

Annual Report 2022



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

We are the Pharmaceutical Society of Ireland (PSI), 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 2022 is submitted to the Minister for Health in accordance with paragraph 17(1) of Schedule 1 of the Pharmacy Act 2007. The Report covers the period from 1 January 2022 to 31 December 2022.

Our Mission, Vision 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 of our commitment to equality and human rights in how we fulfil our role.

Our values support us in achieving our objectives and to 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 counts

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 2022

Approval of Core Competency Framework

After a review and consultation on the Core Competency Framework for Pharmacists, a revised Framework was approved in December 2022. The Framework will be implemented during 2023.



Continued increase in registered pharmacists

The number of pharmacists registered with the PSI continued to increase and surpassed 7,000 for the first time in December. There was an increase during 2022 in EU, UK and other third country route registration applications compared to recent years.



Appointment of new PSI Registrar and Chief Officer

Joanne Kissane was appointed PSI Registrar and Chief Officer by the PSI Council in October 2022 after a public recruitment process. She commenced in the role in January 2023.

Ukraine Emergency Response Group

In March, we established an internal response group to initially coordinate and address matters arising in relation to our regulatory role due to the war in Ukraine. The focus involved engaging with external stakeholders in Government Departments, the HSE and other regulators to improve knowledge and support awareness-raising and communication on the significant issues involved.

Pharmacist Workforce Survey

In late 2022, we ran a workforce survey of registered pharmacists and pharmacy students to establish a baseline view of the current pharmacy workforce in Ireland. 1,272 responses were received. The survey formed part of our strategic project to assess emerging risks to the future pharmacist workforce, and the survey findings will feed into a Workforce Intelligence Report in 2023.

Return to in-person engagement following decrease in COVID-19 restrictions

Across our regulatory work there was a welcome increase in face-to-face interactions, meetings, inspections, and inquiries as the year progressed. The continued benefits of online and hybrid working have also been incorporated into many of our work practices, providing additional flexibility in the way we operate and engage.



Falsified Medicines Directive

Following an extended 'use and learn' period, national regulations commenced in June 2022 that made verification and decommissioning of medicinal products in pharmacies a legal requirement. We continued our work to promote pharmacy compliance with the legislation, which aims to prevent falsified medicines from entering the medicines supply chain and causing patient harm.

Introduction from the President

On behalf of the Council, Registrar, and staff of the PSI, I am pleased to present the PSI Annual Report and financial statements for 2022 in accordance with the requirements of the Pharmacy Act 2007.

This report documents the activities, outputs, and development progressed in pursuit of our mission. That mission and our statutory responsibilities centre on regulating pharmacists and pharmacies effectively to protect the health, safety and wellbeing of patients and the public in Ireland. This report is the second under our Corporate Strategy 2021-2024, which provides us with an ambitious agenda.

I started 2022 by taking the opportunity to thank registered pharmacists, pharmacy owners and pharmacy teams for their ongoing work and commitment in the face of the ongoing challenges of COVID-19, recalling that the year commenced with many public health restrictions still in place. Fortunately, these lifted significantly by Spring. Compared to our reports for 2020 and 2021, this one notes a relative return to normality, with the opportunity to conduct more of the PSI's work on the road and face-to-face again.

While society largely shed the COVID-19 restrictions of previous years, we recognise that healthcare settings remain places where infection prevention and control measures are a necessary high priority for patient and staff safety. For pharmacy, there were other challenges around pharmacists' availability for patient-facing roles and concerns regarding medicines shortages, all of which placed demands on continuity of care. Pharmacists, pharmacy owners and pharmacy teams continued their efforts to support and protect vulnerable members of the public and played a

significant part in the COVID-19 and flu vaccination programmes throughout the year.

From first involvement in June 2021, community pharmacies have administered more than 1.3 million COVID-19 vaccines, representing 10.5% of all vaccines administered since the commencement of the national programme. Added to that is the key role performed by many pharmacists and pharmacy students across the centralised vaccination centres and other health settings. Work continued with the 2022-2023 autumn/winter vaccination campaigns, with pharmacies delivering over 25% of national flu vaccinations during that period. This contribution is appreciated by the PSI and recognised and commended by the Health Service Executive and the Department of Health.

The PSI acknowledged a busy year on the registration front, a core part of our role as the pharmacy regulator. While the number of registered pharmacies remained stable at 1,981, there was a return to pre-COVID-19 levels of pharmacist applicants for registration and increased use of our new registration portal for all applications. The number of registered pharmacists surpassed 7,000 for the first time in December 2022, and there was an increase in EU, UK and other third-country route applicants compared to the previous two years.

