

# Annual Report 2023

## Contents

## Introduction

Who we are, what we do and why we do it
Highlights of 2023
Introduction from the PSI President
Message from the Registrar

## **Our Results and Activity**

Progress on our strategy and improvement agenda	10
Activity in support of our mission	20

## **Governance and Accountability**

How we ensured high standards of internal governance	44
Report from our Audit and Risk Committee	53
Our Risk Management Report: Principal Risks and Uncertainties	55
Our Financial Report	57

## **Financial Statements**

1

2

4

5

7

63

## Who we are, what we do and why we do it

We are the Pharmaceutical Society of Ireland PSI - The Pharmacy Regulator, a public body established by the Pharmacy Act 2007 to protect the health, safety and wellbeing of patients and the public by regulating pharmacists and pharmacies in Ireland. While we are an independent regulatory body, we operate for public accountability purposes under the aegis of the Minister for Health. We are governed by the PSI Council, whose 21 members are appointed by the Minister.

#### What we do

- We register pharmacists, pharmaceutical assistants and pharmacies;
- We set standards for pharmacy education and training and ensure all pharmacists are undertaking appropriate continuing professional development (CPD);
- We promote good professional practice by pharmacists, by raising standards and sharing information for the benefit of patients and the wider health system;
- We conduct fieldwork to assess how pharmacies comply with pharmacy and medicines law and, where necessary, act to address poor performance and/or unsafe practices;
- We consider formal complaints made against a pharmacist or a pharmacy, including imposing sanctions and
- We provide advice, support and guidance to the public, the pharmacy profession and to the Government on pharmacy care, treatment, and services in Ireland.

#### Why we do it

We believe that the public is entitled to expect, and to receive, a high standard of care from pharmacists and that pharmacies are operated to high standards. We believe that the public should always be able to trust pharmacists and pharmacies to deliver this standard of care and service. We want to play a key role in facilitating this to happen, and we believe that this is best done through adopting a collaborative approach involving all those who share our commitment to high quality pharmacy care and services.

We believe it is important that, as part of our ongoing development and in seeking to provide continued assurance in an evolving healthcare, regulatory and public sphere, that we set challenging strategic objectives so that we create impact for those we serve, build on our strengths and effectiveness, and ensure communication and engagement underpins all our work. Our Corporate Strategy 2021-2024 is designed to advance these objectives.

This Annual Report overviews how we progressed all aspects of our statutory responsibilities and our strategy.

The PSI Annual Report for 2023 is submitted to the Minister for Health in accordance with paragraph 17(1) of Schedule 1 to the Pharmacy Act 2007. The Report covers the period from 1 January 2023 to 31 December 2023.



### **Our Vision, Mission and Values**

#### **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.

#### **Our Values**

Our values underpin how we deliver on our mission. They guide our behaviour, the expectations we set ourselves, and the experience of others who engage with us. They provide evidence as to our commitment to equality and human rights in how we fulfil our role.

Our values ensure that we achieve the objectives we set and meet with the high standards that are expected of public bodies and of the public servants who work within them.

### **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.

#### Serve the public

The safety of the public is at the heart of everything we do, and we act to ensure that safety.



#### Everyone count

We value, appreciate and respect everyone we engage with.

#### Work together

We work in partnership with our colleagues and all our stakeholders.

#### Lead by example

#### We behave with integrity and objectivity. Our actions are evidence-based.

#### Embrace change

We are innovative and we adapt to achieve results and continuously improve.

## Highlights of 2023

#### Future Pharmacy Workforce Project

We published The Workforce Intelligence Report in September and launched the second annual pharmacist workforce survey in November.



### HEA report on building capacity in higher education for pharmacy programmes

We participated in the Higher Education Authority's (HEA) Expert Advisory Panel to review institutions' proposals for expanding the capacity of academic places for pharmacy.

## Climate action mandate and sustainability activities

We developed our first Annual Climate Action Roadmap, demonstrating our ongoing commitment to sustainability and emissions reduction.

#### **Regional roadshows**

In October 2023, we ran a series of regional roadshows, marking another significant milestone in our ongoing commitment to engaging with registrants. The aim of the roadshows was to provide updates on topical issues such as pharmacy governance roles, the Workforce Intelligence Report, and Fitness to Practise matters.

### CPD Model for Pharmaceutical Assistants

A report setting out a recommended CPD model for pharmaceutical assistants was developed.

## Expert Taskforce to support the expansion of pharmacist roles

We were invited to contribute to this important work in partnership with health stakeholders. The purpose of the Taskforce is to support the delivery of specific policy decisions, which will serve to align services and practices that can be delivered by pharmacists, and pharmacies, with the needs of the health service and patients.

#### **Council appointments**

Five Council members completed terms in office during 2023 and the Minister for Health appointed new Council members in June and October.

### Public survey on medicines administration services in

#### pharmacies

We carried out a survey with the public during August and September 2023 to learn more about some of the services that patients and the public use in pharmacies.



### **CPD Model for pharmacists**

A report setting out the outcome and recommendations arising from a review was carried out.

#### **Core Competency Framework**

The revised Framework for pharmacists was launched in September.

#### **Business transformation**

The next stage of our business transformation project was launched in August. This included an online registration platform for completing Internet Supply List applications and a comprehensive, searchable online internet supply list.

## **Introduction from the President**

On behalf of the PSI Council, I am pleased to present the PSI Annual Report and Financial Statements for 2023, in accordance with the requirements of the Pharmacy Act 2007.

As the pharmacy regulator, the PSI regulates all registered pharmacists and retail pharmacy businesses. We do this in the public interest, which means that we work to assure the public that pharmacists are always working to high standards of practice and professionalism. This annual report documents the activities, outputs and progress made in 2023 in pursuit of our mission to protect the health, safety and wellbeing of patients and the public.



The PSI Council governs the PSI and is responsible for overseeing its functions. A key role of Council is to set the strategic direction for the organisation, as evidenced in the current Corporate Strategy 2021-2024, and to ensure that these strategic objectives are met. During 2023, the PSI Council had oversight of the delivery and completion of significant strategic projects and programmes of work in the public interest, as outlined in this report.

In September 2023, we were pleased to launch the Workforce Intelligence Report, the first report of its kind for pharmacy in Ireland. The report examined the issues relating to the recruitment and retention of pharmacists in both community and hospital settings. It serves as a significant milestone, providing a baseline view of pharmacy workforce data and views from pharmacists on the profession. Workforce planning is complex and multi-factorial. It requires a collaborative, multi-stakeholder approach to ensure that there are enough pharmacists available to meet patient needs and play a full role in the development of the future integrated health system. The report contains a number of actions for the PSI which have been approved by the Council. In collaboration with the Department of Health, we are establishing a multi-agency Pharmacy Workforce Working Group to focus on progressing these and the other actions contained within the report, with this work continuing into 2024.

We were also pleased to launch a revised Core Competency Framework for Pharmacists. The Core Competency Framework acts as an important statement on the range of competencies expected of pharmacists in the early stages of their career. It supports a number of statutory functions and provides structure and guidance for all pharmacists when reflecting on their continuing professional development needs.

The PSI Council also approved two reports relating to CPD. The first related to the development of an appropriate CPD model for Pharmaceutical Assistants, while the second related to a review of the existing CPD model for pharmacists. Both of these projects move to the implementation phase as we look to ensure that the professionals providing pharmacy services to patients and the public are undertaking appropriate learning and development within a progressive and innovative CPD model.

The expansion of the role of pharmacists in Ireland in the public interest has been a strategic focus for the PSI Council and the Department of Health for some time. In July 2023, an Expert Taskforce to support the expansion of the role of pharmacists in Ireland was established by the Minister for Health. The Taskforce was charged with considering and examining ways in which pharmacists can expand upon their present scope of practice for the benefit of patients, the public and the wider health system. The PSI Council strongly supports this initiative and the potential benefits that could be realised by expanding the range and scope of services pharmacists could provide in a future integrated health system. The Council also recognises and endorses the important contribution being made by the PSI to ensure the work of the Taskforce and any policies aimed at expanding the scope of practice for pharmacists are underpinned by appropriate and proportionate regulatory frameworks and supports.

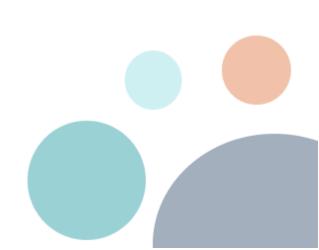
I was honoured to be appointed to the role of President of the PSI Council in June 2023. I would like to express the gratitude of the Council and staff to Muireann Ní Shúilleabháin, President of the PSI Council, from June 2021 to June 2023, and thank her for her dedicated service and guiding hand over the previous two years. I would also like to thank the Council and Committee members who completed their terms this past year for their contributions and expertise to the work of the PSI.

I also acknowledge the work of our Registrar and Chief Officer, Joanne Kissane, since taking up the role in January 2023. Her dedication and effectiveness as Registrar have permeated the organisation, and we look forward in 2024 to working with her and the organisation to develop our new Corporate Strategy that will pave our way forward for the years ahead.

As the sector moves through this exciting period of change, we are both assured by and appreciative of the consistent commitment and dedication of the Council, Committee members, and PSI staff. I look forward to continuing to work with the team at the PSI to progress our work and continue the delivery of our core objective of assuring public trust in pharmacy through effective regulation.

Kamene m

Ms Katherine Morrow President



### **Message from the Registrar**

As we present our annual report for 2023, I am pleased to take the opportunity to reflect on my first year in the PSI. Having been appointed to the role of Registrar in January 2023, I have been highly impressed by the dedication and commitment of the PSI Council, Committees, our colleagues in PSI, and all those who have contributed to our work in the past year.

I took on this role during a time of significant and ongoing change for the PSI and the system and society in which we operate. I foresee that period of change accelerating through 2024 as we develop our new Corporate Strategy. While the practice of pharmacy and pharmacists continues to evolve, our commitment to assuring public trust in pharmacy through effective regulation is unwavering.



The Workforce Intelligence Report, commissioned by the PSI and published in September, shed light on many of the challenges being experienced in relation to pharmacist recruitment and retention. Encouragingly, we have consistently seen an increase in the number of pharmacists registered with the PSI, currently sitting at over 7,400. In fact, 2023 saw the highest number of pharmacists added to our registers since they were established over 15 years ago. However, the Workforce Intelligence Report identified that simply increasing the number of registered pharmacists is not the solution. The report contains six key recommendations with a series of actions, highlighting that a multi-agency stakeholder response is required to address the complex issue of workforce planning. The PSI is committed, along with other stakeholders across the system, to progress actions identified as necessary to ensure a future sustainable pharmacy workforce.

There is a strong ambition among pharmacists to play an expanded role in a future integrated health system, with over 90% of those who responded to our Workforce Survey indicating a willingness and appetite to expand their scope of practice. The establishment of the Expert Taskforce to support the expansion of the role of pharmacists was a significant development in 2023. The first recommendation of the Taskforce was accepted by the Minister for Health in November 2023. Under the recommendation, pharmacists will be enabled to extend the validity of a prescription from six months up to a maximum period of 12 months if, in their professional judgement, it is safe and appropriate to do so. Prescribers will also be enabled to issue prescriptions for up to 12 months. This recommendation is the first step in expanding the role of pharmacists in Ireland with the aim of improving patient access, streamlining healthcare delivery at the lowest point of complexity, and contributing to better patient outcomes, in line with the principles of Sláintecare. We look forward to continuing to participate in the multi-stakeholder Taskforce in 2024 to support the safe development and expansion of pharmacist-delivered services.

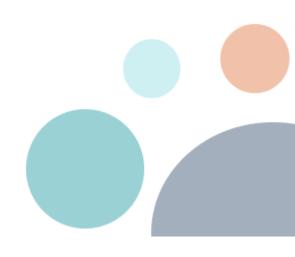
Providing information and raising awareness of our role and work is a fundamental part of our regulatory remit. Throughout 2023, we contributed to national health and social care consultations, working groups and other cross-organisational meetings. Our regular engagements continued with government departments and other stakeholders from across the pharmacy and health and social care sectors. One of the highlights for us as an organisation during 2023 was returning to running inperson events. We held a series of regional roadshows in October, providing an important opportunity to engage and interact with registrants.

The PSI deeply values the crucial role played by our colleagues in achieving our mission. I would like to thank our colleagues at PSI for their hard work, commitment, and professionalism. I thank our Council and Committee members for their continued support and dedication throughout 2023. I would also like to thank the President of the PSI Council, Katherine Morrow, for her commitment, guidance and support. Finally, I would like to thank all pharmacists and their teams for their ongoing outstanding contribution to patient safety and public protection. Through their delivery of high standards of care and services, they continue to uphold their valuable and hard-earned reputation as trusted healthcare providers in communities and healthcare settings across Ireland.

I look forward to working with all those internal and external to the PSI as we progress our work and continue to deliver on the final year of our Corporate Strategy 2021-2024. As we collaborate on the development of our next strategy, the message is clear - the healthcare system is ready for pharmacists to play a new and expanded role in support of the public and patients. We must ensure that future services are underpinned by the appropriate regulatory framework so that patients can be assured of the quality and safety of the services delivered. We have a strong foundation from which to build, and I am confident that the PSI will play its part at a critical moment of growth and development for the pharmacy profession.

loanne Kinane.

Ms Joanne Kissane Registrar and Chief Officer



## **Our results and activity**

#### Assuring public trust in pharmacy through effective regulation is our continued commitment.

This Annual Report overviews how we progressed all aspects of our statutory responsibilities and our Corporate Strategy 2021-2024 during its third year. There are three strategic areas under which we aim to deliver specific results.



Strategic Objective 1: Advancing the Role of Pharmacy and Pharmacists 
 Better Ways

 of Working
 in the Future Integrated

Assuring Public Trust in Pharmacy Through

Effective Regulation

**Strategic Objective 2:** 

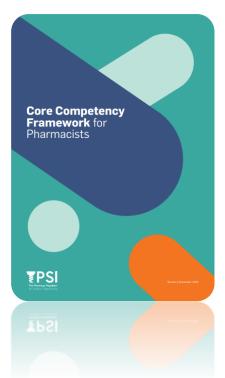
ment will Connunication and engagement will underpin all our work

# Progress on our strategy and improvement agenda

Strategic objective 1: Advancing the role of pharmacy and pharmacists in the future integrated healthcare system

#### **Reviewing the Core Competency Framework for Pharmacists**

The Core Competency Framework acts as a statement of the range of competencies expected of a pharmacist as they commence their career. It is also used to provide structure and guidance for pharmacists when reflecting on their continuing professional development needs. The revised Core Competency Framework for Pharmacists was launched by the PSI and the Irish Institute of Pharmacy during a webinar for pharmacists on 13 September 2023. In addition, the IIOP delivered a series of roadshows nationwide for pharmacists, providing information on using the revised framework for continuing professional development purposes. The development of the revised framework follows work initiated in 2021, which brought stakeholders together to identify the changes and improvements needed. The Schools of Pharmacy have agreed on an implementation plan that will see the revised framework incorporated fully into the MPharm curriculum by 2025.



#### **Reviewing the CPD Model for Pharmacists**

In 2023, we continued our multi-annual project to review the Continuing Professional Development (CPD) model for pharmacists with independent consultancy



support. The stages involved in the review included comprehensive desk-based research, consultation, and engagement with pharmacy regulators in other jurisdictions, as well as a range of relevant stakeholders in Ireland. In addition, we held three online focus groups with pharmacists from different practice areas. The purpose of the focus groups was to gather feedback on how the current CPD model for pharmacists could be adapted, changed, or improved to ensure it supports future pharmacists' practice in all settings.

A report setting out the outcome and recommendations arising from the review was accepted and approved by the PSI Council at its meeting on 14 December. We will commence work on implementing the recommendations within the report in 2024.

#### Development of a CPD Model for Pharmaceutical Assistants

The PSI Council approved the Report to support the development of a CPD Model of Pharmaceutical Assistants at its meeting on 22 June 2023. The report, developed by Mazars, who provided external support on this project, includes a recommended CPD model based on desk-based research and consultation with national and international stakeholders. An implementation plan was agreed in 2023. We have engaged with the Pharmaceutical Assistants Association and pharmaceutical assistants throughout this project and will continue to do so in 2024 to support the introduction of this new CPD model.

## Assessing emerging risks to the continued availability of the pharmacy workforce

In 2023, we continued work on this multi-annual project, which commenced in 2022. This project is being undertaken to assess emerging risks to the continued availability of a professional pharmacy workforce within community and hospital pharmacy in Ireland and is being supported by an independent consultancy agency.

During 2023, the Working Group that was established as part of this project held three meetings. This group comprises individuals from organisations across the health and pharmacy sectors, including the Department of Health, HSE, Schools of Pharmacy, APPEL (the Affiliation for Pharmacy Practice Experiential Learning), the Irish Institute of Pharmacy, pharmacy representative organisations, and a practising pharmacist. The outputs of the various components of this project culminated in the approval of the Workforce Intelligence Report.

#### • Workforce Intelligence Report

The Workforce Intelligence Report was launched by Mr Robert Watt, Secretary General of the Department of Health, on 25 September 2023. The report was launched in the Department of Health and coincided with World Pharmacists Day. The report is the first of its kind for pharmacy in Ireland

and was commissioned by the PSI in the absence of any previous strategic workforce planning initiatives for pharmacy in Ireland. The aim of the report was to assess risks to the continued availability of the pharmacy workforce within community and hospital pharmacy and propose mitigating actions for implementation with agreement from relevant health system and pharmacy stakeholders.



Katherine Morrow, PSI President, Secretary General Robert Watt, Department of Health and Joanne Kissane, PSI Registrar and Chief Officer at the launch of the Workforce Intelligence Report

The six recommendations and associated actions in the report were developed following extensive consultation and engagement and by triangulation of evidence from a literature review, a workforce survey, and focus groups. These recommendations were critically evaluated by the Working Group. We would like to acknowledge the significant contribution of the Working Group, which included stakeholders who influence or develop policy and impact decisions relating to the future role of and demands for pharmacists in the health system.

One of the recommendations within the report is to establish a multi-agency group focused on national strategic workforce planning.



Workforce Intelligence Report launched by Mr Robert Watt, Secretary General of the Department of Health, on 25 September 2023

Responsibility for this action rests with the PSI and the Department of Health. In this context, in 2024, we intend to convene an implementation group to drive progress against the recommendations in the report. We look forward to continuing to work collaboratively with all relevant stakeholders as we progress with the recommendations and actions outlined in the report.

#### **Revising the Third Country Qualification Recognition Route**

Pharmacists who qualify in a non-EU or non-EEA country and wish to practise in Ireland must first have their qualification recognised as 'appropriate for practice' before they can apply to register with the PSI. This process is called the Third Country Qualification Recognition (TCQR) route. The existing TCQR route for third-country applicants is a multi-stage process in place since 2009. The PSI Council has recognised that this policy is resource-intensive, costly, and onerous for both the applicant and the PSI. We have been reviewing the process to streamline it to benefit applicants, our administrative process, and the wider public. A revised TCQR policy was approved by Council in 2019; however, the realisation of this was significantly impacted by the subsequent onset of the COVID-19 pandemic in March 2020.

In 2023, the PSI (Registration) Rules 2023 were amended by the Minister for Health. These amendments were part of the ongoing review of the TCQR process and facilitate the revised TCQR route enabling the PSI to implement a new quality-assured five-step approach to qualification recognition.

We are in the process of implementing the revised TCQR route, with the current focus being on developing a new approach to the adaptation placement system through a quality-assured process. It is expected that the new route will be implemented before the end of 2024.

#### Revising the accreditation standards for CPD programmes and courses for pharmacists and commence the revision of the MPharm Accreditation Standards

Progress on the revision of the Accreditation Standards for continuing professional development (CPD) programmes and courses for pharmacists was temporarily suspended in 2023, pending the outcomes of the review of the CPD model for pharmacists and the publication of the associated review report. This report was accepted, and its recommendations approved by the PSI Council at its December meeting. This project will recommence in 2024.

Desk-based research and a benchmarking exercise against national and international accreditation standards to underpin the MPharm Accreditation Standards review project commenced in 2023. Consultation with relevant stakeholders to gather their feedback and experiences on the MPharm Accreditation Standards will commence in early 2024.

#### Engaging with the Department of Health on Sláintecare implementation

The PSI Service Plan 2023 included stakeholder engagement with the Department of Health and the HSE on Sláintecare implementation and pharmacy integration. In light of the establishment of the Expert Taskforce to support the expansion of the role of pharmacists in Ireland, the Council agreed that this engagement would be achieved through the commitment of PSI to its involvement in the Expert Taskforce and contribution to the delivery of its outputs.

#### Expert Taskforce to support the expansion of the role of pharmacists in Ireland

An Expert Taskforce to support the expansion of the role of pharmacists in Ireland was established in July 2023 by the Minister for Health. The Taskforce is charged with considering and examining ways in which pharmacists can expand upon their present scope of practice for the benefit of patients, the public and the wider health system. The Taskforce will also assess options to enable pharmacists to extend prescriptions for a range of medicines and is tasked with advising on a comprehensive approach to facilitate prescribing by pharmacists, including prescribing for common minor ailments.

