The Committee also oversees the work of the PSIs Internal and External Auditors.

The Audit and Risk Committee advise the Council on:

the PSI's policies and procedures for the management of risk, internal controls and governance;

- the assurance it has received that the correct procedures are being applied across the organisation with regards to the PSI's internal control, and its procurement function;
- PSI's quarterly financial accounts, the PSI's annual financial statement as published in the PSI's
 Annual Report, including issues of concern, levels of error or omissions, and the Executive
 Leadership Team's letter of representation to the external auditors;
- the schedule and results of both the PSI's internal and external audits;
- the adequacy of management response to issues identified in audits, including the external audit's management letter of representation;
- assurances relating to the management of risk, and corporate governance, in the PSI;
- proposals for tendering for either internal or external audit services or for purchase of non-audit services from contractors who provide audit services;
- anti-fraud policies and procedures, protected disclosure processes, and arrangements for special investigations; and
- the Audit and Risk Committee will review its own effectiveness each year and report the results of that review to the Council.

Where the Audit and Risk Committee's monitoring and review activities reveal cause for concern, or scope for improvement, it makes recommendations to the Council on actions needed to address the issue.

The Council, Advisory Committees, Registrar and employees of the PSI are obliged to prepare and file a written report to the PSI's Audit and Risk Committee if they become aware that any part of the organisation is exceeding their authority, behaving in a manner that is irresponsible or otherwise engaging in conduct which is likely to be damaging to the affairs of PSI or its reputation.

11.5 Risk Management

The PSI is exposed to a range of potential risks which, were they to materialise, would impact adversely on its ability to service the needs of its stakeholders, and meet its legal remit. The management of these risks involves identifying them, evaluating the likelihood of them occurring, assessing their potential impact, and taking steps to mitigate them, by either reducing the likelihood of them occurring, or their impact. The PSI's Risk Management Framework provides a structure for managers and their teams to consider how they manage risk, and the strategies to put in place to mitigate them.

The PSI's Chief Risk Officer (CRO) reports both to the Audit and Risk Committee, and the Council. The CRO is responsible for updating the PSI's Corporate Risk Register. High level risks and cross-organisational risks are logged on the Corporate Risk Register and reviewed by both the Audit and Risk Committee, and Council.

The Audit and Risk Committee reviews the PSI's Corporate Risk Register, as well as one business area's risk register, at each of its quarterly meetings. The Council reviews the Corporate Risk Register at each of their meetings.

11.6 Reporting on Compliance with Governance Standards

The PSI's code of governance adheres to the "comply or explain" principle. The PSI reports to the Minister for Health on an annual basis on how it has complied with the Code of Practice for the Governance of State Bodies (2016) or explains the reasons why its standards or requirements have not been implemented. The PSI has three governance meetings a year with officials from the Department of Health to update them on governance related matters and to discuss progress against targets set down in the PSI's performance delivery agreement.

12. Review and Approval of the Corporate Governance Framework

The Council keeps this document under review, and commits to reviewing it on an annual basis, and to update it to incorporate any change to corporate governance best practice, the law, or Government directives.

The Corporate Governance Framework should be read in conjunction with other PSI policies such as:

- 1. Code of Conduct for Council and Advisory Committee Members
- 2. Code of Conduct for employees
- 3. Resolution procedure for possible breaches of the Code of Conduct for Council and Advisory Committee members
- 4. Conflict resolution procedure for Council and Advisory Committee members
- 5. Procedure for Council Members Seeking Independent Professional Advice
- 6. Council Closed Session Policy
- 7. Protected Disclosure Policies
- 8. Gifts and Hospitality Policy
- 9. Procurement Policy, including Corporate Procurement Plan
- 10. Travel and Subsistence Policy
- 11. Risk Management Framework
- 12. Treasury Management Policy
- 13. Reserves Policy
- 14. Business Continuity Policy and Plan
- 15. Safety Statement, including Health and Safety Policy
- 16. PSI Child Protection Policy
- 17. Publication and Disclosure Policy
- 18. Customer Charter
- 19. Data Protection and Data Breach Management Policy
- 20. CCTV Policy
- 21. PSI Information Security User Manual (incorporating all ICT user policies)
- 22. Employee Handbook
- 23. Media and Online Engagement Guidelines for Council and Committee Members
- 24. Terms of Reference of the Council and Advisory Committees, and their memberships
- 25. Terms of Reference for the Business Transformation Programme Board
- 26. Internal Audit Charter

Appendix A: Matters reserved for Council

PSI is required to have a formal schedule of matters specifically reserved for Council decision. The matters reserved for decision for the PSI Council are as follows:

1. Planning and Performance Functions

- Approve the Corporate Strategy, the annual Service Plan and budget.
- Approve any strategies underpinning the delivery of the Corporate Strategy e.g.,
 Communications Strategy, HR Strategy and ICT Strategy.
- Approve PSI's annual financial statements and Annual Report including the statement on systems of internal control.
- Approve the appointment, remuneration and assessment of the performance of, and succession planning for the Registrar (Chief Officer).
- Where necessary, approve removal of the Registrar (Chief Officer).
- Approve significant amendments to the pension benefits of the Registrar and Staff.
- Appoint or remove the Secretary to the Council.
- Approve delegations of functions of the Council.
- Approve of a Corporate Governance Framework and underpinning documentation such as:
 - 1..1. Terms of Reference of the Council;
 - 1..2. Codes of Conduct;
 - 1..3. Standing Orders of the Council and Committees;
 - 1..4. Procedure for setting strategy; and
 - 1..5. Procedure for recording Council members concerns.

2. Council Membership and Committees

- 1.1 Approve the establishment of and appointment to Advisory and Disciplinary Committees.
- 1.2 Approve the Terms of Reference of Advisory Committees.
- 1.3 The Council will review on an annual basis its own performance and that of its Committees.
- 1.4 Council is responsible for electing a President and Vice-President.

3. Financial Transactions

- 1.1 Significant acquisitions, disposals and retirement of assets.
- 1.2 Major investment and capital projects.
- 1.3 All requests for tender i.e., contracts for works, services or supplies, must be approved by Council through the Service Plan and Budget. Any requests which were not incorporated as part of the Budget and Service Plan must seek separate approval from Council.

4. Internal Controls and Risk Management

- a. Approval of the Internal Audit Charter.
- b. Annual review of the effectiveness of internal control (including financial, information governance, operational, compliance controls and risk management systems), including evaluating management's actions on material incidents, to ensure the effective

- identification, monitoring and control of external risks and identification of opportunities to support the PSI's statutory objectives (supported by the Audit and Risk Committee).
- c. Approval of statements for inclusion in the Annual Report concerning internal controls and risk management including the annual Financial Review (supported by the Audit Risk and Governance Committee).
- d. Approval of any significant change in accounting policies or practices (supported by the Audit and Risk Committee).
- e. Review and approve the policies that are reserved for Council approval. These policies include:
 - a. Risk Management Framework (including the risk appetite)
 - b. Protected Disclosure Policy
 - c. Procurement Policy and Corporate Procurement Plan
 - d. Gifts and Hospitality Policy
 - e. Closed Session Policy
 - f. Treasury Management Policy
 - g. Reserves Policy
 - h. Publication and Disclosure Policy
 - i. Data Protection Policy
 - j. Child Protection Policy

5. Regulation and Compliance

The Council shall approve policies/guidance/standards relevant to the work of the PSI, as the pharmacy regulator e.g. Accreditation Standards, Inspection Policy.

6. Miscellaneous

The Council shall take specific decisions that the Council or Executive Leadership Team consider to be of such significance as to require Council decision.