We also had increases in queries and applications for the Third Country Qualification Recognition (TCQR) route. Work remains ongoing in relation to the PSI's revision of this route for pharmacists who have qualified in a non-EU/EEA country. The Council approved a policy and an approach for the roll-out of a new qualification recognition process, and we hope to consult on aspects of the proposed changes in 2023, together with progressing its

implementation. This new process will benefit applicants and improve overall efficiency. Ultimately, our focus is to ensure that fair and robust qualification recognition and registration systems are in place that facilitate the entry of suitably qualified pharmacists into the Irish pharmacy workforce.

In total, 53 complaints were made to the PSI in 2022 under the statutory provisions of the Pharmacy Act, a reduction of 33% on the previous year. In the context of the number of visits to pharmacies and engagements with pharmacists in any given year, there appear to be relatively low levels of concerns and complaints made, but it remains that the matters arising can be considerable. The Council is keen to continue to share information from complaints and inquiries by way of learning and to promote collective consideration regarding quality improvement and professionalism in the interest of safe patient care.

Part of our work involves responding to other information that raises concern about the conduct, professionalism or operation of a pharmacist or pharmacy. In 2022, the PSI dealt with 118 such concerns, with 86% of these being from members of the public. This number is down marginally from the 120 concerns raised in 2021. These concerns are issues brought to the PSI's attention, where a formal complaint is not made initially, however six of the concerns raised in 2022 resulted in formal complaints being made after further investigation.

In March, like many others, the PSI turned its attention to the impacts and challenges of the Russian invasion of Ukraine. We engaged during the initial months with the Department of Health and the Health Service Executive about professional registration and medicines availability so that we might contribute and

respond appropriately to the challenges arising for people coming to Ireland from Ukraine. The Council also extended a waived application fee for qualification recognition applications to Ukrainian pharmacists coming to Ireland under Temporary Protection Status, as is the case for applicants with refugee status.

It matters to us that we demonstrate, through our work, that we make a difference and create public value. We continue to advocate for change where necessary and to work with others to ensure that the role of pharmacists, across all healthcare settings, is part of the future healthcare system as proposed under Sláintecare.

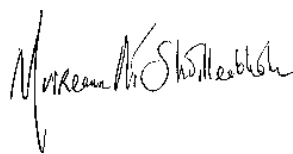
We were pleased to submit two position papers to the Department of Health in 2022. The first contains recommendations for legislative reform of the Pharmacy Act 2007, a matter of importance for the Council to ensure the legislation that underpins the regulation of pharmacies and pharmacy professionals in Ireland, can support effective regulation now and into the future. The second paper, which aligns with the Council's recommendations on reform, sets out our current and future proposals for development in relation to the regulation of pharmacies. We look forward to continuing our discussions on these matters with the Department.

I would like to thank the members of the PSI Council for their dedication and support throughout a busy year. I would also like to thank those who served on our Advisory and Disciplinary Committees and others who supported our various work programmes. I thank all PSI staff for their dedication, hard work and commitment to the organisation as we seek to keep pace with ongoing changes and upcoming challenges. In particular, I would like to thank Dr Lorraine Horgan, who expertly

guided the PSI as Interim Registrar throughout the 12 months of 2022.

I extend a warm welcome to the PSI's new Registrar, Joanne Kissane, whose role commenced in early January 2023. I look forward to the PSI's continued engagement with registrants, the Minister and the Department, and a wide network of stakeholders to continue to ensure the delivery

of safe, quality pharmacy services and assure public trust in the PSI and our valuable profession.

A handwritten signature in black ink, appearing to read 'Muireann Ní Shúilleabháin', written in a cursive style.

Muireann Ní Shúilleabháin
President

Message from the Registrar

I am delighted to have joined the PSI as Registrar and Chief Officer in January 2023, and I am pleased to reflect on the work outlined in this annual report as a testament to the dedication and commitment of the PSI Council, the Interim Registrar for 2022, Dr Lorraine Horgan, the PSI's staff and to all those who contributed to the pharmacy regulator's work last year.

I take up this role at a time of ongoing change in PSI as we continue to progress strategic commitments and organisational developments that are intended to support excellence in patient care through the work of pharmacists, pharmaceutical assistants and pharmacies, and which will enable the PSI to carry out its role as effectively as possible in the public interest. I look forward to working with the highly committed and dedicated team in PSI to progress our work under our Corporate Strategy and to continue to deliver our core objective to assure public trust in pharmacy through effective regulation.