The Expert Taskforce is comprised of representatives from across the health, pharmacy, and pharmacy education sectors. It includes the PSI Registrar and Chief Officer, who attend fortnightly meetings of the Expert Taskforce, which commenced in August 2023. An internal working group was established within the PSI to coordinate our response and any input required to progress the objectives and policy direction emanating from decisions made on foot of recommendations from the Expert Taskforce.

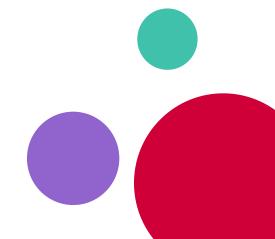
The work of the Taskforce will be carried out in two phases. The first phase, which took place between July and October 2023, examined empowering pharmacists to extend prescriptions. The second phase will examine how pharmacists can be empowered to prescribe within their scope of practice.

#### • Implementing the first recommendation

In October, the Minister for Health accepted the first recommendation of the Expert Taskforce, which will empower pharmacists to extend the validity period of certain prescriptions for up to a maximum of 12 months, in accordance with defined criteria, and when, in the pharmacist's professional opinion, it is safe and appropriate to do so. The decision to extend will be subject to person-centred criteria such as the current stability of the patient's clinical regime, continuity of care and lack of relevant change.

As part of preparing to implement the first recommendation in late 2023, we engaged with several key stakeholders, including pharmacists. All registered pharmacists were invited to join a PSI panel, and we received 104 expressions of interest.

We held an online pharmacist workshop on 12 December to explore the regulatory tools, supports and information, such as guidance, that may be needed to support pharmacists in their decisionmaking when extending prescriptions for patients. A total of 21 pharmacists from the panel attended the workshop and were selected based on their role, area of practice and years of experience with the aim of having a diverse representation. We look forward to further engagement with our pharmacist panel in 2024 as part of future engagement activities to support our work.



## Strategic objective 2: Evolving a more effective regulatory model for community pharmacies

#### Advancing reform of the Pharmacy Act

Following the submission of a PSI position paper to the Department of Health in June 2022 on the need for reform of the Pharmacy Act 2007, we met with the Department of Health in March 2023 to agree on the next steps in the project approach. The position paper outlined why significant legislative reform is needed and the challenges the PSI experiences with using the Act in practice.

It was agreed that the PSI would proceed with commissioning an evidence-based review to examine reform of the regulation of pharmacies in the first instance. We engaged with the Health Research Board regarding the development of research questions to inform the evidence review process and began an initial preliminary market consultation exercise to support the overall tendering process.

#### Advancing our actions to contribute to Ireland's second National Action Plan on Antimicrobial Resistance 2021-2025

We are committed to continuing to play our part in helping to improve knowledge and awareness of antimicrobial resistance among the public and registrants.

In February, at the request of AMRIC (Antimicrobial Resistance and Infection Control) in the HSE and the Irish Institute of Pharmacy (IIOP), we attended a Royal College of Surgeons in Ireland (RCSI) Charter Day. As part of this, we participated in an in-person session focusing on antimicrobial stewardship. The aim of this collaborative forum was to help drive this important agenda forward and start the national conversation on empowering pharmacists to contribute to antimicrobial stewardship.

We also attended several conferences during the year relating to antimicrobial resistance. These included an online Westminster Health Forum policy conference that discussed the 'Next steps for tackling antimicrobial resistance' and an Environment, Health and Wellbeing Conference in May that included a session on Antimicrobial Resistance. We also attended the 'Global Sepsis Summit' in Dublin Castle in September and the 'Collaborating Across Borders: a multidisciplinary approach to AMS' conference in October, which brought together multidisciplinary participants from around the Republic and Northern Ireland working on antimicrobial stewardship and antimicrobial resistance who shared research and recent developments in this area.

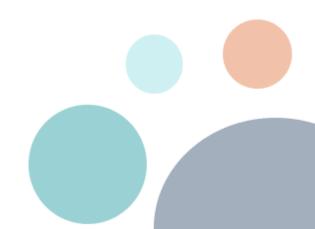
We shared information and resources in each of our 2023 newsletters aimed at supporting pharmacists with antimicrobial stewardship to improve the safe and appropriate use of antimicrobials and reduce antimicrobial resistance. For example, in our March newsletter, we highlighted how pharmacists can join and use the Pharmacist Antimicrobial Stewardship Network (PAMS-net), which aims to support pharmacists across all sectors to work towards the common goal of promoting responsible use of antimicrobials in all patients and limiting the emergence of antimicrobial resistance. We also signposted to HSE information, tools, and resources on antimicrobial stewardship and antibiotic prescribing.

We also promoted several established global antimicrobial resistance awareness campaigns that take place annually, such as European Antibiotic Awareness Day and World Antimicrobial Awareness Week, through our social media channels.

#### **Operationalising our Regulatory Risk Statement**

Regulatory bodies have a duty to recognise and respond appropriately to risks and potential harms that relate to our area of accountability, and in our case, with the purpose of protecting the health and safety of patients and the public. The PSI Council approved a Regulatory Risk Statement in 2019. In adopting this statement, we have made a public commitment to becoming a more risk-based regulator with the aim of assessing and mitigating risks that have the greatest potential to impact patient safety. This approach allows the PSI to direct resources more efficiently and allows for a more proportionate response to an identified risk.

In 2023, we reviewed our approach under this model, reviewed the operation of the Regulatory Risk Analysis and Response Group and made changes to our approach to regulatory risk. The work in relation to regulatory risk continues in conjunction with the work of the Community Pharmacy Assurance area to support our approach to risk-based inspection of pharmacies.



## Strategic objective 3: Building our capability and performance as a regulatory organisation

#### Progressing our Business Transformation Programme

Our Business Transformation Programme is intended to achieve better ways of working across the PSI to ensure we optimise our use of technology and colleagues' time and expertise in the best way possible. A key deliverable of this programme is a new digital platform to serve as our single customer view. The most recent phase launched in August. This included an online registration platform for completing Internet Supply List applications and a comprehensive, searchable online Internet Supply List. Other functionalities from this phase included the integration of the public register with outcomes from the fitness to practise process and the facility to permit superintendent



pharmacists to make one registration application on behalf of several pharmacies. We also completed work with an independent third party in 2023 to complete an assessment of the proposed approach and associated effort estimates for the Business Transformation Programme's next phase of work, Phase 2: complaints, concerns, and queries.

## Utilising our new digital systems to support our regulatory purpose and mission

In 2023, we commissioned external expertise to guide the development of our ICT strategy in order to further support the achievement of objectives under the Corporate Strategy 2021-2024 and beyond. During 2023, we completed horizon scanning and an assessment of the current state of our ICT infrastructure. Workshops with all staff and engagement with management and Council took place in November, and a survey was administered to external users in the November newsletter.

The development of an ICT strategy will assist with utilising new systems, data and digital tools to support our regulatory mission. This new ICT strategy will document how technology will be used to support and shape the implementation of strategic goals and ongoing continuous improvement initiatives.

#### Implementing our HR Strategy

In 2023, work continued in embedding a new organisation structure. We received sanction for additional posts identified under the new operating model and filled the positions through comprehensive recruitment efforts.

In line with our HR strategy, the support, development and training of colleagues continued to be a priority in 2023. We rolled out a Blended Working Policy and also introduced monthly Anchor Days during 2023, which enable all colleagues to come together onsite in PSI House for training and development initiatives and also provide an opportunity for collaboration and engagement under the blended working model. Through operating a blended working model, we are also contributing to the Programme for Governments commitment and PSI commitments through its Climate Action Plan to reduce emissions through the reduction in commuting by PSI colleagues.

#### Completing our Strategic Financing Review

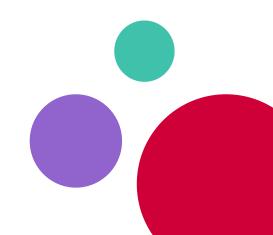
A key element of our strategic plan is the alignment of our future funding streams. This alignment will ensure we will have the requisite resources available to carry out our regulatory functions to the standard expected by the public. In 2023, the Council approved an updated Reserves Policy as part of the ongoing PSI Strategic Financing Review project, and in November, the Performance and Resources Committee considered the assumptions underpinning the Strategic Financing Review Model.

## Maintaining or current 4-star recognition with the European Quality Management (EFQM)

We recognise the importance of quality in our work in terms of how we carry out our functions,

formulate our strategies and interact with our stakeholders. Further to our achievement of 4\* EFQM recognition in 2019, we continue to promote EFQM throughout the organisation, embedding the quality management approach into our ways of working. In 2023, we continued our awareness-raising with staff on working within the EFQM model and held an EFQM workshop on one of our Anchor Days, facilitated by our EFQM consultant. We continue to make progress in planning our approach to maintaining and improving on our EFQM award as we prepare for submission in 2025.





## **Our continued response to COVID-19**

The COVID-19 pandemic continued to play a part in all our lives during 2023. We continued to work in partnership with the pharmacy profession and other stakeholders to support pharmacy teams in their work to provide safe and effective care and services.

In this section, we outline some of the COVID-19-related work that the PSI was involved in during 2023.

#### Training for pharmacists to administer COVID-19 vaccines

Under the legislation, registered pharmacists who have completed approved training by the PSI are permitted to supply and administer certain COVID-19 vaccines. During 2023, we approved the HSE National Immunisation Office (NIO) training for seven new or adapted COVID-19 vaccines.

The training on one new COVID-19 vaccine was assessed by the valuable contributions of an external assessment team comprising pharmacists with relevant expertise from a variety of settings. In March, we introduced a new risk-based approach to the assessment of National Immunisation Office training modules on COVID-19 vaccines. Certain products did not need approval from an external assessment team due to this. This risk-based approach and assessment is guided by our principles of regulatory risk and focuses on whether the NIO training module(s) relates to a new COVID-19 vaccine or an adapted COVID-19 vaccine. Consideration is also given as to the intended patient cohort for the vaccine, i.e., adults or children. A risk-based decision support tool has been developed to underpin the risk assessment process.

#### Pharmacy involvement in COVID-19 and Influenza vaccination programmes

We continue to be involved in the pharmacy workstream working group to support the national COVID-19 and Influenza vaccination campaigns. By the end of 2023, the Health Service Executive reported that 990 community pharmacies had administered COVID-19 vaccinations since the Autumn/Winter 2023/2024 campaign commenced. As of 19 December 2023, 1,327 pharmacies had administered influenza vaccinations as part of the Autumn/Winter 2023/2024 campaign.

## National COVID-19 vaccination programme – Pharmacy Workstream Working Group

We continued to contribute to the National COVID-19 Vaccination Programme – Pharmacy Workstream Working Group throughout the year. The working group supports the coordination of national COVID-19 and influenza vaccination programmes in community pharmacy, including pharmacists' involvement in COVID-19 booster campaigns and the seasonal influenza vaccination programme. It is chaired by the HSE and includes representatives from the IPU as well as the PSI.

In March, we met with the HSE and IPU to discuss future developments proposed for the Pharmavax system, which is used to record the administration of publicly funded vaccines within community pharmacy, while in September, we met with the National Immunisation Office (NIO) to discuss the involvement of pharmacists in delivering the Live Attenuated Influenza Vaccine within primary schools.

## Activity in support of our mission

As well as continuing and commencing strategic change and development projects in 2023, our core functions are intrinsic to meeting our statutory responsibilities. The following pages report on the operational activity taking place across registration, regulatory compliance and inspection activity, investigation, consideration of complaints and disciplinary matters, professional standards, and the effective governance of the organisation on an ongoing basis.

## **Registrant and Customer Relations**

We are responsible for managing the qualification recognition and registration processes for pharmacists and the registration processes for pharmacies and pharmaceutical assistants in Ireland and for ensuring the accuracy of the registers which we make available online to the public. We process complaints from the point of receipt so that they are considered by the Preliminary Proceedings Committee (PPC) – our complaint screening committee. Through engagement with our registrants and the wider public, we also deal with and address expressions of concern and general queries on a wide variety of topics.

#### Register of pharmacists, pharmaceutical assistants, and pharmacies

All pharmacists, pharmaceutical assistants, and pharmacies must be registered with the PSI. Where they meet the requirements to register, they are entered in the relevant register to provide pharmacy care, treatment, or services to the public. Registrants must apply for their continued registration each year to maintain registered status.

There were 7,483 registered pharmacists on Part A of the PSI register at the end of 2023, which was an increase of 416 pharmacists from 2022. This was the largest single-year increase in registration numbers to date.

Overall, 2023 saw an increase of 56% in new registrations compared to 2022. This was made up of an increase of:

- 19% in the number of new registrations through our national route
- 27% of UK and NI applicants through the Third Country Qualification Recognition route (TQQR) and
- 63% of non-UK and NI applicants through the TCQR route.
- The most significant increase was through the EU route, which saw an increase of 165% on 2022 registrations.

There were 202 pharmaceutical assistants on the register at the end of 2023, down from 224 in 2022.

There were 107 voluntary cancellations from the Register of Pharmacists, with 19 pharmacists removed involuntarily for reasons such as failure to apply for continued registration, failure to pay their annual registration fee, and then failing to apply for voluntary cancellation. Three pharmacists were cancelled from the Register in 2023 as a result of sanctions arising from Fitness to Practise

complaints. In 2023, 16 pharmaceutical assistants voluntarily cancelled their registration. A total of 6 pharmaceutical assistants had their registration involuntarily cancelled.

A total of 18 pharmacists restored their registration under Section 61. This includes restoration following both voluntary cancellation and involuntary cancellation.

A total of 1,985 retail pharmacy businesses appeared on the PSI Register at the end of 2023, an increase of 4 from 2022. This increase came about as 31 new pharmacies were registered and opened, and 27 pharmacies cancelled their registration due to closure. We also processed 90 re-applications for existing pharmacies that changed ownership or location during the year.

#### **Certificates of Current Professional Status**

We issue Certificates of Current Professional Status on behalf of registrants accessing registration in other jurisdictions. In 2023, we issued 61 certificates.

#### **European Professional Card (EPC)**

The EPC mechanism is an electronic procedure that EU residents can use to have their professional qualifications recognised in another EU country. When an EU resident seeks to move and work in another EU member state, the home state facilitates the verification of the applicant's Internal Market Information (IMI) file. The prospective host state makes the decision to recognise the qualification held. The recognition of a qualification does not give an automatic entitlement to practise. In Ireland, all pharmacists must be registered with the PSI before being entitled to practise, and registration with the PSI must be undertaken only after qualification recognition has been obtained. A total of seven EPC applications were received, approved, and processed in 2023.

#### Alert mechanism procedure

The alert mechanism procedure between EU countries requires all Member States to inform each other where there are practice restrictions on professionals in a health or child-related profession. Alerts also apply to professionals who have used falsified diplomas for the recognition of their qualification. Alerts are received daily and are recorded by the PSI. We investigate these alerts if they relate to pharmacists. In 2023, we issued seven pharmacist alerts regarding PSI registered pharmacists to competent authorities in other EU countries. These alerts were issued due to substantial reasons concerning the practice of the professional involved.

#### Internet supply of non-prescription medicines

We are responsible for the registration and maintenance of the Internet Supply List for registered pharmacies and non-pharmacy retailers involved in the internet supply of non-prescription medicinal products. There were 140 pharmacies and 176 non-pharmacies on the internet supply list at the end of 2023. We have information about compliance activity in this area under the Pharmacy Quality and Safety section of this report.

Click to verify if this website is operating legally redarry

#### Query management

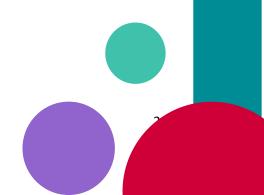
In line with our role as the pharmacy regulator, the PSI responds to requests for information and provides clarifications to registrants, patients, and the wider public in relation to areas relevant to our remit. During 2023, we received 333 such queries in total. Of the queries received last year, 39% were from members of the public, and 45% were from pharmacists. The range of queries we receive is varied, spanning all aspects of our responsibilities. We do our best to make information available on our website, including FAQs, in response to queries most frequently raised with us.

#### Assessment of concerns

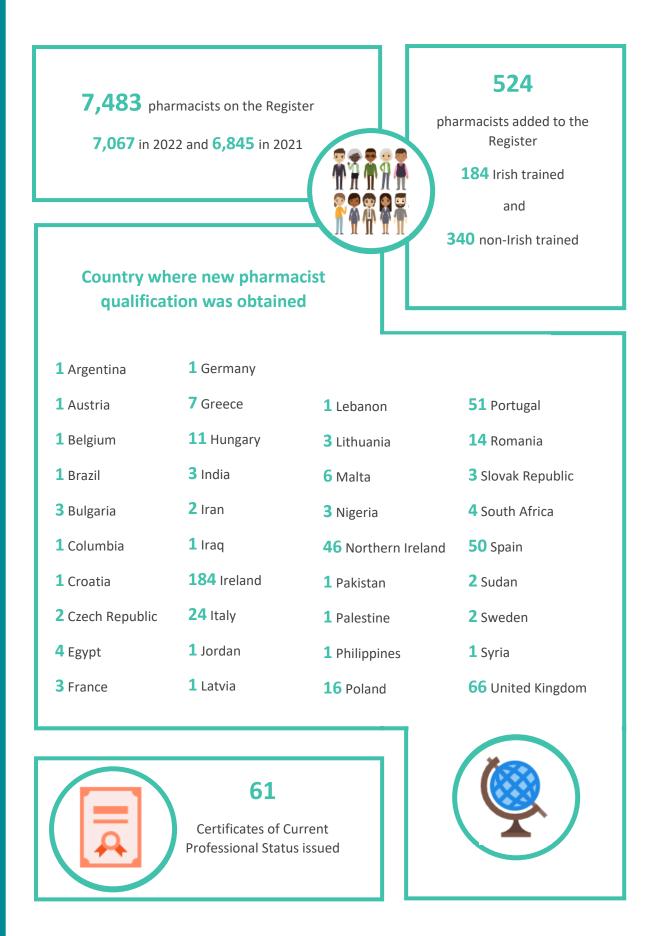
We also take action to ensure general concerns reported to us are reviewed and actioned as appropriate.

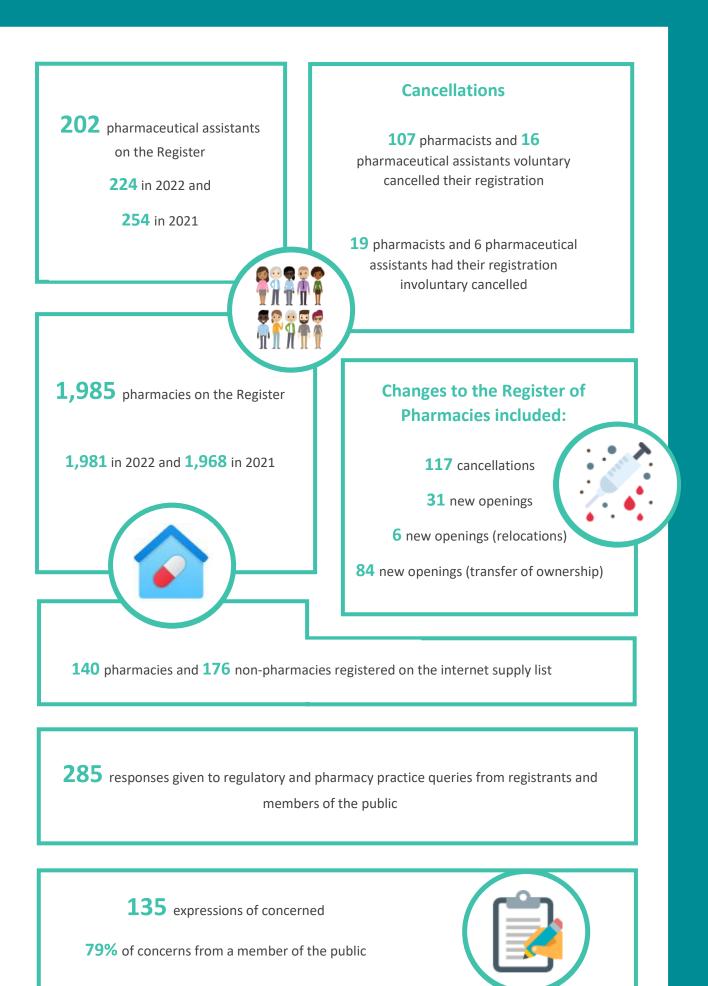
Expressions of concern arise where a person does not wish to make a formal complaint but wants to bring something to the attention of the PSI. All concerns are reviewed internally by a multidisciplinary panel to assess risk and determine what action is required. A total of 135 expressions of concern were received in 2023, representing an increase of 14% versus 2022. In 2023, 39% of the concerns received related to pharmacy practice issues. The majority of concerns (78%) were raised by members of the public, while 16% were raised by pharmacists.

Sometimes, a concern may become a complaint, at which point it will be processed under Part 6 of the Pharmacy Act 2007. Of the 135 concerns received in 2023, six resulted in formal complaints being made. Further information on formal complaints can be found on page 32 of this report.



## **Registrant and Customer Relations in Numbers**

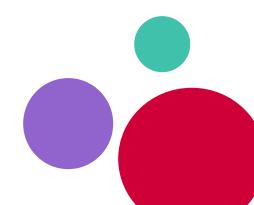






#### **Concerns received by source**

2 doctor	<b>1</b> other health professional	
<b>106</b> member of the public	<b>3</b> other organisation	
1 nurse	22 pharmacist	



### **Professional Standards**

We are responsible for ensuring that pharmacy education and training is in line with best practice and operates to the highest international standards. We do this by developing rules and standards and arranging for the accreditation of educational programmes for pharmacists and those seeking to become pharmacists. We also monitor the system of continuing professional development for pharmacists through the Irish Institute of Pharmacy (IIOP).

#### Accreditation matters - qualification for practice

The pharmacist qualification in Ireland, the integrated Master's degree in pharmacy (MPharm), is a five-year programme which incorporates experiential learning placements of varying lengths at different stages during the programme. These take place across a variety of practice settings, including community, hospital, pharmaceutical industry, and role-emerging practice.

We are required to approve and keep under review, the programmes of education and training leading to the professional qualification (MPharm), which allow graduates to apply for registration as pharmacists in Ireland. Following the introduction of the annual reporting process in 2020, the Schools of Pharmacy continue to submit Annual Reports to the PSI, which, among other things, provide information on how the MPharm programmes within their universities continue to align with the relevant accreditation standards since their accreditation in 2020. As part of our ongoing engagement, meetings were held throughout the year with the three Schools of Pharmacy, together with the Affiliation for Pharmacy Practice Experiential Learning (APPEL).

#### Irish Institute of Pharmacy and the PSI CPD Model for Pharmacists

The Irish Institute of Pharmacy (IIOP) was established by the PSI in 2013 to oversee the development and management of the continuing professional development (CPD) system for pharmacists in Ireland.



Pharmacists must maintain an ePortfolio documenting their CPD. Each year, those eligible for selection from the Register of Pharmacists are selected by the PSI so that an extract from their ePortfolio is submitted to the IIOP for review. Of the 1,329 pharmacists selected for ePortfolio Review in 2023, a total of 1,288 met the standards. Pharmacists who fail to meet the standard are given one additional opportunity to complete the ePortfolio Review in the following year. The PSI meets with pharmacists who fail to meet the standard required for two consecutive years and with any pharmacists who fail to engage with the Review process.

All pharmacists practising in a patient-facing role who have been called for ePortfolio Review in the previous years are then eligible for selection for Practice Review. This comprises a clinical knowledge review and assessment against standardised pharmacy interactions.

Two Practice Review events took place in April and October 2023, with 120 pharmacists participating. Of these, 118 pharmacists demonstrated competence. Pharmacists who do not demonstrate competence initially are given a further opportunity to engage with available supports and to attend for up to two additional Practice Review events.

#### Consultation and engagement in the development of the IIOP Workplan

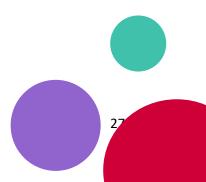
As part of the contract that oversees the operation of the IIOP, an Annual Work Plan must be developed in anticipation of the activities to be delivered by the IIOP in the following year. Towards the end of 2023, we held engagement meetings with the Department of Health, the Department of Health Pharmacy eHealth Group and representatives from the Health Service Executive, including the Primary Care Reimbursement Services, Antimicrobial Resistance and Infection Control, National Immunisation Office, Addiction Services, ePharmacy Health Group, Acute Hospitals Drugs Management Programme and the National Cancer Control Programme. The purpose of the engagement meetings was to identify expected training needs for pharmacists for 2024. The Annual Work Plan for 2024 was subsequently approved by the PSI Council at its December meeting.

#### Student placements in the PSI

In 2023, we continued our support of the MPharm programme and its experiential learning placements. Two Masters of Pharmacy students attending the Royal College of Surgeons in Ireland joined the PSI on their 4th year, four-month statutory placement from September to December 2023. During their placement, the students made valuable contributions to the work of the PSI through their involvement in activities supporting the Professional Standards, Strategic Policy, Research and Communications, Corporate Services and Community Pharmacy Assurance Teams.



They were also involved in our presentations to first-year MPharm students across the three Schools of Pharmacy and ran an environmental awareness campaign aimed at PSI colleagues.



## **Pharmacy Quality and Safety**

Through our regulatory activity, we seek to regulate the profession of pharmacy in Ireland having regard to the need to protect, maintain and promote the health and safety of the public. We provide public assurance of safe standards of pharmacy practice, promote good and safe practice within pharmacies and work to ensure compliance with pharmacy and medicines legislation, guidelines, best practice, and the Code of Conduct for pharmacists. We engage with our registrants in different ways and using a range of methods. We inspect pharmacies to supervise compliance with statutory requirements. We undertake investigations when we receive information that raises concern about the practice of a pharmacist or pharmacy or where a matter needs to be considered in more detail after an inspection. As we continue to enhance our effectiveness as a regulator, we review how we regulate, including adopting a risk-based approach, which is now being utilised within our range of regulatory tools.

#### Inspection activity

We conduct pharmacy registration visits where we have registration applications for new pharmacies or changes of ownership and relocations of pharmacies.

In 2023, 85 first-time registration applications for pharmacies were processed using selfdeclarations. We conducted 13 online new opening inspections and 19 onsite new opening inspections.

A total of 143 risk-based pharmacy inspections were conducted in 2023, including 3 re-inspections following the Registrar's decision under S71 of the Pharmacy Act. The nature of these inspections is provided below:

- Risk-based inspections are undertaken following a review of information available to the PSI and may be focused on a particular area or the general operation of the pharmacy, including inspection/compliance history, or where a member of the public or an external body has raised a concern.
- We also conduct themed inspections as may be required from time to time. These inspections assess certain other services provided by pharmacists. In 2023, we conducted six themed vaccination inspections. Other types of themed inspections include professional cover visits and visits assessing compliance with the Falsified Medicines Directive.

## Compliance with requirements for internet supply of non-prescription medicines

All pharmacies and other retailers selling non-prescription medicines online in Ireland must be registered with the PSI and act in accordance with the requirements of that registration. At the end of 2023, 140 pharmacies and 176 other retailers were registered with the PSI on the internet supply list.

In 2023, 175 websites were audited from the Internet Supply List, and subsequently, 20 compliance actions were taken in relation to the internet supply of non-prescription medicinal products, including letters issued to pharmacies regarding compliance with relevant requirements.

#### Supervising and superintendent pharmacist vacancies

The Pharmacy Act 2007 establishes the roles of superintendent and supervising pharmacists. It places the clinical and professional management and accountability of a pharmacy within these two key roles in cooperation with the pharmacy owner.

Legislation requires that there must be a supervising pharmacist appointed to each pharmacy and this person can act in the role for one pharmacy only. The supervising pharmacist is the professional in whole-time charge of the operation of the pharmacy, and they must have three years' post-registration experience to be appointed. This individual is responsible for all operations of the pharmacy and has a reporting relationship to the superintendent pharmacist for the pharmacy or group of pharmacies.

The PSI monitors the appointment of, and changes to, these governance roles, and this information is required to be notified to us. We have been monitoring supervising pharmacist vacancies as part of our continuous regulatory work, mindful of the increased number of vacant positions over recent years and the challenges in recruiting for this role. The PSI has developed an escalation process which monitors vacancies in all pharmacies and seeks to manage the risks these vacancies may have on the pharmacies concerned. As part of the escalation process, we conducted nine meetings with superintendent pharmacists and pharmacy owners who have a high number of supervising pharmacist vacancies or vacancies for a prolonged period of time in their pharmacies. The purpose of these meetings is to ensure that those pharmacies without a nominated supervising pharmacist have an effective governance structure in place and continue to provide high-quality, safe, effective pharmacy services to patients and the public.

#### Falsified Medicines Directive (FMD)

The Falsified Medicines Directive (FMD) introduced a coordinated and IT-enabled approach across the European Union to enhance patient safety by protecting the medicines supply chain from the risk of falsified (or counterfeit) medicines. Under the Delegated Regulations on Safety Features, the PSI has a role with others in the implementation of the Directive in Ireland, which was in a 'use and learn' phase from 2019.

We continued to engage with pharmacies and pharmacists in governance positions during 2023 to explain and encourage compliance with the Directive. We also used this engagement to explore broader issues on how the overall FMD approach works within Irish pharmacies and with the systems used in day-to-day work. In 2023, we continued to be represented on the National Safety Features Oversight Group, which is a multi-stakeholder collaboration group with representatives from various bodies such as the IMVO, HPRA and Department of Health.

Engagement with pharmacies on FMD requirements continued in 2023, with FMD requirements being assessed at routine inspections and at FMD focus visits. We issued 214 emails to pharmacies in relation to their level of compliance, where limited or no FMD scanning and decommissioning activity on the relevant repository system was detected during selected dates. FMD decommissioning rates for Ireland have been consistently reported by the European Medicines Verification Organisation as above 60%, with a peak of 77.9% in December 2023. This compliance rate is based on data determined by IQVIA that the Irish market stands at approximately 107 million packs for 2023. IQVIA data does not include medical devices or unlicensed medicines.

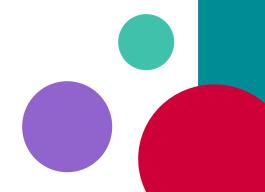
#### Investigations

Investigations are undertaken where there is reason to believe that serious safety issues and/or serious non-compliance issues exist in relation to a pharmacist or a pharmacy. Nine investigations were commenced, and eight investigation files were closed during 2023. Sixteen investigation files were opened at the end of 2023.

#### Consideration by the Registrar of inspection reports

The Registrar considers significant issues identified during an inspection or an investigation under Section 71 of the Pharmacy Act 2007. This is a function designated to the Registrar by the Council. In 2023, seven reports were considered by the Registrar. Following consideration of these:

- Seven pharmacists were referred to the complaints process (under Section 71(1)(b))
- In two of these seven complaints (under Section 71(1)(d)), the PSI Council was requested to formally consider making an application to the High Court seeking an Order pursuant to section 45 of the Pharmacy Act 2007 suspending the registration of the pharmacist pending further procedures under Part 6 the Pharmacy Act 2007



## **Pharmacy Quality and Safety in Numbers**



## **Complaints and Fitness to Practise**

As the statutory regulator charged with protecting public health and safety by regulating pharmacists and pharmacies, we take action to address poor professional performance, professional misconduct and failings in legislative compliance. One of the ways we do this is by considering formal complaints made against pharmacists and pharmacies under the Pharmacy Act 2007. Complaints are heard by our statutory Disciplinary Committees. We share information and learning from complaints and the outcomes of inquiries in the interest of maintaining and upholding professional standards, raising awareness around patient and public safety matters from a public safety perspective, and to promote compliance with pharmacy and medicines legislation. Dealing effectively with complaints is at the heart of our commitment to protecting patients and the public and maintaining public confidence in pharmacists and pharmacies.

#### Formal complaints

Formal complaints about pharmacists and pharmacies are generally made to the PSI in writing. They can relate to the conduct, practice, behaviour, health of a pharmacist or how a service is provided by a pharmacy. Formal complaints must be processed strictly in line with the provisions of the Pharmacy Act 2007.

We received a total of 73 new formal complaints in 2023, an increase of 36% on the previous years.

#### **Preliminary Proceedings Committee**

Once the PSI has received and processed a complaint, it is referred to the Preliminary Proceedings Committee (PPC) for consideration in accordance with the process as set out in the Pharmacy Act 2007. The PPC, upon reviewing the complaint, advises the PSI Council whether there is sufficient cause to warrant further action being taken in relation to either the pharmacist and/or pharmacy, the subject of the complaint. The PPC can then refer the complaint to either mediation or for hearing before a statutory Committee of Inquiry.

In 2023, the PPC considered 77 complaints, some of which had been initially considered in previous years. Of these, 74% were considered within the KPI target of six months.

Following review of the complaints considered in 2023, the PPC sent forward 29 complaints for further action. Of these, 25 were referred to the Professional Conduct Committee, three were referred to the Health Committee, and one was referred to mediation.

Of the complaints considered, the PPC advised the Council that 36 complaints did not warrant further action, and the Council agreed with the advice of the PPC. Eight complaints were adjourned.

#### Withdrawal of complaints

It is possible that once a complaint process has started, a complainant may later choose to withdraw that complaint. This can happen at any time during the process. Once a complaint has been withdrawn, the relevant Committee will update the Council and may advise the Council to:

- take no further action or
- proceed as if the complaint had not been withdrawn.

A total of six complaints were withdrawn in 2023. A total of four complaints were withdrawn before the PPC, and the Council agreed with the PPC that no further action should be taken in relation to those complaints. Two complaints were withdrawn before the Professional Conduct Committee (PCC), and the PSI Council also agreed with the Committee that no further action should be taken.

#### Professional Conduct and Health Committees overview

The Committees of Inquiry hear complaints against pharmacists and pharmacies, and they consist of the PCC and Health Committee. There were 18 inquiries held or commenced in 2023, of which sixteen concluded in 2023. Seven were held fully remotely online, five took place fully in-person at PSI House, and six took place in a hybrid manner, namely where some parties appeared in person before the Committee, and some appeared online.

The PCC and the Health Committee, sitting with an independent Legal Assessor, also hold Callover meetings several times a year. These meetings consider updates on matters involving inquiries and hear requests such as setting dates for inquiries, applications for adjournment, privacy applications and/or other preliminary applications. The Committees may also direct that specific timelines be complied with to ensure that a complaint is ready for hearing. In 2023, four PCC and four Health Committee callovers took place. The callovers took place fully remotely using technology.

#### Inquiry hearing outcomes

A total of 18 inquiries relating to 22 respondents were heard before a Committee of Inquiry in 2023. This amounted to over 31 hearing days. This represents an ongoing increase in the length of time it is taking the conclude inquiries, due in part to the increasing complexity of complaints and the number of respondents and witnesses involved. A total of 16 inquiries were concluded in 2023, with the remaining two being part-heard in 2023 and adjourned to be completed in early 2024. The PCC heard or commenced 14 inquiries, and the Health Committee heard or commenced 4 inquiries.

Findings were made in almost all concluded inquiries, or an undertaking (for example, not to repeat the conduct and consent to sanction) was accepted by the relevant Committee under section 46 of the Pharmacy Act 2007. When an undertaking is invited and accepted, no findings are made against the respondent to the complaint. The findings by the Committee of Inquiry (i.e. where the allegations are proved beyond all reasonable doubt) were deemed to amount to professional misconduct and/or poor professional performance and/or impairment, and some related to convictions against the respondents. Of the 16 inquiries included, eight were resolved through the acceptance of undertakings.

#### Sanctions and outcomes following fitness to practise hearings

A pharmacist or pharmacy may have one or more sanctions imposed against them following an inquiry. When an inquiry concludes, the Council considers the Report of the Committee of Inquiry and formally decides upon (where relevant) and imposes any sanction on the pharmacist or pharmacy and makes any other decision required under the Pharmacy Act 2007 in relation to that complaint.

In 2023, the Council considered 19 reports from the Committees of Inquiry under section 47 of the Pharmacy Act 2007, some of which had related to inquiries heard before a Committee of Inquiry in 2022. Of these 19 reports, eight involved undertakings, of which six involved consents to sanction.

The Council imposed a total of 15 sanctions following the consideration of the reports from the Committee of Inquiry, and in some cases, the Council imposed one or more sanctions on a respondent. Two complaints were found by the relevant Committee to be unsubstantiated following applications by the Registrar not to lead evidence, and the Council dismissed these complaints in accordance with its statutory obligation to do so under section 48(1)(a) of the Pharmacy Act 2007. Seven complaints resulted in findings against a pharmacist and/or pharmacy and involved the imposition of one or more sanctions on the pharmacist or pharmacy. Sanctions under section 48(1)(b) of the Pharmacy Act 2007 included three censures (3), four admonishments (4), the imposition of conditions (2), suspension from the register for a defined period (3), and three cancellations of the registration of the pharmacist/or pharmacy (3). There were no sanctions in respect of a prohibition on restoration to the register.

In accordance with section 52 of the Pharmacy Act 2007, four applications were made to the High Court to confirm any sanction involving suspension, conditions and cancellation of registration, some of which related to complaints which had been considered by the Council in late 2022.

#### **Appeals**

Under section 51 of the Pharmacy Act 2007, a pharmacist or pharmacy may apply to the High Court to cancel the sanction imposed by the PSI Council, and the High Court may either confirm or vary the decision of the Council. No such applications were made to the High Court in 2023; however, the PSI still awaits a decision (judgment) from the High Court in relation to an application that took place in late 2022.

#### Monitoring of conditions

We monitor compliance with any conditions imposed on an individual's registration due to findings made at a fitness to practise inquiry as well as any undertakings given at a fitness to practise inquiry by a registrant. This means that the PSI engages with the registrant as they work to achieve the expected outcomes according to the undertakings given or the conditions attached to their registration. In 2023, we facilitated three individuals/pharmacies with High Court conditions imposed after findings being made at fitness to practise inquiries to demonstrate adherence to the conditions imposed. We also engaged with and monitored the adherence of three individuals who provided undertakings at fitness to practise inquiries.

#### Interim suspensions

The PSI Council may apply to the High Court under section 45 of the Pharmacy Act 2007 for an order to immediately suspend, on an interim basis, the registration of a registered pharmacist and/or a registered pharmacy against whom a complaint has been made, pending resolution of that complaint. This is done if the Council considers that there is a risk to the health and safety of the public, which is of such magnitude that the registration should be suspended pending the conclusion of the complaint process.

Two interim suspension applications were considered by the Council in 2023 against two pharmacists. In both cases, the Council decided to proceed to seek an order from the High Court suspending the registration of the pharmacists on an interim basis pending resolution of the complaints against them, and the High Court granted those interim Suspension orders.

#### Remote meetings and hearings

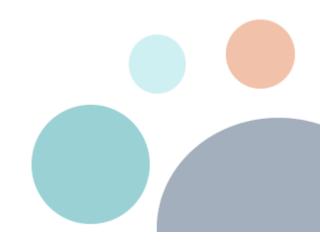
The Committees of Inquiry have indicated a preference to hold fitness to practise inquiries in person at PSI House, and therefore, this is the default position of the PSI when scheduling inquiries. If, however, applications are made to the Committee to hold an inquiry fully remotely or in a hybrid fashion, the Committee are empowered to facilitate this under their Procedures, provided that in all cases, the scheduling of remote hearings is in accordance with provisions of the Civil Law and Criminal Law (Miscellaneous Provisions) Act 2020. However, the Committees of Inquiry now typically sit fully remotely to hear callovers and some preliminary and other applications; in the interest of efficiency, The Preliminary Proceedings Committee tends to sit on a hybrid basis.

#### Effective decision-making in statutory complaints and Disciplinary Committees

The Disciplinary Committees established under the Pharmacy Act 2007 are charged with consideration of statutory complaints against registered pharmacists and pharmacies and make decisions and recommendations to the PSI Council in relation to those complaints. They are, by law, separate and independent to the PSI Council and Executive, comprise a lay majority, and are appointed through an independent process.

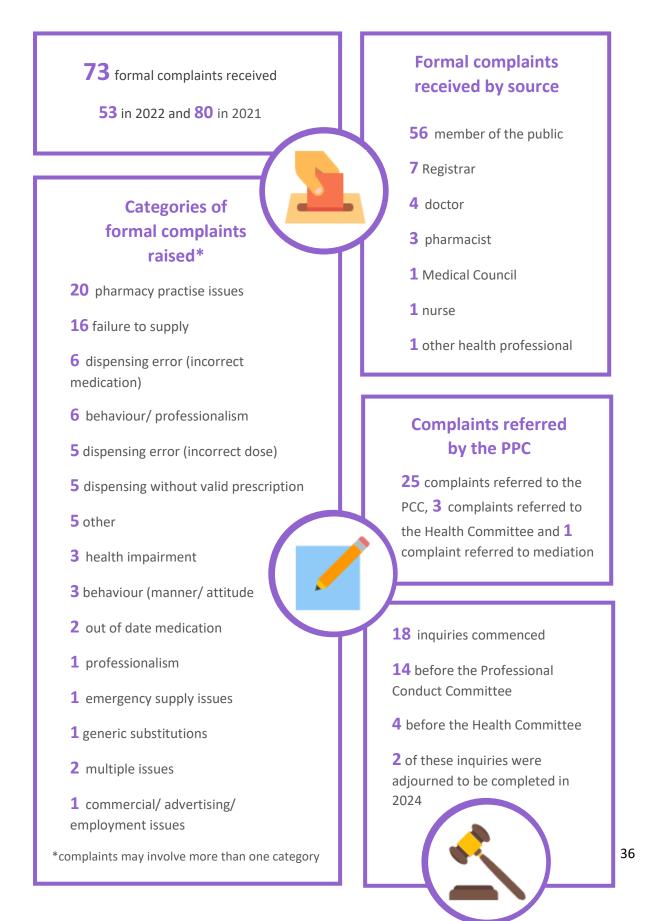
In 2023, ten new Disciplinary Committee members were appointed to replace those who had retired, resigned, or completed their term. All new members receive detailed induction training on their statutory duties and responsibilities and are required to observe inquiries before they sit to hear complaints. In addition, all Disciplinary Committee members are required to attend annual training sessions, at which independent external training is provided on fair procedures, professional regulation, the statutory complaints process and decision-making. In 2023, the PSI held two training sessions for the Preliminary Proceedings Committee and two training sessions for the Committees of Inquiry.