This report highlights the many ways we have engaged in learning, consulting, and supporting safe healthcare provision, healthcare regulation, education and policy development. This was achieved in collaboration with individuals, other agencies and organisations. Our regulatory role is one part of the broader healthcare system, and we appreciate and acknowledge those who engaged with us and informed our work.

Providing safe, quality healthcare is rewarding and impactful, but not without challenge. Some of those challenges are reflected in this report and are well documented elsewhere. Pharmacy is often a less-mentioned part of the healthcare story, yet the requirement for the intervention, treatment, medication management,

counselling and advice provided by pharmacists and the wider pharmacy team is embedded in our understanding of modern healthcare. The PSI's role is to support the safe and appropriate provision of quality pharmacy services so that the public can rely on trusted professionals and the services provided by the pharmacy team.

The significant contribution by pharmacists and pharmacy teams, particularly in the national vaccination programmes over the past two years, represents a shift in how healthcare is delivered across our communities, accelerated by changes due to the COVID-19 pandemic. The PSI continued to work with the Department of Health on legislative changes and with the HSE and others to ensure accredited training was provided to pharmacists. Relevant guidance was made available to pharmacies to keep pace with the roll-out of each new vaccination made available to the public.

Amongst the projects commenced last year, the PSI prioritised and was committed to undertaking the important work involved with our strategic project to assess the emerging risks to the future availability of pharmacists in patient-facing roles. We are grateful for the level of response received to the first pharmacist workforce survey conducted at the end of the year. As well as examining the medium to longer-term issues as part of this project, we will continue to engage across different fora on this key pharmacy workforce matter. In addition, we are actively considering short-term solutions in conjunction with the Department of Health and the Irish Pharmacy Union. The work to date will inform this project and the recommendations to be proposed by way of outcomes in 2023.

The Annual Report and financial statements for 2022 represent the commitment, hard work

and ongoing professionalism of colleagues across the organisation, our Council, and our Disciplinary and Advisory Committee members, who continue to work collectively in the public interest to meet our statutory functions. I have been struck by the extent of activity, the balancing of commitments, and the drive for improvement amongst colleagues since taking up my role, and I look forward to being part of PSI's continued progress.

In carrying out our role, we rely on the public to engage with us and inform us of their experiences with pharmacists and the pharmacy care they receive. Furthermore, we

rely on the engagement of our registrants – pharmacists, pharmaceutical assistants and pharmacy owners – in our regulatory processes and for sharing their input and feedback. We remain focused on our commitment to assuring public trust in pharmacy by working collaboratively with those at the forefront of providing pharmacy care and services.

A handwritten signature in dark ink, reading "Joanne Kissane." The signature is written in a cursive, flowing style.

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 second year. There are three strategic areas under which we aim to deliver specific results.



Our continued response to COVID-19

The COVID-19 pandemic continued to play a part in our work during 2022, although many of the public health restrictions that had been in place were eased early in the year. With the circulation of the virus remaining an ongoing national health priority, the PSI continued our engagement with public health authorities, particularly around the national COVID-19 vaccination programme and the involvement of pharmacists in it. Pharmacists and pharmacy teams have continued to make an extraordinary contribution in ensuring the continuity of pharmacy services for patients and the public, as well as making a significant and valuable contribution to public protection through their role in national vaccination programmes once again.

For a third year, we outline in this section some of the COVID-19 specific work undertaken by the PSI.

National COVID-19 Vaccination Programme

The PSI worked in partnership with the pharmacy profession and other stakeholders to support the continued safe involvement of pharmacists in the national COVID-19 vaccination programme. During 2022 community pharmacies administered 635,475 vaccination doses, 23.5% of all COVID-19 vaccines delivered nationwide and had provided almost 1.3 million COVID-19 vaccines since becoming involved in the programme in June 2021. This is in addition to the extensive work of pharmacists and pharmacy students within specialist centres and centralised vaccination centres throughout the country. Some of the PSI's pharmacist staff also volunteered in medicines management roles for a period early in the year to support work undertaken in the vaccination centres.

During 2022, four statutory instruments were drafted by the Department of Health to amend the Medicinal Products (Prescription and Control of Supply) Regulations 2003 to provide for changes to the COVID-19 vaccination programme, as new COVID-19 vaccines were authorised. The PSI reviewed and provided feedback on the legislative provisions as they arose.