This induction and ongoing training are part of our commitment to ensure that the statutory complaints process is managed strictly in accordance with the legal and statutory framework and that all Disciplinary Committee members are supported in their roles and provided with the specialist knowledge and guidance needed to fulfil their roles. The training sessions are also an important opportunity for Committee members to meet with each other and share their experiences, report any feedback on the process and provide mentoring support to newer members.



## **Formal Complaints and Fitness**

## to Practise in Numbers



## **Strategic Policy and Communication**

Providing information and raising awareness of our role and work is a fundamental part of our regulatory role. Our work includes developing policy positions in relation to strategic policy issues, including national regulatory and healthcare strategy. We work in collaboration with many others from outside the PSI across all areas of our regulatory work to achieve our mission in the public interest and in consideration of the wider health context.

#### Working with others

We recognise the importance of working collaboratively with others, and we continued to work in collaboration with our key stakeholder organisations throughout 2023. This included contributing to national health and social care consultations, working groups and other cross-organisational meetings. The PSI regularly engages with the Department of Health, the Health Service Executive (HSE), the Health Products Regulatory Authority (HPRA), the Health Information and Quality Authority (HIQA), other regulators of the health and social care sector, as well as the Schools of Pharmacy, the Irish Institute of Pharmacy (IIOP), Irish Pharmacy Union (IPU), the Hospital Pharmacists Association (HPAI), Pharmacists in Industry, Education and Regulatory (PIER), among others.

#### Submissions to external consultations

In 2023, we made 12 submissions to external public consultations and requests for input, where the subject matter was of relevance and significance to our role and of those we regulate. These included the Department of Health's draft Patient Voice Partner Policy, the draft Code of Practice on the Public Sector Equality and Human Rights Duty, and the draft National Standards for Information Management in Health and Social Care.

#### Participation in external working groups

As part of our regulatory remit, the PSI regularly participates in and contributes to several external working groups.

In March, we were invited by the Department of Health to the sodium valproate stakeholder group. The aim of this stakeholder group is to discuss actions taken to date to ensure the adoption of the European Medicines Agency pharmacovigilance risk assessment committee recommended valproate pregnancy prevention programme in practice and oversee the implementation of actions identified if necessary.

We were invited in 2023 to join the Pharmacy eHealth Group, established by the Department of Health, and have attended four meetings in 2023. This special advisory committee is intended to be used as a forum for cooperation and engagement, aligned with the implementation of the eHealth Strategy for Ireland. Membership includes the Department of Health, HSE, IPU and practising pharmacists. The group hopes to advance the delivery of patient-centred pharmacy-related healthcare and promote the adoption of eHealth initiatives by building on existing collegiate collaborations to continually improve patient experience and outcomes.

We are also a member of the Medical Council Overprescribing Working Group, which discusses

strategies to address the overprescribing of controlled drugs. The stakeholder group also includes representatives from the Medical Council, HSE, HPRA, Department of Health, and Irish College of General Practitioners. The group drafted a submission to the Department of Health examining the impact of the overprescribing of benzodiazepines, Z drugs and pregabalin in Ireland.

The PSI is also a member of the Preventing Paracetamol-Related Intentional Drug Overdose Working Group, which meets several times a year. The overall aim of the Group is to collaborate on actions to prevent paracetamol-related intentional drug overdose by optimising adherence to existing legislation that limits access to paracetamol. In October we also attended the launch of a new information campaign by the Department of Health on the safe sale of paracetamol.

#### Collaboration and engagement with the Department of Health

Throughout the year, we engaged and collaborated with the Department of Health on policy developments relating to pharmacy, including reviewing and providing comment on a number of statutory instruments related to medicines legislation, engagement on the substitution of biosimilars by pharmacists and exploring the subject of expanding pharmacists' scope of practice.

#### Stakeholder engagement on medicines shortages

We are committed to working collaboratively on medicine shortages as part of the broader healthcare system to ensure that the appropriate information and guidance regarding medicine shortages is available.

Throughout the year, we attended several meetings of the Medicines Criticality Assessment Group, a multi-agency group convened by the HSE, HPRA and Department of Health to discuss and respond to medicine shortages. We also supported the development of joint messages for healthcare professionals and the public on steps being taken to manage medicine shortages and to highlight the important role in supporting patients by ensuring the ongoing appropriate, rational and safe use of medicines.

In March and May we attended the HPRA Medicines Shortages Framework stakeholder meetings to discuss communication, shortage notification and escalation mechanisms concerning medicines availability. In June, we participated in and presented as part of a multi-stakeholder event attended by health media correspondents to inform the public and relevant stakeholders about how medicines shortages are prevented, where possible, and mitigated when they occur through the work of the Medicines Shortages Framework. We collaborated with the DoH, HPRA, HSE and ICGP as part of this event.

#### Collaborating with pharmacists, pharmacies and other stakeholders

#### PSI Roadshows

In October 2023, we ran a series of five regional roadshows, marking another significant milestone in our ongoing commitment to engaging with registrants on patient safety and quality initiatives.

The roadshows were the first in-person events held by the PSI following the pandemic and were an

opportunity to discuss several important topics, including pharmacy governance roles, pharmacist workforce planning and fitness to practise. The events took place in Sligo, Limerick, Cork, and Dublin. Attendees commended the events for providing useful insights into the ongoing work of the PSI.

The events enabled PSI to capture feedback from pharmacists in person at each roadshow and through a postevent questionnaire. Recordings of each presentation have also been made available on the PSI website for those registrants and stakeholders who could not attend in person.



Caroline Murphy, Fitness to Practise and Legal Affairs Manager, Joanne Kissane, PSI Registrar and Chief Officer, Laura Irwin, Community Pharmacy Quality and Safety Manager and Dan Burns, Head of Strategic Policy, Research and Communication at the PSI Roadshow events in October 2023

#### • Survey on medicines administration services in pharmacies

We carried out two surveys with pharmacists and the public between July and September. This was part of a regulatory review of the administration of medicines, in particular, injectable medicines, by pharmacists in community pharmacies. The purpose of the surveys was to better understand the full range of medicines currently being administered by pharmacists in community pharmacies to help



us determine if the existing regulatory framework is sufficient to support pharmacists in providing safe, consistent and high-quality medicines administration services to patients and the public. We received 614 responses from the pharmacist survey and 159 from the public survey, both of which were anonymous. The results of the survey will be included as part of PSI's overall regulatory review of medicines administration in community pharmacies.

#### **Communication channels**

Our Communications Strategy supports effective engagement with all stakeholders. It is designed to ensure patient safety is core to our communications and create awareness and understanding of the PSI's role. We acknowledge that our website is one important source of information supporting our mission and meeting stakeholder needs. During the year, we continued to prepare for the redevelopment of the website, and a successful website developer was procured to help us better meet our customer needs and improve the way we provide access to information. Our new contemporary and flexible PSI website will be launched in 2024.

We continued to use our social media platforms as an additional way of sharing information about our role and about regulatory and public health updates. We also issued four PSI newsletters to registrants and all those who subscribe to receive our updates. The newsletter provides regulatory updates, pharmacy practice guidance, medicines and safety notices, and other relevant professional and public health updates. All newsletters are archived on the PSI website.

We provided email updates to our registrants on a variety of topics throughout the year. These included vaccine guidance and provision information, important medicine updates, invitations to PSI Roadshow events and opportunities to contribute to our work, such as the second annual workforce survey and an expression of interest for pharmacists to participate in an Expert Taskforce workshop.

We responded to media queries, supported media attendance at public Council meetings and public inquiries, issued press releases, wrote articles for external publications, answered 32 parliamentary questions, and responded to other requests for information from various stakeholders throughout the year.

# Strategic Policy and Communications in Numbers

4 newsletters issued to our registrants and subscribers

9 press releases issued

**32** responses provided to parliamentary questions

1 public consultation held on Registration Rules to facilitate revision of the Third Country Qualification Recognition route

#### **12** submissions to external consultations

- HIQA public consultation on Draft National Standards for Information Management in Health and Social Care (January)
- ii Medical Council stakeholder consultation on draft Rules for Maintenance of Professional Competence and accompanying Guidelines. (February)
- Organisation for Economic Cooperation and Development (OECD) Product Market Regulation Questionnaire on Retail Trade in relation to the retail sale of prescription and non-prescription medicines. (February)
- iv Department of Health Public Consultation on the draft Patient Voice Partner (PVP) Policy. (March)
- We provided initial comments and observations to the Department of Further and Higher Education, Research, Innovation and Science on proposed updates to the minimum training requirements for pharmacists as part of the work being undertaken at EU Commission level. (April)
- vi National Risk Assessment Strategic Risks 2023 for the Department of the Taoiseach (April).
- vii Nursing and Midwifery Board of Ireland (NMBI) draft Digital health competency standards and requirements for undergraduate nursing and midwifery education programmes (May)
- viii Department of Health Statement of Strategy 2023-2025
- ix Irish Human Rights and Equality Commission (IHREC) Consultation on the draft Code of Practice on the Public Sector Equality and Human Rights Duty (June)
- x Office of the Government Chief Information Officer (OGCIO a division of the Department of Public Expenditure NDP Delivery and Reform) Data Collection and Reuse Survey.
- xi Comments to support the development of Ireland's first World Breastfeeding Trends Initiative (WBTi) assessment report, developed by the Core Group for WBTi Ireland. (November)
- xii Department of Health and the Pharmaceutical Strategy Working Group on the Revision of the EU General Pharmaceutical Legislation - Policy Area 1 - Security of Supply / Shortages. (December)

## **Organisational services**

Organisational services support the PSI and its staff to deliver on our functions and provide the means for others to engage with us and utilise our services.

#### Human Resources

A key pillar of our HR Strategy is investing in our staff and putting in place learning and development pathways. In 2023, we offered a diverse range of training programmes that were crucial in enhancing the skills and knowledge of our workforce. These programmes included Manual Handling, EFQM, Occupational First Aid, Fire Warden, LGBT Awareness, Dealing with Difficult Customers and Situations, AsIAm – Autism Awareness, GDPR, Stress Management, Belbin Team Roles, and Safety Officer Training, alongside core skills training.

In 2023, we also rolled out a new HR Information system to support all colleagues and introduce greater efficiencies both within the HR Team and for the wider organisation.

It was a busy year for the HR Team due to the volume of recruitment campaigns to fully support the new organisation structure while also continuing our commitment to the development and wellbeing of our workforce.

#### Information and Communications Technology (ICT)

In 2023, we continued to monitor and review our internal systems and processes to implement appropriate information and communications technologies to support the delivery of technology, operations, and services.

We also continued to review and implement measures to ensure that a suitable level of ICT systems security was in place, with a view to ongoing enhancement and increased security levels. During 2023, four vulnerability tests and one penetration test were carried out.

In 2023, we closed 1,270 support tickets. There were also 30 employee moves processed for new starters, transfers and leavers in 2023.

A gap analysis on the National Cyber Security Centre Baseline Standards was carried out in 2023 and the recommendations from that exercise have been included in development initiatives for 2024. An incident response tabletop exercise was also carried out with a respected industry leader to ensure our security posture remains up to date, and the results from that will inform updates to our Business Continuity Policy and Plan.

#### **Business Transformation**

We have committed to building an agile and high-performing organisation so that we are better equipped to deliver on our mission and achieve PSI's strategic and developmental objectives. A key enabler to deliver on this objective is the Business Transformation Programme- The outputs from these initiatives will ensure that the PSI has the right technology to underpin our processes in order to maximise our resources as we evolve our regulatory reform model.

#### Information Governance

Work began in October 2023 on the PSI Information Governance Project. As part of this project, many policies were updated, including the PSI's Records Management Policy and Records Retention Schedule. We introduced a Clean Desk Policy to ensure that files containing personal and confidential information are always maintained securely. Electronic Destruction Certificates were also introduced to help streamline the process.

We established a records quarter beginning in October and ran until the end of the year. During that time, all colleagues were encouraged to remove hard and soft copy files in accordance with the PSI's Retention Schedule. The project will continue throughout 2024, when we will begin to work on files currently held offsite.

#### Climate action mandate and sustainability activities

The government's Climate Action Mandate sets out objectives for public bodies, including the reduction of greenhouse gas emissions by 51% and improvement in energy efficiency by 50% by 2030. Under the Mandated requirements, in 2023, we developed our first Annual Climate Action Roadmap, demonstrating our ongoing commitment to sustainability and emissions reduction and ensuring that we, as a public sector body, lead by example on climate action activities.

In developing this plan, the PSI has established its baseline to measure our progress towards the Mandate's targets, drawing from our reporting data, an audit of existing processes, and an organisation-wide staff engagement workshop. This baseline, along with PSI's progress towards our climate action objectives to date, has been used to calculate our 'gaps to target' and identify opportunities for further action.

#### Energy efficiency and greenhouse gas emissions

We are committed to making every effort possible to be energy efficient and to operate appropriate conservation and recycling measures. PSI personnel occupy 1,920 m2 of office space located in Dublin. In 2023, we consumed 396,765 kWh of energy, consisting of 177,900 kWh of electricity and 218,865 kWh of gas. In comparison, we consumed 386,496 kWh of energy in 2022, consisting of 154,850 kWh of electricity and 231,646 kWh of gas.

This is an overall year-on-year increase in energy use of 2.7%, including a 15% increase in electricity and a 6% reduction in gas in 2023. The increase in electricity can be attributed to staff working on a hybrid basis, having previously worked remotely due to COVID-19, as well as an increased number of Committee and Council meetings and inquiries being held on-site. The decrease in gas usage can be attributed to energy-saving measures implemented during 2023 in support of the 2030 public sector energy and CO2 targets.

In 2022, the PSI produced 88,598 kg CO2 of energy-related-CO2 emissions, comprised of 41.2% gasrelated and 58.8% energy-related emissions, equating to a 10.6% emissions reduction from 2021. This value represents an approximate reduction of 43,000 kg CO2 required to meet the 2030 emissions reduction targets under the Climate Action Mandate, as outlined further in PSI's Climate Action Roadmap. Emissions data for 2023 will be published on the PSI website in 2024. Greenhouse gas emissions are reported retrospectively using the SEAI Public Sector Monitoring and Reporting System, and updated emissions data is published on the PSI's website on an ongoing basis.

### **Governance and Accountability**

#### How we ensured high standards of corporate governance

All PSI staff and office holders have a role to play in assuring the good governance of the PSI, including compliance with the statutory requirements to which it is subject, as well as Government guidelines and transparency about the way we carry out our functions. The PSI is responsible to the public and accountable to the Minister for Health and the Oireachtas for meeting its regulatory remit. We adhere to our Corporate Governance Framework, Codes of Conduct (for our Council, Committees, and staff), as well as the Code of Practice for the Governance of State Bodies. We comply with the Pharmacy Act 2007, the Ethics in Public Office Act 1995, and the Standards in Public Office Act 2001.

The PSI is an aegis body of the Department of Health. Three governance meetings were held with Department of Health officials during 2023, and the PSI Council was provided with the minutes of those meetings.

#### Corporate Strategy 2021-2024

Our Corporate Strategy 2021–2024 recognises the importance of effective communication and

stakeholder engagement to underpin the achievement of our key strategic objectives. In March, The PSI Council agreed to extend the period of its Corporate Strategy by one year. This was on the basis that the strategic objectives and development agenda were ambitious and provided enough strategic direction for an additional year. There was also an acknowledgement of the impact that COVID-19 had on implementing objectives within the original timeframe.

In addition to supporting and promoting compliance, we have a duty to ensure that the public is aware of the services and standards they can expect from pharmacists and pharmacies. Our approach to our work is designed to ensure patient safety, which is at the core of our communications, and we continually strive to increase awareness and understanding of our role.

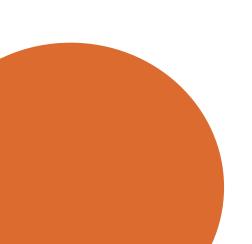


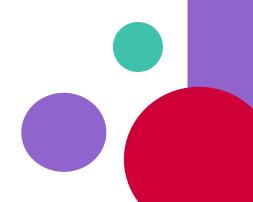
#### **PSI Council**

The PSI is governed by a 21-member Council with a non-pharmacist majority. Each member of Council is appointed by the Minister for Health. In addition to setting the PSI's risk appetite and strategic direction, each Council member has a fiduciary duty to all PSI stakeholders. The PSI Council is also responsible for ensuring the development of PSI policies and standard operating procedures, as well as workforce capacity and leadership planning. It holds the Registrar to account for their performance. The PSI Council is accountable to the Minister for Health and the Oireachtas for the discharge of these duties. The PSI Council held a total of 10 meetings in 2023. The agenda and minutes of the public meetings of Council are published on the PSI website.

2023 marked the end of terms of office for some Council members, and following consultation with the Department of Health and an election, new appointments were made to the Council by the Minister. Following calls for expressions of interest, the PSI Council made appointments to the PSI Advisory and Disciplinary Committees as required. The work and commitment of current and past Council and Committee members is acknowledged.

All PSI Council members who held office during 2023 are listed below on page 46, along with records of attendance, fees and expenses paid.





#### PSI Council members 2023

Council Member (as at 31 December 2023)	Meetings attended	Meetings attended online	Fees paid in 2023	Expenses paid in 2023
Ms Katherine Morrow *	9/10	0	€9,947.60	€150.71
Ms Joan Peppard *	5/5	0	€4,143.46	€267.60
Mr Rory O'Donnell *	9/10	0	€7,695.00	€5,230.50
Mr John Given *	6/10	2	-	€2,353.82
Mr Mark Jordan *	6/10	3	€7,695.00	€903.43
Ms Dorothy Donovan **	7/10	3	€7,695.00	-
Ms. Grainne Power **	9/10	0	-	-
Ms Geraldine Crowley **	6/10	1	-	-
Ms Geraldine Campbell **	9/10	0	€7,695.00	€1,669.56
Mr Sean Reilly *	9/10	2	€7,695.00	-
Ms Marie Louisa Power *	7/10	0	-	€787.65
Mr Peter Dennehy **	7/10	0	€7,695.00	-
Dr Paula Barry Walsh **	8/10	0	€7,695.00	-
Dr Ann McGarry **	10/10	0	€7,695.00	-
Ms Emily Kelly *	5/5	0	€4,143.46	-
Mr Martin Sisk **	4/5	0	€4,143.46	-
Dr Cyril Sullivan **	3/5	0	€4,143.46	€362.58
Prof Laura Sahm *	4/5	1	-	€640.38
Mr Martin Higgins **	5/5	2	€4,143.46	-
Dr Denis O'Driscoll *	3/5	0	€4,143.46	-
Mr Richard Hammond S.C. **	1/1	0	€10,35.86	-
Council Members in office for part of 2023 but no longer holding office:				
Mr Roy Hogan *	2/5	0	€3,551.54	-
Ms Ann Sheehan **	3/5	0	€3,551.54	€3,209.18
Prof Brian Kirby *	5/5	0	€3,551.54	-
Ms Muireann Ní Shúilleabháin *	4/5	0	€5,524.62	€3,835.32
Mr Paul Turpin **	3/5	0	€3,551.54	-
Mr Graham Knowles **	4/5	0	€3,551.54	€2,178.91
Mr Fintan Foy **	4/5	0	€3,551.54	-
Ms Avril Ryan *	5/5	0	€3,551.54	-

\*Pharmacists appointed by the Minister for Health in accordance with s.10(3)(f) and (g) of the Pharmacy Act 2007

\*\*Non-pharmacists appointed by the Minister for Health in accordance with s.10(3)(a) to (e) of the Pharmacy Act 2007

<sup>1</sup>The total number of meetings attended varies according to dates of appointment, re-appointment, and completion of term in office.

<sup>2</sup>Fee payment is in line with the duration of term in office during 2023. Council Members

<sup>3</sup>Aggregate expenses paid up to 31 December 2023. Council members employed in the public sector were not paid fees in 2023.

#### **PSI Committees**

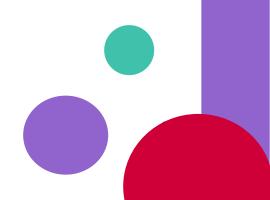
The PSI Advisory Committees advise and support the Council on the performance of its functions. The PSI has four Advisory Committees:

- Audit and Risk Committee
- Performance and Resources Committee
- Regulatory and Professional Policy Committee
- Special Purposes Committee

In general, our Advisory Committees are made up of Council members. The Audit and Risk Committee includes external members who are appointed to contribute their expertise in the areas of compliance, finance, risk management and governance. Each Committee meets throughout the year and reports to the PSI Council on the work they have undertaken. The agenda and minutes of Advisory Committee meetings are published on the PSI website.

The PSI also has three Disciplinary Committees as required under the terms of the Pharmacy Act 2007. Their work is outlined in the Complaints, Inquiries and Fitness to Practise section of this report. The membership of the Disciplinary Committee includes pharmacists and non-pharmacists who can bring a range of experience to the consideration of complaints. They are appointed through a formal process and receive extensive training.

As part of their role and ongoing effective contribution to the statutory fitness to practise processes, Disciplinary Committee and Council members undertook several training and development activities throughout 2023, including training in relation to Committee procedures, recent case law in professional regulation, and equality, diversity and inclusion issues in decision-making.



#### PSI Advisory Committee members 2023

Addit and KISK Committee		
Committee member	Meetings attended	
Ms Geraldine Campbell	4/4	
Mr Liam Burke	4/4	
Mr John Given	3/4	
Mr Peter Dewhurst	3/4	
Dr Paula Barry Walsh	4/4	
Dr Cyril Sullivan	1/1	
Ms Ciara Lynch	3/3	
Mr Graham Knowles	2/2	

#### Audit and Risk Committee

#### **Special Purposes Committee**

Committee member	Meetings
	attended
Ms Katherine Morrow	5/5
Ms Geraldine Campbell	6/6
Mr Rory O'Donnell	5/5
Dr Ann McGarry	3/3
Ms Muireann Ní	4/4
Shúilleabháin	
Mr Paul Turpin	4/4

#### Performance and Resources Committee

Committee member	Meetings attended
Dr Ann McGarry	5/5
Mr Sean Reilly	3/5
Ms Emily Kelly	1/1
Mr Denis O'Driscoll	1/1
Mr Martin Sisk	1/1
Mr Martin Higgins	0/1
Mr Paul Turpin	3/3
Ms Geraldine Crowley	3/4
Mr Fintan Foy	2/3
Mr Roy Hogan	3/3
Mr Mark Jordan	2/4
Ms Avril Ryan	1/3

#### Regulatory and Professional Policy Committee

Committee member	Meetings
	attended
Ms Katherine Morrow	3/3
Prof Brian Kirby	2/3
Ms Ann Sheehan	2/3
Ms Gráinne Power	6/7
Ms Marie Louisa Power	7/7
Mr Peter Dennehy	3/7
Ms Dorothy Donovan	7/7
Mr Rory O'Donnell	2/2
Mr Mark Jordan	1/2
Prof Laura Sahm	2/2
Ms Geraldine Crowley	2/2



#### Compliance

As a public body, the PSI complies with a range of legislation and Government directives. This section of our report provides information about how we comply with those requirements.

#### **Children First Act**

While PSI staff are not 'mandated persons' as defined in the Children First Act 2015, we are committed to ensuring the principles of the Children First Act are upheld across the organisation and the pharmacy profession, as they are aligned with our remit to protect the health and safety of the public. The PSI has a child protection policy in place to guide its staff and officeholders. We also have a designated liaison and deputy to oversee compliance with the policy and to act as the point of contact for reporting child protection concerns. All PSI colleagues are required to complete the Tusla eLearning programme: An Introduction to Children First.

#### **Customer Charter**

The PSI Customer Charter sets out the nature and quality of service that customers can expect when they interact with PSI colleagues. This is based on the twelve principles of quality customer service used by Government Departments. In 2023, we continued to seek to perform against the standards set out in the Customer Charter and identify areas for continued improvement. We welcome feedback from all those who engage with us.

#### **Data Protection**

The PSI is a data controller in relation to the personal information that we hold about registrants, patients, our employees, and other parties. We use personal information to enable us to meet our responsibilities in the public interest as the regulatory body for pharmacists and pharmacies in Ireland. All personal information provided to the PSI is treated in the strictest of confidence, maintained securely and treated in accordance with the Data Protection Acts 1988 to 2018, the General Data Protection Regulation (GDPR), and the Pharmacy Act 2007. We received 20 data sharing requests and four subject access requests in 2023.

#### Compliance with Circular 1/2020 Offsetting Emissions for Official Air Travel

PSI continues to ensure compliance with Circular 1/2020, implementing procedures for offsetting the emissions associated with official air travel. In 2023, the PSI offset a total of 0.117 CO2 emission Tonnes, resulting in an offset payment of €5.69. In 2022, the PSI offset a total of 3.397 emission Tonnes for foreign air travel, resulting in an offset payment of €319.28.

#### Ethics in Public Office Act

Under the provisions of the Ethics in Public Office Act 1995 and the Standards in Public Office Act 2001, Council members and some PSI staff members are required to disclose material interests.

PSI Council members' disclosures of interest are published on the PSI website. Annual statements of interests are requested from all PSI Council members as, under ethics legislation, they are designated directors, and these annual statements must be submitted to the Standards in Public Office Commission. Any member of PSI staff who is deemed to hold a designated position of employment is also required to complete a disclosure of interest statement if they have interests to disclose, both on appointment and annually thereafter.

#### **Freedom of Information**

The PSI is a prescribed organisation under the Freedom of Information (FOI) Act 2014. We publish as much information as possible in an open and accessible manner on a regular basis on our website, having regard to the principles of openness, transparency, and accountability. In 2023, we ensured compliance with the legislation by responding in a timely manner to FOI requests and reporting on our engagement with the legislation. In 2023, we received nine freedom of information requests and no requests for an internal review.

#### Health and safety

The PSI complies with its statutory responsibilities under the Health, Safety and Welfare at Work Act 2005 and the Health and Welfare at Work (General Application) Regulations 2007. We seek to provide a safe and healthy work environment for all PSI staff, whether onsite at PSI House, when they are conducting pharmacy visits, or when working remotely from home. This is done through the provision of safety training, conducting risk assessments, and the provision of specialist equipment where required. We also meet our safety responsibilities to others, including those who attend PSI House. In 2023, as part of the rollout of the PSI's Blended Working Policy, ergonomic assessments were provided for all colleagues working remotely. Ergonomic equipment and supports continue to be made available to all colleagues.

A Health, Safety and Sustainability Committee advises the Executive Leadership Team on health and safety matters and acts as an independent forum in which staff may raise any safety concerns.

#### **Official Languages Act**

In accordance with our legal obligation under the Official Languages Acts 2003 to 2021, the PSI publishes public-facing documents, such as our annual report and audited financial statements in Irish. For those seeking information on the PSI's official complaints process, information is available both in Irish and English. We will engage in the Irish language with those who wish to communicate with us in Irish. During 2023, we attended information updates about the Official Languages (Amendment) Act 2021 in preparation for the phased commencement of new requirements that seek to increase the provision of information and services in the Irish language by public bodies.

#### **Protected Disclosures**

The Protected Disclosures (Amendment) Act 2022 provides for the protection of workers from being penalised because of disclosures they make that they believe are in the public interest. New changes were introduced in 2022 to the annual reporting requirements surrounding protected disclosures

received. The PSI will publish a separate report relating to its obligations under the legislation by 31 March 2024.

#### Prompt payments

We publish quarterly reports on our website of our compliance with the prompt payment of accounts legislation and submit these quarterly to the Department of Health. In 2023, 48% of our creditors had been paid within 15 days and a further 30% within 30 days.

#### Equality, Diversity, and Inclusion Working Group Report

The PSI's Equality, Diversity, and Inclusion (EDI) Working Group, now in its fourth year, has membership from staff at every level of the organisation. The Working Group was established to advise the Executive Leadership Team (ELT) on implementing the values outlined in the PSI Equality Diversity & Inclusion Statement, as well as its statutory duties with regard to human rights and equality.

The Working Group promotes awareness amongst PSI colleagues of our EDI obligations as a public body and assists the PSI in becoming a more inclusive and diverse workplace. In 2023, the membership of the Working Group was updated following an expression of interest to PSI colleagues. Throughout the year, the Working Group arranged a programme of talks and information sessions to raise awareness and understanding of equality, diversity and inclusion topics. These included a presentation by LGBT Ireland that included information on some of the issues that impact members of the LGBTQIA+ community, particularly older members of the community and the challenges they can experience when accessing health and social care services. A presentation from Ireland's National Autism charity, AsIAm, was also organised. This aimed to raise awareness of autism and highlight ways in which the PSI can support employees with autism and become a more autisticfriendly workplace.

The Group conducted the second annual survey of PSI staff on equality, diversity and inclusion. The purpose of these surveys is to better understand diversity within the PSI as well as to gather sentiment from colleagues about their views on the PSI as a diverse and inclusive workplace. The results of the survey will be compared with the 2022 results and recommendations will be made by the Working Group for consideration by the ELT. The Group continues to seek ways to enhance levels of equality, diversity and inclusion in the PSI, as well as in the way it engages with its stakeholders, including members of the public and the pharmacy profession.

#### Section 42 Public Sector Equality and Human Rights Duty

The Public Sector Duty is provided for under Section 42 of the Irish Human Rights and Equality Act 2014 and requires that public bodies seek to eliminate discrimination, promote equality of opportunity and treatment, and protect the human rights of its staff and its stakeholders.

As part of our ongoing commitment to meeting the Duty, all PSI staff complete the Irish Human Rights and Equality Commission's e-learning course, Equality and Human Rights in the Public Service. The PSI seeks to ensure that we continue to embed equality and human rights in our work and in the way we engage with our stakeholders. To this end, in 2023, PSI staff attended an in-house workshop on the Public Sector Equality and Human Rights duty, facilitated by one of our Council members, Geraldine Campbell. The objective of this workshop was to understand better how we integrate the duty into our work. It allowed colleagues to explore and identify how our work impacts equality and human rights. To further progress this work, one of the activities set out in the PSI's 2024 Service Plan is to undertake a formal assessment of human rights and equality issues relevant to the functions and purpose of the PSI.

#### **Disability Act**

The Disability Act 2005 places a statutory obligation on public service organisations to provide support and access to services and facilities for people with disabilities. In line with the obligation placed on all public bodies, we promote and support the employment of people with disabilities. In 2023, the PSI exceeded the minimum 3% target of employment for people with disabilities. To meet those requirements, we enable all staff to carry out their work on an equal basis through the provision of all necessary supports and accommodations.

## **Report from our Audit and Risk Committee**

The PSI's Audit and Risk Committee maintains oversight of and ensures the integrity of the PSI's governance, internal audit, external audit, and financial controls, as well as assessing the risks the PSI may be exposed to and the organisation's mitigation of those risks.

As set out in the Code of Practice for the Governance of State Bodies, the PSI's Audit & Risk Committee acts independently to provide assurance to all PSI stakeholders.

It does this by ensuring the PSI's business, financial reporting and internal controls are robust and its assurance framework is fit for purpose.

The Committee also monitors the PSI's compliance with the law as it applies to public bodies, and the provisions of the Code of Practice for the Governance of State Bodies.

The PSI's assurance framework includes a programme of internal audits presented to the Committee for consideration and approval.

In 2023, the Audit and Risk Committee met in closed sessions with the internal auditor and considered internal audit reports on the following operational areas:

- The PSI's Pharmacy Inspection Processes,
- The PSI's Online Registration Processes,
- A Gap Analysis of the PSI's Cyber Security,

The Committee received regular reports from the PSI's Executive Leadership Team on progress regarding the implementation of recommendations from previous internal audit reports, as well as updates on the PSI's quarterly financial position, as well as briefings on the PSI's quarterly financial position and the management of current regulatory risks. The Committee also met with the External Auditors in closed session on 15 March 2023, following which it approved the PSI's 2022 annual report and year-end financial statements.

The Committee also received updates from the PSI's Data Protection Officer and Internal Health and Safety Appointee at each of its meetings.

The Committee continued to monitor the implementation of the Protected Disclosures (Amendment) Act 2022 across the organisation, as the PSI seeks to bring its policies and standard operating procedures into compliance with the requirements of the Act.

At each of its meetings, the Committee reviewed the PSI's corporate risk register with the PSI's Chief Risk Officer, and in 2023, conducted a deep dive on each of the following Business Area/Programme risk registers:

- The Business Transformation Programme Risk Register,
- The Corporate Services Risk Register
- The Community Pharmacy Assurance Risk Register
- The Governance & Programme Delivery Risk Register

A review of the effectiveness of the Committee was carried out in 2023, and the Committee is satisfied that it is operating effectively. The Committee also discussed additional training and development opportunities to support it in its work.

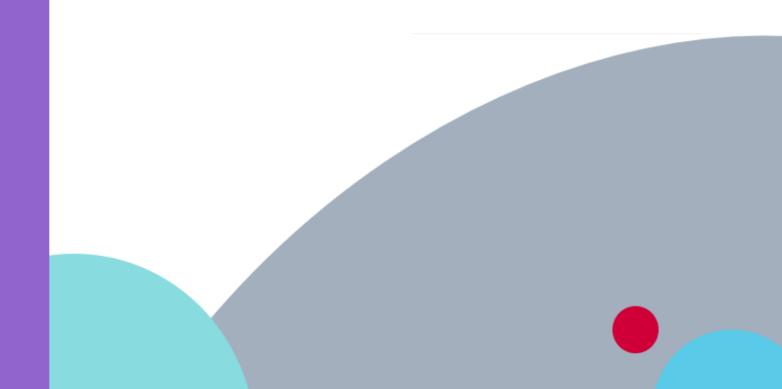
In 2023, the Committee was satisfied with the integrity of the PSI's assurance framework and believed it sufficient to provide the PSI Council with a basis for informed decision-making.

The Committee has reviewed the external audit management letter and is satisfied with the response received from the PSI's Executive Leadership Team. It is currently the opinion of the Audit and Risk Committee that the PSI has adequate systems of risk management and internal control in place and that the PSI is meeting its legal obligations.

On a personal note, I would like to thank former Committee member Mr. Graham Knowles for his hard work and commitment, from which both the PSI and the Audit and Risk Committee have benefitted enormously.

peradone Campbell

Ms Geraldine Campbell Chair PSI Audit and Risk Committee



## Our Risk Management Report: Principal risks and uncertainties

The Pharmaceutical Society of Ireland (PSI), through its Risk Management Framework, seeks to minimise or eliminate the impact of the risks to which it is exposed, ensuring it meets its strategic objectives and protects its core processes and functions, thereby meeting the expectations of its stakeholders.

The PSI Council is responsible for the PSI's system of internal control and is advised by the Audit and Risk Committee on its efficacy. The Council is responsible for setting the PSI's risk appetite and, with the assistance of the Audit and Risk Committee, monitoring the effectiveness of the organisation's risk management.

As a public body tasked with protecting public and patient safety, the PSI seeks to manage and mitigate risks that have the potential to affect the organisation's ability to meet its statutory remit.

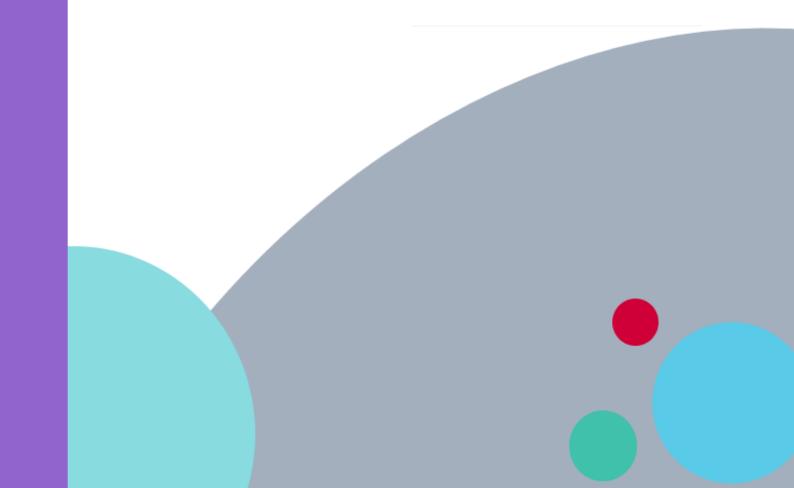
The PSI corporate risk register is a record of the principal risks to which the organisation is exposed at any given time. The PSI's Executive Leadership Team works closely with staff and stakeholders to identify and assess those risks and agree on mitigating measures to manage them. These risks are reviewed by both the Audit and Risk Committee and the Council. The Council has also considered the nature and extent of the risks it is willing to take to achieve the PSI's strategic objectives and reviews the corporate risk register at Council meetings.

This is a summary of the principal risks and uncertainties to which the PSI is exposed as of 31 December 2023:

- 1. The Council has continued to deliberate on the absence of rules in relation to the matter of temporary absence of registered pharmacists from a retail pharmacy business, which may occur where a registered pharmaceutical assistant is in place during that absence as provided for under the Pharmacy Act. To mitigate this risk, the Council proposed a draft set of statutory rules to the Minster for Health in 2019, which were subsequently the subject of a Judicial Review, which has concluded. The Council is of the view that the absence of rules remains a risk for the public and for the PSI, and in 2023, they continued to keep this matter under review.
- 2. The PSI relies on technology as a significant enabler for the delivery of our functions. The PSI carries risks related to operational effectiveness and service user access and experience owing to ageing ICT systems while new infrastructure is being developed, and risk to the PSI's business continuity should this be impacted by malicious cyber activity. To mitigate these risks, the PSI has taken steps to ensure ongoing system updates and testing take place, a business continuity plan is established, and antivirus software and cybersecurity infrastructure are in place.
- 3. The PSI keeps under review the potential for resource shortages arising from delays in recruiting suitable staff, and the potential impact on PSI's capacity to deliver at a time of change within the organisation. The PSI is taking steps to utilise recruitment panels where

suitable and will carry out a review of the current operating model to ensure it is operating as effectively as possible.

- 4. The PSI has a responsibility to ensure the effective operation of the Pharmacy Act, to take appropriate actions in accordance with its remit and to maintain the integrity of the system of pharmacy regulation in the public interest. The PSI has examined the model of regulation that applies to the regulated element of hospital pharmacies and is seeking to bring clarity to this matter.
- 5. The PSI Council continues to keep under review the number of pharmacies operating without a nominated supervising pharmacist in breach of the Pharmacy Act 2007. In order to fully understand the risk and put mitigation measures in place, the Council commissioned a project to be carried out in 2023 to look at factors impacting the pharmacy workforce. In addition, PSI also implemented an escalation process for pharmacies that failed to comply with the Pharmacy Act 2007.



## **Our Financial Report**

The 2023 Financial Statements of the PSI have been audited by Crowe Ireland. Extracts from these Financial Statements are contained below, together with commentary on the financial performance of the PSI for the year ended 31 December 2023.

#### Income

The total income in 2023 was €8.363m, which is an increase of 3.8% compared to the income received in 2022 of €8.058m. The PSI is mainly self-funded, currently with two main sources of income: registration and administration fee income and funding from the Department of Health for the Irish Institute of Pharmacy (IIOP) services.

The total fee income for 2023 is €7.763m, which is an increase of €305k compared to the fee income received in 2022. The increase was driven by the rise in the number of applications received for the recognition of pharmacist qualifications from EU/EEA and non-EEA applicants of €121k and an increase in the income from continued registration application fees of pharmacists of €118k.

The majority of continued registration fees are collected in November and December each year and are released over the applicable income period. The resultant deferred income (prepaid fees) held on 31 December 2023 was  $\in$  6.134m ( $\in$  6.024m in 2022) and is reflected in the cash held at that date in the Statement of Financial Position.

In 2023, funding of €0.600m was received from the Department of Health with respect to the Irish Institute of Pharmacy (IIOP). The drawdown of €0.600m represents the full allocation of funds from the Department of Health for 2023.

#### Cost of operations

The total cost of operations increased by  $\leq 1.167$ k in 2023 to  $\leq 9.196$ m, compared to  $\leq 8.029$ m in the previous year. This was due to a variety of factors, including the continued investment in the new online registration system (REGIE) and the application of the nationally agreed upon adjustments to public service pay, in accordance with the Public Service Agreement, *Building Momentum – A New Public Service Agreement 2021–2023*, as well as increased costs due to inflation. The most significant increases in expenditure were in the following areas, legal, consultancy, managing the third country qualification recognition route and pay costs.

In 2022, as part of the budget approval process, Council authorised the use of the Consolidated Income and Expenditure Reserves to fund a number of projects amounting to €639k, of which €542k was spent in 2023. Of the €542k, €198k was spent on Strategic Projects as defined under the Strategic Objective Reserve and €344k on the Business Transformation Project. The Fitness to Practise Rolling Reserve was also used to fund €187k of fitness to practise-related expenditure in 2023.

#### Pay costs

The level of permanent whole-time staff approved by the Department of Health in 2023 was not exceeded. The average number of staff on payroll during the year was 46. In 2023, the PSI also engaged temporary resources, namely agency staff, to enable the PSI to continue to fulfil its statutory obligations. The total pay costs, including employer PRSI, pension costs and temporary staff costs in 2023, were €4.132m, an increase of €0.542m or 15% on the 2022 cost of €3.590m.

In compliance with Schedule 1, paragraph 14 of the Pharmacy Act 2007, staff pay rates are approved by the Minister for Health with the consent of the Minister for Public Expenditure, NDP Delivery and Reform for health sector and civil sector grades. No bonuses, overtime, or performance payments were paid by the PSI in 2023, in accordance with the directive of the Department of Public Expenditure, NDP Delivery and Reform.

In compliance with the Code of Practice for the Governance of State Bodies 2016, the Registrar's salary costs, as approved by the Minister for Health with the consent of the Minister for Public Expenditure, NDP Delivery and Reform, are disclosed in the annual financial statements.

Travel and subsistence expenses, including international travel expenses, are disclosed in the annual financial statements and are subject to scrutiny through internal audit on a periodic basis.

#### Non-pay costs

The total non-pay costs in 2023 were €5.064m (2022: €4.881m). The major elements were:

• Legal fees	<b>2023</b> €m 1.025	2022 €m 0.895
Council/Committee fees and other costs	0.309	0.265
• Printing, postage, and stationery	0.119	0.097
• Energy costs	0.105	0.085
<ul> <li>Consultancy, professional fees, including consultancy costs on projects</li> </ul>	0.301	0.105
Third Country Qualification Recognition	0.306	0.179
• ICT costs	0.537	0.631
Repairs, maintenance, and other property costs	0.228	0.188
Depreciation	0.316	0.279
Insurance	0.112	0.099
Institute of Pharmacy (IIOP)	1.233	1.172

The IIOP operated for a full calendar year in 2023 and drew down €1.233m of its full operating budget allocation of €1.231m. This amount was offset by €600,000 from Department of Health funding received.