Under the legislation, registered pharmacists who have completed approved training by the PSI are permitted to supply and administer certain COVID-19 vaccines. Extensive work was undertaken again throughout 2022 to review and approve training for pharmacists to administer COVID-19 vaccines as new vaccines were authorised for use. We approved the training to be undertaken for six new COVID-19 vaccines. This work was supported and enabled with the valuable contributions of an external assessment team, comprising pharmacists with relevant expertise from a variety of settings, to review the training and recommend its approval as appropriate for pharmacists.

Through the dedicated National COVID-19 Vaccination Programme - Pharmacy Workstream Working Group we worked closely with the HSE and the Irish Pharmacy Union (IPU) to identify the ongoing regulatory and operational components necessary to support the continued safe roll-out of vaccination services within community pharmacies. HSE operational guidance was updated throughout the year as the programme progressed, with the PSI and the IPU providing assistance when required.

We also sent communications throughout the year to those in pharmacy governance roles to highlight key aspects of governance and clinical leadership for the continued provision of a safe COVID-19 vaccination service in community pharmacies.

HSE Community Pharmacy Planning Forum

During 2022, the PSI continued our engagement with the HSE-led Community Pharmacy Contingency Planning Forum, now called the Community Pharmacy Planning Forum. This group was established to examine the operational and clinical challenges confronting community pharmacists during the COVID-19 emergency. Its work has now transitioned to discussing the strategic direction of community pharmacy.

COVID-19 Information Hub and related resources

The Irish Institute of Pharmacy (IIOP) continued to support pharmacists and their teams through the availability of the COVID-19 Information Hub and related resources. The Hub was established in 2020 at the request of the PSI and includes practical information, mental health supports, and the ongoing delivery of a webinar series on a variety of topics of relevance and importance to pharmacists.

Remote meetings and hearings

After two years, 2022 saw the return to onsite meetings for our Council, Advisory and Disciplinary Committees at PSI House, including for fitness to practise inquiry hearings. Previous investment in technology and related infrastructure has supported the continuance of remote meetings and hearings, including hybrid meetings, where necessary. In relation to inquiries, it is intended that most will take place onsite and in-person unless the balance of justice requires that a hearing take place remotely or in a hybrid manner, or an application is granted for a hearing in a particular format. The Committees of Inquiry held 17 hearings in 2022, of which 11 were held remotely, five were held onsite, and one in a hybrid manner. The PSI continues to follow Government health guidelines in relation to the conduct of meetings and hearings at PSI House.

Progress on our strategy and improvement agenda

Strategic objective 1: Advancing the Role of Pharmacy and Pharmacists in the Future Integrated Healthcare System

Review of the Core Competency Framework for Pharmacists

In 2022, we completed the review of the Core Competency Framework for Pharmacists. This multi-annual project commenced in 2021 following consideration of a report by Council in October 2020, which recommended an in-depth review of the existing Framework be carried out to ensure that it was fit-for-purpose. Following this review, a public consultation on a revised draft Core Competency Framework took place in late summer and the consultation feedback informed some final changes to the document. The revised Core Competency Framework was approved by Council in December 2022.

The Core Competency Framework underpins the MPharm curricula as part of the pharmacist qualification delivered by the Schools of Pharmacy and reflects the practice of pharmacists in the early stages of their career. It is also used to provide structure and guidance for pharmacists when reflecting on their continuing professional development (CPD) needs throughout their career.

Implementation of the revised Core Competency Framework will commence in 2023. We appreciate the valuable input from members of the Steering Group and Working Group associated with this project, and all those who took the time to meet with us during the review and provide feedback during the public consultation.

Assessing Emerging Risks to the Future Pharmacy Workforce

This multi-annual project which commenced in 2022, and will run into 2023, is being undertaken to assess the emerging risks to the continued availability of a professional pharmacist workforce within community and hospital pharmacy in Ireland. The project is taking a medium to long-term view of this matter, and we have commissioned external support with expertise in workforce planning to assist and support us in delivering this important strategic project.

In the second half of 2022, we established and met with the Working Group appointed under the project. This group comprises individuals from organisations across the health and pharmacy sector, including the Department of Health, HSE, Schools of Pharmacy and APPEL (the Affiliation for Pharmacy Practice Experiential Learning – the shared services consortium established by the three schools of pharmacy), the Irish Institute of Pharmacy, pharmacy representative organisations, and a practising pharmacist. We will continue to meet with the Working Group in 2023.