The PSI continued to use its approved Procurement Policy and the 2023 annual procurement plan to ensure that the best value for money was achieved and costs were contained to the best of our ability.

#### Financial results 2023 against budget

The table below outlines the operating income and expenditure results for 2023 against the original 2023 budget. These figures exclude capital-related transactions, which are accounted for in the Balance Sheet.

Outturns for the year 2023 from operating activities against the original budget as reported in the Management Accounts

	Original Budget	Outturn	Variance	Variance
	€	€	€	%
Total income	8,250,229	8,363,462	113,233	1%
Expenditure				
Pay costs	4,537,277	4,080,651	(456,626)	-10%
Non-pay costs	4,866,264	5,115,443	249,179	5%
Total expenditure	9,403,541	9,196,094	(207,447)	-2%
(Deficit) surplus from operating activities	(1,153,312)	(832,632)	(320,680)	28%
Interest income	59,800	72,076	12,276	21%
(Deficit) / surplus	(1,093,513)	(760,556)	332,957	-30%
Funding from reserves	693,302	728,324	35,021	5%
Adjusted (deficit) / Surplus for the year	(400,210)	(32,232)	367,978	-92%

#### Statement of financial position

The PSI's Statement of Financial Position as at 31 December 2023 shows that total assets exceeded total liabilities by €18.962m compared to €25.023 at 31 December 2021. This is the net assets of the PSI including PSI House. The Property was revalued on 5th October Oct. 2023. The revaluation loss of €5.300m is recognised in the Revaluation Reserve, reducing the Reserve to €6.114m.

It is represented in the Statement of Financial Position as follows:

	2023	2022
	€m	€m
Consolidated reserves	10,348	11.109
Revaluation reserve	6.114	11.414
Designated legal reserve	2.500	2.500
Closing reserves	18.962	25.023

The cash balance in the Statement of Financial Position at 31 December 2023 was €5.468m. This amount excludes €13.183m of cash invested in Exchequer notes with the National Treasury Management Agency and classified as investment assets under the Statement of Financial Position. At that point, the cash balance reached a peak as most registrants had prepaid their fees (deferred income) for the following year. The value of this deferred income was €6.134m (€6.024m in 2021). The investment assets include €5.414m of superannuation funds.

The cash and investment assets balance include the following commitments:

	2023	2022
	€m	€m
Deferred income (prepayment of fees)	6.134	6.024
Statutory staff superannuation scheme funds	5.943	5.586
Designated legal reserve	2.500	2.500
Consolidated reserves minimum level – 50% of fee income	3.882	3.729
Total cash committed	18.459	17.839
Unrestricted cash	0.191	1.338
	18.650	19.177

The PSI's statutory staff superannuation scheme fund of €5.943 million relates to the 'Pharmaceutical Society of Ireland Superannuation Scheme 2016', which was formally established on 10 March 2016, when S.I. 136 of 2016 was signed by the Minister for Health with the consent of the Minister for Public Expenditure and Reform, and which adopted the Rules for Pre-existing Public Service Pension Scheme Members Regulations 2014 (S.I. 582 of 2014).

This is a defined benefit scheme for the granting of superannuation benefits to, or in respect of, members of the staff. However, the scheme funds are held in designated deposit accounts pending approval of the funding mechanism for the scheme. The PSI continues to liaise with the Department of Health and the Department of Public Expenditure, NDP Delivery and Reform to progress this matter.

The Auditors, Crowe Ireland, state in the independent auditor's report that, in their opinion, the financial statements give a true and fair view of the state of the PSI's affairs as at 31 December 2023 and of its results for the year 2023. However, they have added an emphasis of matter note regarding the accounting treatment of the Superannuation Scheme for the reasons outlined in the above paragraph.

They are also of the opinion that the results for the year have been properly prepared in accordance with Schedule 1, paragraph 16 of the Pharmacy Act 2007 and the Financial Reporting Standard 102 'The Financial Reporting Standard applicable in the UK and Republic of Ireland'.

They are also of the opinion that the Statement on the System of Internal Controls in the financial statements reflects PSI's compliance with the requirements of paragraph 1.9 (iv) of the Code of Practice for the Governance of State Bodies 2016. They also confirm that they obtained all the information and explanations necessary for the purpose of the audit and the financial statements are in agreement with the accounting records. In their opinion, the accounting records of the PSI were sufficient to permit the financial statements to be readily and properly audited.

Internal audit activities for 2023 were undertaken for the PSI by the firm Crowleys DFK, 5 Lapps Quay Cork, T12 RW7D.

The external auditor was undertaken by the firm Crowe Ireland, Marine House, Clanwilliam Place, Dublin 2. D02FY24.

Registered office of the PSI: PSI House, 15-19 Fenian Street Dublin 2, D02 TD72 Phone: +353 1 2184000 Fax: +353 1 2837678 E-mail: info@psi.ie Website: www.psi.ie



# Financial Statements 2023





## Contents

Council's Report
Statement of Council's Responsibilities
Report from the President
Statement on the Systems of Internal Control
Independent Auditor's Report
Statement of Comprehensive Income
Statement of Financial Position
Statement of Cash Flows
Notes to the Financial Statements

### **Council Information**

#### President

Registrar

Head Office

Auditors

Vice President Council Members Ms Muireann Ní Shúilleabháin (until 17 June 2023) Ms Katherine Morrow (appointed 22 June 2023)

Ms Joan Peppard (appointed 22 June 2023) Mr Rory O'Donnell Dr Paula Barry Walsh Ms Geraldine Campbell Ms Geraldine Crowley Mr Peter Dennehy Ms Dorothy Donovan Mr Fintan Foy (until 17 June 2023) Mr John Given Mr Roy Hogan (until 17 June 2023) Mr Mark Jordan Prof Brian Kirby (until 17 June 2023) Mr Graham Knowles (until 17 June 2023) Dr Ann McGarry Ms Grainne Power Ms Marie Louisa Power Mr Sean Reilly Ms Avril Ryan (until 17 June 2023) Ms. Ann Sheehan (until 17 June 2023) Mr Paul Turpin (until 17 June 2023) Ms Emily Kelly (appointed 18 June 2023) Dr Denis O'Driscoll (appointed 18 June 2023) Prof Laura Sahm (appointed 18 June 2023) Mr Martin Higgins (appointed 18 June 2023) Mr Martin Sisk (appointed 18 June 2023) Dr Cyril O'Sullivan (appointed 18 June 2023) Ms Joan Peppard (appointed 18 June 2023) Mr Richard Hammond (appointed 13 November 2023) Dr Lorraine Horgan (Interim Registrar to 8 January 2023) Ms Joanne Kissane (appointed 9 January 2023)

PSI House 15-19 Fenian Street Dublin 2

Crowe Ireland 40 Mespil Road Dublin 4

Bankers	Bank of Ireland College Green Dublin 2
	Allied Irish Bank plc 18 Eyre Square Co. Galway
	Allied Irish Bank plc 1-4 Baggot Street Lower Dublin 2
Solictors	NTMA Treasury Dock North Wall Quay Dublin 1 Fieldfisher (incorporating McDowell Purcell) Solicitors The Capel Building Mary's Abbey Dublin 7

O'Connor's Solicitors 8 Clare Street

Dublin 2

## **Council's Report**

The Council presents its annual report and the audited financial statements for the year ended 31 December 2023.

#### **Principal activities**

The Pharmaceutical Society of Ireland (PSI) is an independent statutory body established by the Pharmacy Act 2007. The PSI is governed by a 21-member Council, which is appointed by the Minister for Health. The Council consists of a President, Vice President and 19 other Council members, with a lay member (non-pharmacist) majority.

The PSI has in place Codes of Conduct for Council, Advisory Committee members and employees. The PSI applies the highest standards of disclosure and transparency in respect of interests held by staff, Council and Committee members.

The principal activities of the PSI are as follows:

- Registration of pharmacists, pharmaceutical assistants and pharmacies;
- Improving the pharmacy profession, including ensuring all pharmacists are undertaking continuing professional development;
- Setting of standards for pharmacy education and training;
- Accreditation of educational programmes for the pharmacy profession at different levels;
- Quality assurance of standards and the development of pharmacy practice;
- Inspection and enforcement, including the taking of prosecutions;
- Handling complaints and disciplinary matters, including the imposition of sanctions;
- Provision of advice to the Government on pharmacy care, treatment and service in Ireland.

#### Internal control

The Council is responsible for the PSI's systems of internal control. Such systems can only provide reasonable and not absolute assurance against material misstatement or loss.

#### Audit and Risk Committee

The PSI has an Audit and Risk Committee comprising seven members, which met on four occasions during 2023. The Committee is responsible for reviewing internal control matters, together with any other issues raised by the Internal Auditors, External Auditors and Committee members.

#### **Remuneration Policy**

Remuneration and travel expenses paid to Council members are disclosed in the notes to the financial statements. No public sector Council members receive remuneration as directed by the Minister for Health.

The PSI pays its staff in accordance with Department of Health consolidated salary scales and the Civil Service salary scales.

#### **Financial results**

The financial results for 2023 show an operating deficit of (€832,632) (2022: Surplus of €29,211), which contributed to the total deficit for the financial year of (€760,556) (2022: Surplus of €35,089). The income for the year at €8.363m is a 3.8% increase on 2022 income of €8.058m.

In terms of annual reported expenditure, operating expenditure increased by €1.168k to €9.196m in 2023 compared to 2022 €8.029m, an increase of 15%. In line with the Corporate Strategy 2021-2024, PSI continued its investment in the business transformation programme and its strategic objective to bring more efficiency into its ways of working. As in 2022, 2023 also saw the application of the nationally agreed adjustments to public service pay in accordance with the Public Service Agreement "Building Momentum – A New Public Service Agreement 2021–2023 and the resulting increase in pay costs.

#### Principal risks and uncertainties

Within the current environment, there is a range of strategic, corporate and business level risks which are actively managed on an ongoing basis. These include the prioritisation of resources to deliver on the legal, statutory and professional mandate of the PSI, the maintenance of the efficacy and quality of the regulation, professional development and education, financial management, inspection and enforcement activities, ensuring appropriate and effective interaction with other regulators and registrants, as well as ensuring good governance remains in operation.

The PSI has sufficient cash reserves and does not foresee any cash flow risk in the near future.

#### Books of account

The Council is responsible for keeping proper books of account, which disclose with reasonable accuracy at any time the financial position and performance of the PSI. The Council is also responsible for safeguarding the assets of the PSI and, hence for taking reasonable steps for the prevention and detection of fraud and other irregularities. The books of account of the PSI are maintained at PSI House, 15/19 Fenian Street, Dublin 2.

#### Future developments

The Council is not expecting to make any significant changes in the nature of the business in the near future.

#### Post balance sheet events

There have been no circumstances or events subsequent to the year-end, which require adjustment to, or disclosure in, the financial statements or in the notes thereto since the year-end.

#### Statement of relevant audit information

Each of the persons who is a Council Member at the date of approval of this report confirms that:

- I. so far as the Council Member is aware, there is no relevant audit information of which the PSI auditors are unaware; and
- II. the Council Member has taken all the steps that he/she ought to have taken as a Council Member in order to make himself/herself aware of any relevant audit information and to establish that the PSI auditors are aware of that information.

#### Auditors

Crowe Ireland was appointed as the organisation's auditor in 2021, in accordance with Schedule 1, para 16(2) of the Pharmacy Act 2007.

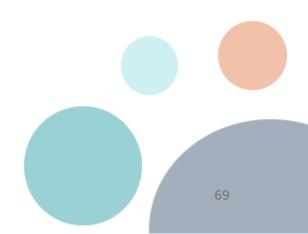
This report was approved by the Council on 21 March 2024 and signed on its behalf.

Kamer

Ms Katherine Morrow President

Peffrand .

Ms Joan Peppard Vice President



## Statement of Council's Responsibilities for year ended 31 December 2023

The Council is responsible for preparing this report and the financial statements in accordance with Irish law and regulations.

Schedule 1, paragraph 16, of the Pharmacy Act 2007 requires the Council to prepare the financial statements for each financial year. Under the law, the Council has elected to prepare the financial statements in accordance with Financial Reporting Standard 102 'The Financial Reporting Standard applicable in the UK and Republic of Ireland', issued by the Financial Reporting Council ("relevant financial reporting framework").

In preparing these financial statements, the Council is required to:

- select suitable accounting policies and then apply them consistently;
- make judgments and accounting estimates that are reasonable and prudent;
- state whether the financial statements have been prepared in accordance with applicable accounting standards, identify those standards, and note the effect and the reasons for any material departure from those standards; and
- prepare the financial statements on the going concern basis unless it is inappropriate to presume that the PSI will continue in business.

The Council is responsible for ensuring that the PSI keeps or causes to be kept adequate accounting records which correctly explain and record the transactions of the PSI, enable at any time the assets, liabilities, financial position and surplus or deficit of the PSI to be determined with reasonable accuracy, enable them to ensure that the financial statements and Council's report comply with Paragraph 16 of the Pharmacy Act 2007 and enable the financial statements to be audited. They are also responsible for safeguarding the assets of the PSI and, hence for taking reasonable steps for the prevention and detection of fraud and other irregularities.

On behalf of the Council on 21 March 2024:

americ

Ms Katherine Morrow

President

Peffrand

Ms Joan Peppard Vice President

## Report from the President in line with the Code of Practice for the Governance of State Bodies for the year ended 31 December 2022

In compliance with the Department of Public Expenditure and Reform's Code of Practice for the Governance of State Bodies 2016, I would like to confirm that:

- I. There were no commercially significant developments affecting the ongoing operations of the PSI in 2023.
- II. All appropriate procedures for financial reporting, internal audit, travel, procurement and asset disposals are being carried out. In 2023, there was one instance where non-compliance with procurement principles occurred, where the actual spend under a contract for the provision of services for bulk printing and mailing of registration certificates and other duty registers was over the advertised spend limit and EU procurement limit. This non-compliance arose out of the need to ensure no disruption in service for the bulk printing and mailing of registration certificates until a competitive procurement process was completed and a new contract put in place. The extension of the contract was approved by the Registrar.
- III. The Corporate Governance Framework also outlines that the PSI complies with disposal procedures for assets as outlined in the Code of Practice for the Governance of State Bodies. The Pharmacy Act 2007 states that any surplus following disposal of assets can be allocated to the development of education, research or any other public purpose connected with pharmacy.
- IV. A statement on the Systems of Internal Control has been included as part of these Financial Statements.
- **v.** Codes of Conduct for Council, Advisory Committee members and employees of the PSI are in place and are being adhered to.
- VI. Government policy on the pay of Chief Executives and all State body employees is being complied with. The PSI also complies with Government guidelines on the payment of Council Members' fees.
- VII. The Guidelines for the Appraisal and Management of Capital Expenditure Proposals in the Public Sector are being complied with.
- VIII. The PSI is primarily self-funding in relation to the vast majority of its expenditure. An annual €600,000 Department of Health grant is allocated via the PSI to part-fund services provided by the Irish Institute of Pharmacy (IIOP). Detailed oversight procedures are in place between the PSI and the Department, and contract and governance arrangements in place between the PSI and the IIOP service provider, which specify use of that funding for specific, and approved, work programmes related to initiatives and training for public health benefit. The PSI complies with its value-for-money strategy and appropriate governance and procurement arrangements, where applicable, in keeping with the Public Spending Code and procurement procedures for public bodies.
  - **IX.** The PSI is in compliance with Circular 25/2016 on the Protocol for the Provision of Information to Members of the Oireachtas by State Bodies.

- There are procedures in place for the making of protected disclosures in accordance with section 21(1) of the Protected Disclosures Act 2014. Details on protected disclosures made to the PSI in 2023 are contained in the PSI's Annual Report.
- XI. The PSI has taken steps to ensure that its systems and processes are compliant with the Department of Public Expenditure and Reform's Code of Practice for the Governance of State Bodies, 2016, except for the pension liability (Section 1.4 (ix) Business and Financial Reporting Requirements), as disclosed in the Financial Statements. The PSI developed a value-for-money strategy as part of its Corporate Procurement Plan covering the 2021-2024 period.
- XII. Government travel policy requirements are being complied with in all respects which include procedures to monitor, report and enforce relevant rules and requirements regarding foreign travel by employees of the PSI or Council members as outlined in the Code of Practice for the Governance of State Bodies.
- **XIII.** The PSI complies with its obligations under tax law.
- **XIV.** The PSI currently has no off-balance sheet financial transactions or significant post balance sheet events.
- **XV.** The PSI currently has no legal disputes with other State bodies.
- **XVI.** The PSI has no subsidiaries on which to report.

Gender Balance in the Council membership as at 31 December 2023:

The Council had [11] 52.4% female and [10] 47.6% male members, with no positions vacant. The Council, therefore, meets the Government target of a minimum of 40% representation of each gender in the membership of State Boards.

Eight new appointments and two re-appointments were made to the Council in 2023.

The following measures are used to maintain and support gender balance on the Council:

- The Council's annual evaluation process incorporates a review of the gender, diversity and skills mix within the Council.
- Submissions to the Minister on Council appointments and re-appointments highlight the gender composition of the Council.

This report has been formally approved by the PSI Council on 21 March 2024 and signed by the President:

Kamena mo

Ms Katherine Morrow President 21 March 2024

# Statement on the Systems of Internal Control for the year ended 31 December 2022

# Responsibility for the system of Internal Control

On behalf of the Council, I acknowledge our responsibility for the system of internal control in the PSI, and for putting in place processes and procedures for the purpose of ensuring that the system is effective. This responsibility takes account of the requirements of the Code of Practice for the Governance of State Bodies (2016) and the PSI's Corporate Governance Framework.

The system of internal control is designed to manage risk to a tolerable level rather than to eliminate it. The system can provide only reasonable and not absolute assurance that assets are safeguarded, transactions authorised and properly recorded, and that material errors or irregularities are either prevented or would be detected in a timely period.

# The Council has taken steps to ensure an appropriate internal control environment is in place by:

- Establishing formal procedures through various Committee functions to monitor the activities and safeguard the assets of the organisation.
- Clearly defining and documenting management responsibilities, powers, policies, and procedures in relation to activity.
- Developing a strong culture of accountability across all levels of the organisation.
- Establishing procedures for monitoring the effectiveness of internal control, which includes the appointment of Internal and External Auditors who operate in accordance with the Code of Practice for the Governance of State Bodies and report to the Audit and Risk Committee.
- Working closely with Government and various agencies and institutions to ensure that there is a clear understanding of the functions of the PSI and support for the PSI's strategies to fulfil its statutory obligations.

# The Council has also established processes to identify and evaluate risks to the organisation. This is achieved in a number of ways, including:

- Identifying the nature, extent and financial implications of risks facing the PSI.
- Assessing the likelihood of identified risks occurring.
- Assessing the PSI's ability to manage and mitigate the risks that do occur.
- Carrying out regular reviews of strategic plans and objectives, both short and long-term, and evaluating the risks of bringing those plans to fruition.
- Setting annual and longer-term targets for each area of the organisation followed by regular reporting on the results achieved.
- Presenting risks to the Audit and Risk Committee and Council at each meeting to ensure the risk management framework is operating effectively.

The system of internal control is based on a framework of regular management information, administrative procedures including segregation of duties, and a system of delegation and accountability. In particular, it includes:

- A detailed budgeting system with an annual budget, which is reviewed and agreed by the Council.
- Regular review by the Performance and Resources Committee, the Audit and Risk Committee and Council of quarterly management accounts, which indicate performance against agreed budget and provide explanation of significant deviations from budget.
- Setting targets to measure financial and other performance.
- Schedule 1, paragraph 16 of the Pharmacy Act 2007 requires the Council to prepare financial statements for each financial year, which give a true and fair view of the income, expenditure, assets, and liabilities of the PSI.
- The Performance and Resources Committee in 2023 also had an oversight role in relation to the organisation's performance against plan and capacity to deliver results, including funding of the annual Service Plan and strategic financing and investments, in line with the PSI's Corporate Strategy 2021-2024.
- Addressing financial implications of major business risks through setting authorisation limits and segregating duties.
- Establishing procurement policy and procedures to ensure compliance with procurement rules and guidelines set out by the Office of Government Procurement.

In 2023, the following controls were reviewed:

- Quarterly management accounts were reviewed by the Audit and Risk Committee, the Performance and Resources Committee, and the Council with an explanation of significant deviations from budget.
- Annual Accounts for 2022 were reviewed, approved and published by Council with explanation of significant variances.
- In keeping with the PSI's system of internal control, as provided for in the PSI's Internal Audit Plans, the Internal Auditors conducted reviews in the following areas:
  - The PSI's Pharmacy Inspection Processes,
  - The PSI's Online Registration Processes,
  - A Gap Analysis of the PSI's Cyber Security.

No weaknesses in internal control resulted in material losses, contingencies or uncertainties which require disclosure in the financial statements or the Auditor's Report on the financial statements. Appropriate steps recommended by the Internal Auditors are being undertaken, and responsibility for the implementation of all audit recommendations is attributed to the relevant manager and a timeline of implementation assigned. Implementation of internal audit recommendations are reported to the Audit and Risk Committee at each meeting. No breaches were reported for 2023. All elements of the control system were operational. No material losses or frauds were identified in 2023.

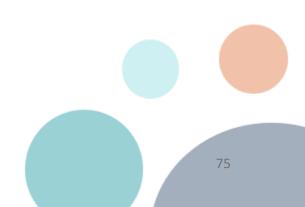
The PSI complies with current procurement rules and guidelines set out by the Office of Government Procurement. In 2023 there was one instance of non-compliance with the rules and guidelines, which is outlined in more detail in the Report from the President in the Financial Statements.

PSI's monitoring and review of the effectiveness of the system of internal control is informed by the work of the Internal and External Auditors, the Audit and Risk Committee and senior management within PSI, who are responsible for the development and maintenance of the internal control framework.

The Council is satisfied in relation to the effectiveness of the internal control systems based on the information and assurances provided. This Statement of the Systems of Internal Control has been formally reviewed and approved by the PSI Council on 21st March 2024 and signed on its behalf by the President of the PSI Council.

Kamena mm

Ms Katherine Morrow 21 March 2024



# Independent Auditors Report to the Council of the PSI

# Opinion

We have audited the financial statements of the Pharmaceutical Society of Ireland (PSI) for the year ended 31 December 2023, which comprise the Income Statement, Statement of Comprehensive Income, Statement of Financial Position, Statement of Cash Flows and related notes. The financial reporting framework that has been applied in their preparation is Irish Law and Financial Reporting Standard 102 'The Financial Reporting Standard applicable in the UK and Republic of Ireland'.

In our opinion, the accompanying financial statements:

- give a true and fair view of the state of the PSI's affairs as at 31st December 2023 and of its results for the year then ended;
- have been properly prepared in accordance with the Financial Reporting Standard 102 'The Financial Reporting Standard applicable in the UK and Republic of Ireland';
- have been prepared in accordance with the requirements of the Pharmacy Act 2007; and
- the Statement on the System of Internal Controls on pages 73 to 75 reflects the PSI's compliance with the requirements of paragraph 1.9 (iv) of the Code of Practice for the Governance of State Bodies 2016 and is consistent with the information gathered during our audit.

# Basis for opinion

We conducted our audit in accordance with International Standards on Auditing (Ireland) (ISAs (Ireland)) and applicable law. Our responsibilities under those standards are further described in the Auditors' responsibilities for the audit of the financial statements section of our report. We are independent of the body in accordance with the ethical requirements that are relevant to our audit of financial statements in Ireland, including the Ethical Standard issued by the Irish Auditing and Accounting Supervisory Authority (IAASA), and we have fulfilled our other ethical responsibilities in accordance with these requirements.

We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our opinion.

# Emphasis of matter- treatment of retirement pension

In forming our opinion, which is not qualified, we have considered the adequacy of the disclosures in Note 20 to the financial statements concerning the accounting treatment for retirement benefits. The PSI has not been advised on how best to administer the funds of the defined benefit pension scheme as the Department of Public Expenditure and Reform has yet to approve the funding mechanism for the scheme. The pension scheme has been accounted for in the financial statements as if it were a defined contributions scheme. Should the pension scheme have been accounted for under FRS 102 Section 28 the actuarial gain/loss would be recognised in the Statement of Comprehensive Income, and the surplus/deficit of the funds' assets over its liabilities would be recognised in the Statement of Financial Position as an asset or liability.

# Conclusions on going concern

In auditing the financial statements, we have concluded that the PSI's use of the going concern basis of accounting in the preparation of the financial statements is appropriate.

Based on the work we have performed, we have not identified any material uncertainties relating to events or conditions that, individually or collectively, may cast significant doubt on the PSI's ability to continue as a going concern for a period of at least twelve months from the date when the financial statements are authorised for issue.

Our responsibilities and the responsibilities of the Council with respect to going concern are described in the relevant sections of this report.

# Other information

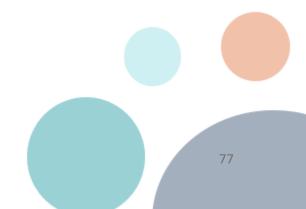
The Council is responsible for the other information. The other information comprises the information included in the Annual Report, other than the financial statements and our auditor's report thereon. Our opinion on the financial statements does not cover the other information, and except to the extent otherwise explicitly stated in our report, we do not express any form of assurance conclusion thereon.

In connection with our audit of the financial statements, our responsibility is to read the other information and, in doing so, consider whether the other information is materially inconsistent with the financial statements or our knowledge obtained in the audit or otherwise appears to be materially misstated. If we identify such material inconsistencies or apparent material misstatements, we are required to determine whether there is a material misstatement in the financial statements or a material misstatement of the other information. If, based on the work we have performed, we conclude that there is a material misstatement of this other information, we are required to report that fact.

We have nothing to report in this regard.

# Matters on which we are required to report by Schedule 1, Paragraph 16, of the Pharmacy Act 2007

- We have obtained all the information and explanations which we consider necessary for the purposes of our audit.
- In our opinion, the accounting records of the PSI were sufficient to permit the financial statements to be readily and properly audited.
- The financial statements are in agreement with the accounting records.



# Matters on which we are required to report by exception

Based on the knowledge and understanding of the body and its environment obtained in the course of the audit, we have not identified any material misstatements in the Council's report.

We have nothing to report in respect of our obligations under Schedule 1, paragraph 16, of the Pharmacy Act 2007 to report to you if, in our opinion, the disclosures of Council's remuneration and transactions specified by law are not made.

# Respective responsibilities of the Council and Auditors

As explained more fully in the Council's statement of responsibilities, the Council is responsible for the preparation of the Annual Report and the financial statements and, for being satisfied that they give a true and fair view, and for such internal control as the Council determines is necessary to enable the preparation of financial statements that are free from material misstatement, whether due to fraud or error.

In preparing the financial statements, the Council is responsible for assessing the body's ability to continue as a going concern, disclosing, as applicable, matters related to going concern and using the going concern basis of accounting unless the Council either intends to liquidate the organisation or to cease operations, or have no realistic alternative but to do so.

# Auditor's responsibilities for the audit of the financial statements

Our objectives are to obtain reasonable assurance about whether the financial statements, as a whole, are free from material misstatement, whether due to fraud or error and to issue an auditor's report that includes our opinion. Reasonable assurance is a high level of assurance but is not a guarantee that an audit conducted in accordance with ISAs (Ireland) will always detect a material misstatement when it exists. Misstatements can arise from fraud or error and are considered material if, individually or in the aggregate, they could reasonably be expected to influence the economic decisions of users taken on the basis of these financial statements.

As part of an audit in accordance with ISAs (Ireland), we exercise professional judgment and maintain scepticism throughout the audit. We also:

- Identify and assess the risks of material misstatement of the financial statements, whether due to fraud or error, design and perform audit procedures responsive to those risks, and obtain audit evidence that is sufficient and appropriate to provide a basis for our opinion. The risk of not detecting a material misstatement resulting from fraud is higher than for one resulting from error, as fraud may involve collusion, forgery, internal omissions, misrepresentations, or the override of internal control.
- Obtain an understanding of internal control relevant to the audit in order to design procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion of the effectiveness of the organisation's internal control.
- Evaluate the appropriateness of accounting policies used and the reasonableness of accounting estimates and related disclosures made by the Council.

- Conclude on the appropriateness of the Council's use of the going concern basis of accounting and, based on the audit evidence obtained, whether uncertainty exists related to events or conditions that may cast significant doubt on the organisation's ability to continue as a going concern. If we conclude that a material uncertainty exists, we are required to draw attention in our Auditors' Report to the related disclosures in the financial statements or, if such disclosures are inadequate, to modify our opinion. Our conclusions are based on the audit evidence obtained up to the date of our Auditors' Report. However, future events or conditions may cause the organisation to cease to continue as a going concern.
- Evaluate the overall presentation, structure and content of the financial statements, including the disclosures, and whether the financial statements represent the underlying transactions and events in a manner that achieves fair presentation.

We communicate with those charged with governance regarding, among other matters, the planned scope and timing of the audit and significant audit findings, including any significant deficiencies in internal control that we identify during our audit.

# The purpose of our audit work and to whom we owe our responsibilities

This report is made solely to the PSI Council. Our audit work has been undertaken so that we might state to the Council those matters we are required to state to them in an auditors' report and for no other purpose. To the fullest extent permitted by law, we do not accept or assume responsibility to anyone other than the Council for our audit work, for this report, or for the opinions we have formed.

Shaw McClung for and on behalf of Crowe Ireland Chartered Accountants and Statutory Audit Firm 40 Mespil Road Dublin 4 27 March 2024



# **Statement of Comprehensive Income for year ended 31 December 2023**

	Notes	2023	2022
		€	€
Income			
	3	8,363,462	8,057,712
Operating expenses		(9,196,094)	(8,028,501)
Operating surplus/(deficit)		(832,632)	29,211
Interest Receivable	9	72,076	5,878
Surplus/(deficit) before taxation		(760,556)	35,089
		(700,550)	
Taxation	11	-	-
Surplus/(deficit) for the financial year		(760,556)	35,089
		(,,	53,005

The statement of comprehensive income has been prepared on the basis that all operations are continuing operations.

The notes on pages 83 to 102 form part of these financial statements.

# Statement of Financial Position for year ended 31 December 2022

	Notes	2023	2022
		€	€
Fixed assets			
Tangible assets	12	13,460,301	18,805,196
Investment assets	13	13,182,685	12,000,000
Current assets	-	26,642,986	30,805,196
Debtors	15	229,580	192,400
Cash at bank and in hand	16	5,467,540	7,176,843
		5,697,120	7,369,243
Creditors: amounts falling due within one year	18	(13,377,904)	(13,151,681)
Net current assets/(liabilities)	-	(7,680,784)	(5,782,438)
Total assets less current liabilities	-	18,962,202	25,022,758
<b>Reserves</b> Revaluation Reserve	-		
	19	6,113,635	11,413,635
Designated Legal Reserve	19	2,500,000	2,500,000
Consolidated Reserves	19	10,348,567	11,109,123
Closing Reserves	-	18,962,202	25,022,758
	-		

The financial statements were approved and authorised for issue by the Council on 21 March 2024. Signed on behalf of the Council:

Kamen m

Joan Peffrand.

Ms Katherine Morrow

President

Ms Joan Peppard

Vice President

21 March 2024

# Statement of Cash Flows for year ended 31 December 2022

	€	2023 €	€	2022 €
Cash flows from operating activities	C	C		C C
Surplus/(deficit) for the financial year	(760,556)		35,089	
Depreciation on tangible assets	315,987		278,790	
Interest received Decrease/(increase) in debtors Increase/(decrease) in creditors due within one year	(72,076) (37,180) 226,223		(5,878) (11,832) 940,764	
Net cash flows from operating activities		(327,602)		1,236,933
Cash flows from investing activities	-			
Payments for tangible fixed assets	(271,092)		(256,823)	
Payments for investment assets	(1,182,685)		(4,800,000)	
Interest received	72,076	_	5,878	
Net cash flows from investing activities	_	(1,381,701)		(5,050,945)
Net decrease in cash and cash equivalents	_	(1,709,303)		(3,814,012)
Cash and cash equivalents at beginning of	financial year	7,176,843		10,990,855
Cash and cash equivalents at end of finance	ial year	5,467,540		7,176,843
<b>Relating to:</b> Cash at bank and in hand	_	5,457,540		7,176,843

The notes on pages 83 to 102 form part of these financial statements.

# Notes to the Financial Statements for year ended 31 December 2023

# 1. Accounting Policies

#### 1.1. Compliance with accounting standards and basis of preparation

The financial statements have been prepared on the going concern basis and in accordance with the historical cost convention modified to include certain items at fair value. The financial reporting framework that has been applied in their preparation is the FRS 102, "The Financial Reporting Standard applicable in the UK and Republic of Ireland", issued by the Financial Reporting Council, with the exception of the superannuation scheme, as the provisions of FRS 102 Section 28, Accounting for Employee Benefits, have not been applied.

The preparation of financial statements in compliance with FRS 102 requires the use of certain critical accounting estimates. It also requires the Council to exercise judgement in applying the organisation's accounting policies (see note 2).

The financial statements are prepared in euros, which is the functional currency of the organisation. Monetary amounts in these financial statements are rounded to the nearest €.

The financial statements have been prepared under the historical cost convention modified to include certain items at fair value. The following accounting policies have been applied:

# 1.2. Income

Income is recognised in the financial statements in the year to which the income relates to. To the extent income is received in advance, it is deferred and recognised in the relevant period for which services for these applications for registration or fees are given.

# 1.3. Tangible fixed assets

Tangible fixed assets under the cost model are stated at historical cost less accumulated depreciation and any accumulated impairment losses. Historical costs include expenditure that is directly attributable to bringing the asset to the location and condition necessary for it to be capable of operating in the manner intended by management.

The PSI adds to the carrying amount of an item of fixed assets the cost of replacing part of such an item when that cost is incurred, if the replacement part is expected to provide incremental future benefits to the PSI. The carrying amount of the replaced part is derecognised. Repairs and maintenance are charged to profit or loss during the period in which they are incurred.

Except as below, depreciation is charged so as to allocate the cost of assets less their residual value over their estimated useful lives, using the straight-line method. The estimated useful lives range is as follows:

# Depreciation

Depreciation is provided on the following basis:

Freehold property	-	Not depreciated
Office equipment & fittings software badges	- -	12.5% Straight-line Computer equipment & 33.3% Straight-line Portraits, medals and Not depreciated
Electrical	-	5% Straight-line
Mechanical & Lift	-	5% Straight-line Refurbishments – Audio Visual 12.5% Straight-line Online Registration and CRM
System	-	20% Straight-line

The freehold property owned by the PSI is re-valued every three to five years to reflect the current market value. The property was revalued on 5 October 2023.

Although FRS 102 Section 17 in relation to Property, Plant and Equipment normally requires the systematic annual depreciation of property, the Council believes the policy of not providing depreciation on the freehold property is appropriate. The policy adopted of revaluation of the property more accurately reflects its value to the PSI because the PSI has a policy and practice of regular maintenance and repairs such that the property is kept to its previously assessed standard of performance and the estimated residual value is material.

The carrying value of tangible fixed assets are reviewed annually for impairment in periods where events or changes in circumstances indicate the carrying value may not be recoverable.

# **1.4. Revaluation of tangible fixed assets**

Freehold property is carried at revalued amount, fair value at the date of the revaluation, less any subsequent accumulated impairment losses. Revaluations are undertaken with sufficient regularity to ensure the carrying amount does not differ materially from that which would be determined using fair value at the Statement of Financial Position date.

Fair values are determined from market-based evidence normally undertaken by professionally qualified valuers.

Revaluation gains and losses are recognised in the Revaluation Reserve unless losses exceed the previously recognised gains or reflect a clear consumption of economic benefits, in which case the excess losses are recognised in the Statement of Comprehensive Income.

# 1.5. Impairment of assets other than financial instruments

At the end of each reporting period, the PSI assesses whether there is any indication that the recoverable amount of an asset is less than its carrying amount. If any such indication exists, the carrying amount of the asset is reduced to its recoverable amount, resulting in an impairment loss. Impairment losses are recognised immediately in the profit and loss account, with the exception of losses on previously revalued tangible fixed assets, which are recognised in other comprehensive income to the extent of any previously recognised revaluation increase accumulated in equity in respect of that asset.

Where the circumstances causing an impairment of an asset no longer apply, then the impairment is reversed through the profit and loss account, except for impairments on previously revalued tangible assets, which are treated as revaluation increases to the extent that the revaluation was recognised in equity.

The recoverable amount of tangible fixed assets, goodwill and other intangible fixed assets is the higher of the fair value less cost to sell of the asset and its value in use. The value in use of these assets is the present value of the cash flows expected to be derived from those assets. This is determined by the reference to the present value of the future cash flows of the cash-generating unit to which the assets belong.

# 1.6. Investment assets

Investment assets are valued at the lower of cost and net realisable value.

# 1.7. Debtors

Short term debtors are measured at transaction price, less any impairment.

# **1.8. Financial instruments**

The PSI only enters into basic financial instrument transactions that result in the recognition of financial assets and liabilities, like trade and other accounts receivable and payable.

Financial assets and liabilities that are payable or receivable within one year, typically trade payables or receivables, are measured, initially and subsequently, at the undiscounted amount of the cash or other consideration expected to be paid or received.

Financial assets and liabilities are offset, and the net amount reported in the Statement of Financial Position when there is an enforceable right to set off the recognised amounts and there is an intention to settle on a net basis or to realise the asset and settle the liability simultaneously.

# 1.9. Cash and cash equivalents

Cash and cash equivalents are basic financial assets and include cash in hand, deposits held with banks, other short-term liquid investments with original maturities of three months or less, and bank overdrafts.

# 1.10. Creditors

Short term creditors are measured at the transaction price. Other financial liabilities, including bank loans, are measured initially at fair value, net of transaction costs, and are measured subsequently at amortised cost using the effective interest method.

# 1.11. Pensions

# The Pharmaceutical Society of Ireland Superannuation Scheme 2016

On 10 March 2016, SI 136 of 2016 was signed by the Minister for Health with the consent of the Minister for Public Expenditure and Reform, which adopted the Rules for Pre-existing Public Service Pension Scheme Members Regulations 2014 (S.I. No. 582 of 2014) and the Pharmaceutical Society of Ireland Superannuation Scheme 2016 came into operation for the granting of superannuation benefits to, or in respect of, members of staff eligible for membership of this scheme.

The PSI's contributions to the scheme are charged to the Income Statement in the period to which they relate. A funding mechanism for this scheme has not yet been approved, and as such, the scheme funds are being collected and held on deposit by the PSI. The provisions of FRS 102 Section 28, Accounting for Retirement Benefits, have not been applied.

# The Single Public Service Pension Scheme

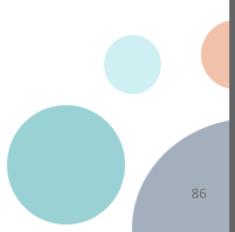
The Single Public Service Pension Scheme came into effect on the 1st January 2013 as provided for in the Public Service Pensions (Single Scheme and Other Provisions) Act 2012. The Act provides for a single scheme for new entrants to the public service. The PSI collects and remits contributions for this scheme to the Department of Public Expenditure, NDP Delivery and Reform.

# 1.12. Holiday pay accrual

A liability is recognised to the extent of any unused holiday pay entitlement, which is accrued at the Statement of Financial Position date and carried forward to future periods. This is measured at the undiscounted salary cost of the future holiday entitlement so accrued at the Statement of Financial Position date.

# 1.13. Interest income

Interest income is recognised in the Income Statement using the effective interest method.



# 1.14. Consolidated reserves

In 2022, the Council approved a new Reserves Policy as part of the PSI Strategic Financing Review. The new policy comprises a consolidated reserves approach, which ringfences the Designated Legal Reserve and consolidates all other reserves as one single, undifferentiated resource termed Consolidated Reserves.

In order to ensure adequacy of reserve requirements for certain identified needs, such as covered by the upper limits outlined below, the Council agreed the minimum threshold amount for all reserves (exclusive of the Revaluation Reserve) is set at the level of 50 per cent of turnover/fee income. This will ensure adequate funding is set aside for identified contingencies.

The limits on these reserves have been agreed by Council and will be kept under annual review to ensure they remain fit for purpose.

The consolidated reserves comprise of the following:

- Income and Expenditure Reserve
- Strategic Objectives Reserve
- Future Technology Investment Reserve
- Building Maintenance Reserve
- Fitness to Practise Rolling Reserve

# 1.15. Designated legal reserve

The PSI established a designated reserve within its reserves, which has been set aside by the Council for a specific purpose, namely for the cost of any future legal cases that the PSI may encounter. Expenditure cannot be directly set against designated reserves but is taken through the Income statement. A transfer is then made from the Income and Expenditure Reserve as appropriate.

# 1.16. Taxation

The Finance Act 2013, Section 35, amends the Schedule to the Taxes Consolidation Act 1997 to include the Pharmaceutical Society of Ireland in the list of specified non-commercial State sponsored bodies that qualify for exemption from certain tax provisions under Section 227 of the Taxes Consolidation Act 1997.

# 2. Judgements and key sources of estimation uncertainty

The preparation of these financial statements requires the Council to make judgements, estimates and assumptions that affect the application of policies and reported amounts of assets and liabilities, income and expenses.

Judgements and estimates are continually evaluated and are based on historical experiences and other factors, including expectation of future events that are believed to be reasonable under the circumstances.

The Council considers the accounting estimates and assumptions below to be its critical accounting estimates and judgements:

# **Going Concern**

The PSI has prepared budgets for a period of at least twelve months from the date of the approval of the financial statements, which demonstrate that there is no material uncertainty regarding the PSI's ability to meet its liabilities as they fall due and to continue as a going concern.

The PSI has a reasonable expectation, at the time of approving the financial statements, that the PSI has adequate resources to continue its operations. For this reason, the PSI continues to adopt the going concern basis in preparing the financial statements.

# 3. Income

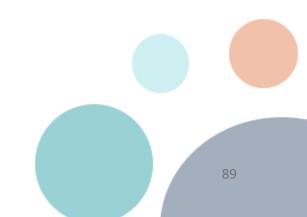
The total income of the PSI has been derived from its principal activity wholly undertaken in Ireland.

	2023	2022
	€	€
Registration of pharmacists	2,909,812	2,710,217
Registration of retail pharmacy business (RPB)	4,552,936	4,478,206
Administration charges and other registration costs	270,256	228,604
Internet Supply	30,458	40,685
Department of Health funding for Irish Institute of Pharmacy (IIOP) services	600,000	600,000
	8,363,462	8,057,712

# 4. Operating surplus

Operating surplus for the year is calculated after charging:

	2023	2022
	€	€
Depreciation of tangible assets	315,987	278,790
Other pension costs	529,485	442,426
Audit Remuneration (including VAT)		
-Audit Fees	18,077	31,094
	863,549	752,310
5. Employees		
5.1. Average numbers		
	2023	2022
Office and management	46	43



# 5.2. Aggregate remuneration

Their aggregate remuneration comprised:

	2023	2022
	€	€
Wages and salaries	3,016,129	3,058,915
Social insurance costs	308,361	254,208
Pension costs	554,418	442,425
	3,878,908	3,755,548
Analysed as follows		
Capitalised into assets	154,065	165,308
Expensed in the year	3,724,843	3,590,240
	3,878,908	3,755,548

# 5.3. Analysis of staff salary costs in excess of €60,000:

The number of employees whose employment benefits fell within each band of €10,000 from €60,000 up is as follows:

	2023	2022
€60,000 to €70,000	6	4
€70,000 to €80,000	8	7
€80,000 to €90,000	4	3
€90,000 to €100,000	2	2
€100,000 to €110,000	1	-
€110,000 to €120,000	3	2
€120,000 to €130,000	-	-
	24	18

# 5.4. Key Management Personnel

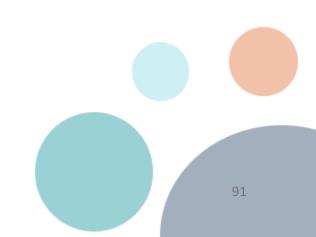
The remuneration of key management personnel was as follows:

	2023	2022
	€	€
Wages and salaries	565,688	474,423
Allowances	323	12,197
Other pension costs	122,404	109,131
	688,415	595,751

# 5.5. Registrar Remuneration

Included in wages and salaries above is Registrar remuneration as follows:

	2023	2022
	€	€
Former Registrar	-	4,506
Other pension costs	-	751
Interim Registrar	4,977	114,881
Other pension costs	301	28,720
Current Registrar	114,191	-
Other pension costs	19,482	
	138,951	148,858



# 6. Other Staff Costs

#### 6.1 Staff Travel and Subsistence

	2023	2022
	€	€
Domestic	21,691	12,635
International	275	7,177
	21,966	19,812
6.2 Hospitality Expenditure		
	2023	2022
	€	€
Staff hospitality	3,191	861
	3,191	861
· · · · · · · · · · · · · · · · · · ·		

	2023	2022
	€	€
Council/Committee members' remuneration	213,648	206,889
	213,648	206,889

# 8. Council/Committee members' travel and subsistence

	2023	2022
	€	€
Domestic	44,295	28,586
International	-	6,117
	44,295	34,703

# 9. Interest receivable

2023	2022
€	€
72,076	5,878
72,076	5,878
	€ 72,076

# **10. Consultancy and legal costs**

# **10.1 Consultancy costs**

Consultancy costs here include the cost of expert analysis and advice that contribute to decision-making or policymaking and exclude expenditure on outsourced 'business as usual' functions.

	2023	2022
	€	€
Business improvement	55,432	5,658
Strategic projects	198,116	48,364
	253, 548	54,022
Consultancy costs capitalised	29,213	-
Consultancy costs charged to the Income and Expenditure and Retained Earnings Reserves	224,335	54,022
	253,548	54,022

# **10.2** Legal costs and settlements

The table below provides a breakdown of amounts recognised as expenditure in the reporting period in relation to legal costs, settlements conciliation and arbitration proceedings relating to contracts with third parties. This does not include expenditure incurred in relation to general legal advice received by the PSI.

	2023	2022
	€	€
Legal fees	977,494	856,819
Conciliation and arbitration payments settlements		-
	32,042	
	1,009,536	856,819

Legal costs primarily relate to PSI's activities arising out of Part 6 of the Pharmacy Act 2007. It includes fees relating to external advisors, barristers, witnesses (expert and factual), legal assessors and third-party legal fees.

In 2023, legal fees amounted to €977,494 (2022: €856,819), which also includes fees relating to advices received regarding other activities arising out of the Pharmacy Act 2007, such as registration, education and other operational costs.

The 2022 figures contain fees in relation to Judicial Review proceedings, which concerned proposed Statutory Rules dealing with the temporary absence of pharmacists in registered retail pharmacy businesses.

The settlement payments arose from two cases and no costs were paid by PSI insurers.

# 11. Taxation

The PSI is exempt from liability to Corporation Tax under Section 227 of the Taxes Consolidation Act 1997.

# 12. Tangible fixed assets

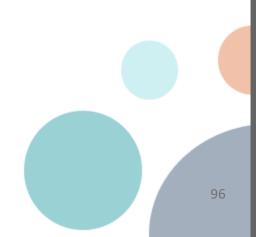
	Freehold land and buildings	Premises improvements	Portraits, medals and badges	Office fixtures and fittings	•	Total
	€	€	€	€	€	€
Cost						
At 1 January 2023	17,700,000	40,808	10,431	269,359	1,644,747	19,665,345
Additions	-	3,025	-	20,152	247,915	271,092
Revaluation	(5,300,000)					(5,300,000)
Cost of Disposal	-	-	-	-	-	
At 31 December 2023	12,400,000	43,833	10,431	289,511	1,892,662	14,636,437
Depreciation and impairment						
At 1st January 2023	-	21,469	-	239,585	599,095	860,149
Depn. eliminated on disposals	-	-	-	-	-	-
Depn. charged in the year		5,038	-	8,367	302,582	315,987
At 31 December 2023	-	26,507	-	247,952	901,677	1,176,136
Carrying amount						
At 1 January 2023	17,700,000	19,339	10,431	29,774	1,045,652	18,805,196
At 31 December 2023	12,400,000	17,326	10,431	41,559	990,985	13,460,301

#### **13. Investment Assets**

#### Investment assets

2023	2022
€	€
13,182,685	12,000,000
13,182,685	12,000,000
2023	2022
€	€
12,000,000	7,200,000
1,182,685	4,800,000
-	-
13,182,685	12,000,000
	€ 13,182,685 13,182,685 2023 € 12,000,000 1,182,685 -

The PSI purchased and reinvested an additional total of €1,182,685 into Exchequer Notes during the year, all with maturity dates in 2024. The fair value at 31st Dec. 2023 was €13,182,685 (2022: €12,000,000). The investment assets include €5,413,650 of superannuation funds. The Designated Legal Reserve funds of €2,500,000 were also invested in Exchequer Notes.



# **14. Financial instruments**

・・・・・・・・・・・・・・・・・・・・・・・・・・・・・・・・・・・・	14. Financial instruments	2023	2022
Bank and cash balances       5,467,540       7,176,843         Investment assets       13,182,685       12,000,000         18,650,225       19,176,843         Financial Liabilities       18,650,225       19,176,843         Trade creditors       393,146       572,918         15. Debtors       2023       2022         C       €       €         Trade Debtors       28,410       65,359         Prepayments and accrued income       192,983       118,854         Other Debtors       8,187       8,187         16. Cash and cash equivalents       2023       2022         C       €       €         16. Cash and cash equivalents       2023       2022         C       €       €         16. Cash and cash equivalents       2023       2022         C       €       €         C       2023       2022         C       €       €         C       €       €         C       €       €         C       €       €         C       €       €		€	€
Investment assets       13,182,685       12,000,000         18,650,225       19,176,843         Financial Liabilities         Trade creditors       393,146       572,918         15. Debtors       2023       2022         Frade Debtors       28,410       65,359         Prepayments and accrued income       192,983       118,854         Other Debtors       8,187       8,187         229,580       192,400       192,400         16. Cash and cash equivalents       2023       2022         €       €       €         E       €       €         E       €       €         E       €       €         E       €       €         E       €       €         E       €       €         E       €       €	Financial assets		
13,182,685       12,000,000         18,650,225       19,176,843         Financial Liabilities       Image: Constraint of the second secon	Bank and cash balances	5,467,540	7,176,843
18,650,225       19,176,843         Financial Liabilities	Investment assets		
I8,650,225       19,176,843         Financial Liabilities       Image: Constraint of the second		13,182,685	12,000,000
Financial Liabilities         Trade creditors       393,146       572,918         15. Debtors       2023       2022         Trade Debtors       €       €         Prepayments and accrued income       192,983       118,854         Other Debtors       8,187       8,187         16. Cash and cash equivalents       2023       2022         €       €       €         0       100,080       1192,980         16. Cash and cash equivalents       2023       2022         €       €       €         0       100,080       100,080         100,080       100,080       100,080         100,080       100,080       100,080         100,080       100,080       100,080         100,080       100,080       100,080         100,080       100,080       100,080         100,080       100,080       100,080		10,102,000	12,000,000
Financial Liabilities         Trade creditors       393,146       572,918         15. Debtors       2023       2022         Trade Debtors       €       €         Prepayments and accrued income       192,983       118,854         Other Debtors       8,187       8,187         16. Cash and cash equivalents       2023       2022         €       €       €         0       100,080       1192,980         16. Cash and cash equivalents       2023       2022         €       €       €         0       100,080       100,080         100,080       100,080       100,080         100,080       100,080       100,080         100,080       100,080       100,080         100,080       100,080       100,080         100,080       100,080       100,080         100,080       100,080       100,080			
Trade creditors       393,146       572,918         15. Debtors       2023       2022         €       €       €         Trade Debtors       28,410       65,359         Prepayments and accrued income       192,983       118,854         Other Debtors       8,187       8,187         229,580       192,400       192,400         16. Cash and cash equivalents       2023       2022         €       €       €         €       €       €         €       €       €		18,650,225	19,176,843
Trade creditors       393,146       572,918         15. Debtors       2023       2022         €       €       €         Trade Debtors       28,410       65,359         Prepayments and accrued income       192,983       118,854         Other Debtors       8,187       8,187         229,580       192,400       192,400         16. Cash and cash equivalents       2023       2022         €       €       €         €       €       €         €       €       €			
Trade creditors       393,146       572,918         15. Debtors       2023       2022         €       €       €         Trade Debtors       28,410       65,359         Prepayments and accrued income       192,983       118,854         Other Debtors       8,187       8,187         229,580       192,400       192,400         16. Cash and cash equivalents       2023       2022         €       €       €         €       €       €         €       €       €	Financial Liabilities		
15. Debtors       2023       2022         Frade Debtors       28,410       65,359         Prepayments and accrued income       192,983       118,854         Other Debtors       8,187       8,187         229,580       192,400       192,400         16. Cash and cash equivalents       2023       2022         €       €       €         €       €       €			
15. Debtors       2023       2022         Frade Debtors       28,410       65,359         Prepayments and accrued income       192,983       118,854         Other Debtors       8,187       8,187         229,580       192,400       192,400         16. Cash and cash equivalents       2023       2022         €       €       €         €       €       €	Trada araditara	202 146	E72 019
Ended       E       E         Trade Debtors       28,410       65,359         Prepayments and accrued income       192,983       118,854         Other Debtors       8,187       8,187         229,580       192,400       192,400         16. Cash and cash equivalents       2023       2022         E       E       E		393,146	572,918
Endextor       E       E         Trade Debtors       28,410       65,359         Prepayments and accrued income       192,983       118,854         Other Debtors       8,187       8,187         229,580       192,400       192,400         16. Cash and cash equivalents       2023       2022         E       E       E			
Endextor       E       E         Trade Debtors       28,410       65,359         Prepayments and accrued income       192,983       118,854         Other Debtors       8,187       8,187         229,580       192,400       192,400         16. Cash and cash equivalents       2023       2022         E       E       E			
Ended       E       E         Trade Debtors       28,410       65,359         Prepayments and accrued income       192,983       118,854         Other Debtors       8,187       8,187         229,580       192,400       192,400         16. Cash and cash equivalents       2023       2022         E       E       E	15 Debter	2022	2022
Trade Debtors       28,410       65,359         Prepayments and accrued income       192,983       118,854         Other Debtors       8,187       8,187         229,580       192,400       192,400         16. Cash and cash equivalents       2023       2022         €       €       €	15. Debtors		
Other Debtors       8,187       8,187         229,580       192,400         16. Cash and cash equivalents       2023       2022         €       €       €		28,410	
229,580       192,400         16. Cash and cash equivalents       2023       2022         €       €       €	Prepayments and accrued income	192,983	118,854
229,580       192,400         16. Cash and cash equivalents       2023       2022         €       €       €			
16. Cash and cash equivalents 2023 2022 € €	Other Debtors	8,187	8,187
2023 2022 € €		229,580	192,400
2023 2022 € €			
€ €	16. Cash and cash equivalents	2023	2022
Cash at bank and in hand         5,467,540         7,176,843			
	Cash at bank and in hand	5,467,540	7,176,843

17. Cash	2023	2022
Cash at hand	€ 163	€ 309
Current accounts	4,269,513	5,398,038
Superannuation funds deposit account	200,950	536,964
Fixed term deposits	996,914	1,241,532
	5,467,540	7,176,843

18. Creditors: amounts falling due within one year		
	2023	2022
	€	€
Trade creditors	393,146	572,918
Other creditors	15,774	12,827
PAYE/PRSI	133,984	162,244
VAT	111	-
PSWT	44,557	29,353
Deferred income	6,133,958	6,023,678
Accruals	713,504	764,838
PSI Superannuation scheme	5,942,870	5,585,823
	13,377,904	13,151,681

# 19. Reserves

In 2022, the Council approved a new Reserves Policy as part of the PSI Strategic Financing Review, which was further updated in 2023. The new policy comprises a consolidated reserves approach, which ringfences the Designated Legal Reserve and consolidates all other reserves as one single, undifferentiated resource termed Consolidated Reserves.

In order to ensure adequacy of reserve requirements for certain identified needs, such as covered by the upper limits outlined in section 19.3, the minimum threshold amount for all reserves (exclusive of the Revaluation Reserve) is set at the level of 50 per cent of turnover/fee income. This will ensure adequate funding is set aside for identified contingencies.

The limits on these reserves have been agreed by Council and are kept under annual review to ensure they remain fit for purpose. Council reviewed the Reserves Policy on 14 December 2023.

# **19.1 Revaluation reserve**

The freehold property was valued by Murphy Mulhall Chartered Surveyors on the 5 October 2023 to a fair value of €12,400,000, down from the valuation of €17,700,000 undertaken in 2019. The PSI has reflected this revised valuation in the accounts for the year ended 31st December 2023.

# **19.2 Designated legal reserve**

In accordance with the PSI's financial strategy, a Designated Legal Reserve has been established as a reserve to cover any significant costs arising from legal challenges to any part of the Pharmacy Act 2007 and from any of the PSI's rulings. In accordance with the PSI's accounting policy, where such funds are no longer required, they will be released back to the General Reserve.

# **19.3 Consolidated reserves**

The consolidated reserves comprise of the following:

- Income and expenditure reserve
- Strategic objectives reserve
- Future technology investment reserve
- Building maintenance reserve
- Fitness to practise rolling reserve

# 19.3.1 Income and expenditure reserve

The Income and Expenditure Reserve represents cumulative surpluses and deficits recognised in the Income Statement, net of transfers to and from other reserves.

# **19.3.2 Strategic Objectives Reserve**

A funding allocation reserve dedicated to funding on an annual basis, strategic projects identified as such as part of the annual planning process, was reviewed by Council on 14th December 2023 and the ceiling is currently set at up to €500,000 per annum. Strategic projects are defined as those that meet the following criteria:

- are once-off in nature and aligned to the PSI's long-term strategic goals and
- are not annual in nature but for which their occurrence is of a frequency that is a minimum of every five years or longer

#### 19.3.3 Future technology investment reserve

A reserve allocated specifically to fund investment in new technologies and future technology development projects for the PSI with an upper limit of €1.2M.

#### **19.3.4 Building maintenance reserve**

A reserve allocated specifically to fund the ongoing life-cycle maintenance of PSI House and future-use refurbishment requirements with an upper limit of €1.5M.

#### **19.3.5 Fitness to practise rolling reserve**

A reserve allocated specifically to fund the management of the complaints system, which is demand-led so as to offset year-on-year peaks and troughs. This is a rolling reserve with a limit of  $\leq$ 300K.

#### **19.4. Movements in Reserves**

The movements in reserves are detailed below:

	At 1 January 2023	Income	Expenditure	Transfers	At 31 December 2023
Income and expenditure reserve	8,409,123	8,435,537	(8,811,386)	(384,707)	7,648,567
Strategic objectives reserve	-	-	(198,116)	198,116	-
Future technology Investment reserve	1,200,000	-	-	-	1,200,000
Building maintenance reserve	1,500,000	-	-	-	1,500,000
Fitness to practise rolling reserve	-	-	(186,591)	186,591	-
Total consolidated reserves	11,109,123	8,435,537	(9,196,093)	-	10,348,567
<b>Revaluation reserve</b>	11,413,635	-	-	(5,300,000)	6,113,635
Designated legal reserve	2,500,000	-	-	-	2,500,000
Total reserves	25,022,758	8,435,537	(9,196,093)	(5,300,000)	18,962,202

#### **20.** Pension Commitments

#### The Pharmaceutical Society of Ireland Superannuation Scheme 2016

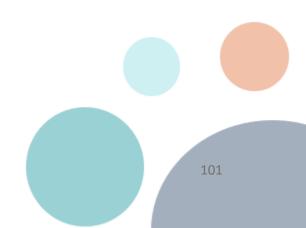
Under Schedule 1 of the Pharmacy Act 2007, the PSI is required to provide a scheme for the granting of superannuation benefits to and in respect of its staff members, subject to Ministerial approval.

The Pharmaceutical Society of Ireland Superannuation Scheme 2016 (SI 136 of 2016) was signed by the Minister for Health with the consent of the Minister for Public Expenditure and Reform on the 10th March 2016, and PSI commenced the operation of the Scheme on that date. The Rules set out in the Schedule to the Rules for Pre-existing Public Service Pension Scheme Members Regulations 2014 (S.I. No. 582 of 2014) are adopted as a Scheme for the granting of superannuation benefits to or in respect of members of the staff eligible for membership of this Scheme. The adoption and approval of this Statutory Instrument incorporates the Staff Superannuation Scheme and the Spouse's and Children's Contributory Pension Schemes under one main scheme, i.e. The Pharmaceutical Society of Ireland Superannuation Scheme 2016. The scheme was closed to new entrants to the public sector as of the 31st December 2012.

The PSI makes agreed employer contributions to the scheme, which are accrued in the year they become payable. The funding mechanism for the Scheme has not yet been approved by the Department of Public Expenditure and Reform. As such the PSI is currently holding the collected contributions on behalf of the State in a designated deposit account until such time as the funding mechanism is formally approved.

Under these circumstances and in view of the above, it is the view of the PSI that the provisions of FRS 102 Section 28, Accounting for Employee Benefits, are currently not appropriate. Accordingly, it is accounting for its contributions as if the Scheme was a defined contribution scheme.

As at the 31st December 2023, superannuation benefits were payable in respect of three members. Total benefits paid amounted to €13,763 (excluding any lump sum paid).



# The Single Public Service Pension Scheme

The Single Public Service Pension Scheme came into effect on the 1st January 2013 as provided for in the Public Service Pensions (Single Scheme and other Provisions) Act 2012.

The Single Scheme applies to all pensionable first-time entrants to the public service as well as to former public servants returning to the public service after a break of more than 26 weeks. The Scheme is a career average defined benefits scheme.

The PSI is responsible for collecting and remitting contributions for this scheme to the Department of Public Expenditure and Reform. These contributions comprise both an employer and employee element. The PSI is responsible for paying all scheme benefits financed from the contributions payable to the Department of Public Expenditure and Reform and in accordance with its instruction. There is one benefit currently payable under the scheme. The PSI considers that the pension arrangements, as described above, have the same financial effect from the PSI's point of view as a defined contribution scheme. The PSI is of the view that the provisions of FRS 102 Section 28, Accounting for Employee Benefits, which arise under defined benefit schemes, are not appropriate in these circumstances.

# **21.** Events after the balance sheet date

There have been no other circumstances or events subsequent to the year-end which require adjustment to, or disclosure in the financial statements or in the notes thereto.

# 22. Related Parties

There were no transactions with related parties that require disclosure.

# 23. Controlling Party

The PSI is controlled by the Council subject to the provisions of the Pharmacy Act 2007.

# 24. Approval of the Financial Statements

The Council approved and authorised these financial statements for issue on 21 March 2024.



The Pharmacy Regulator An Rialtóir Cógaisíochta

# Pharmaceutical Society of Ireland

# **PSI – The Pharmacy Regulator**

PSI House, Fenian Street, Dublin 2, D02 TD72 +353 1 218 4000 info@psi.ie www.psi.ie