In November 2022, we published the first Pharmacy Workforce Survey for Ireland. This was designed to capture information about pharmacists and their roles. It gathered views from pharmacists and students on the profession and about potential risks to the availability of a pharmacy workforce into the future. The survey, along with other inputs,

will be a key source of up-to-date robust and relevant data from which recommendations can be proposed to address Ireland's pharmacist workforce needs into the future. We intend to administer a workforce survey on an annual basis from now on.

In tandem with this project, we are also contributing to other significant work on the topic of strategic workforce planning across the health system. Under the European Commission, DG REFORM's Technical Support Instrument, the Department of Health has appointed Indecon Consultants to undertake a major project on health and social care workforce planning in Ireland. The project, which builds on the National Strategic Framework for Health and Social Care Workforce Planning, is being led by officials in the Department of Health, working in collaboration with the HSE and other key stakeholders, including the PSI, to deliver on this important initiative. We met with Indecon Consultants during 2022 and provided them with data in support of their work. We are also engaged with a sub-group of the Health and Social Care Regulator's Forum, which is tasked with examining the matter of strategic workforce planning across multiple health and social care professions.

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. Council has recognised that the existing policy was resource intensive, costly and onerous on both the applicant and the PSI. We have been reviewing the process to streamline it, both to benefit applicants, our administrative process, and the wider public. A revised TCQR policy was approved by Council in 2019. In 2022, Council considered and approved a report recommending how the policy can be implemented. It is expected that the new process will be in place in late 2023.

Reviewing the CPD Model for Pharmacists

In 2022, we continued with our review of the statutory Continuing Professional Development (CPD) model for pharmacists. The review of the CPD model for pharmacists will continue into 2023, with support from independent external expertise and input from stakeholders and experts in Ireland and abroad.

Developing a CPD Model for Pharmaceutical Assistants

In 2022, we also commenced a project with the aim of proposing a CPD model for pharmaceutical assistants in response to a statutory change which is due to be commenced in 2023. We appointed external expertise to assist with this project and this work will continue in 2023. It is expected that a proposed CPD Model will be approved during 2023.

Contributing to the One Health National Action Plan on Antimicrobial Resistance (AMR)

Recognising that Antimicrobial Resistance (AMR) is an important public health and patient safety issue and one of the leading causes of death worldwide, we have committed to pursuing actions to support the delivery of Ireland's second National Action Plan on Antimicrobial Resistance 2021-2025 (known as iNAP2). iNAP2 has been published jointly by the Department of Health and the Department of Agriculture, Food, and the Marine and it outlines over 150 actions to tackle the threat of AMR.

These actions aim to support strategic objective one of the iNAP2 plan relating to improving awareness and knowledge on

antimicrobial resistance. We have responded to a mid-term review of iNAP2, outlining the progress we have made to date and our future regulatory actions under iNAP2. For example, through our communication with registrants we promoted best practice. We shared key messages on AMR, infection prevention and control (IPC) and antimicrobial stewardship (AMS) in line with HSE-AMRIC campaigns and iNAP2. Following a consultation process, our revised Core Competency Framework for pharmacists contains a new indicative behaviour related to the principles of good AMS, IPC and AMR, and will therefore be included as part of pharmacists' education and CPD. We are committed to continuing to work with our stakeholders to drive this important agenda forward.

Strategic objective 2: Evolving a More Effective Regulatory Model for Community Pharmacies

Advancing Reform of the Pharmacy Act

The PSI Council identified the reform of the Pharmacy Act 2007 as a key priority in our Corporate Strategy. We consider it necessary to review the Act to ensure it continues to be fit for purpose in a changing regulatory and healthcare environment, that it can continue to support effective regulation now and into the future and ensure the safety of patients and the public. The PSI Council is committed to reviewing the Act from a regulatory policy perspective and to working in partnership with the Department of Health on the subject.

A position paper on the need for reform of the Act was approved by Council in April and submitted to the Department of Health in June to inform our continued discussions with the Department on this important matter. The position paper outlines why significant legislative reform is needed and the challenges we experience with the Act in practice. The development of the paper involved significant research and engagement, problem identification and analysis. As well as outlining the most important challenges in the paper, the paper highlights some examples of regulatory tools and practices used by other regulators, which we have identified through our research.

We look forward to continuing our discussions on the position paper with the Department in 2023 and to progressing agreed next steps in advancing reform of the Act.

Actioning our Regulatory Risk Approach

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 become a more risk-based regulator with the aim of assessing and mitigating risks that have the greatest potential to impact on patient safety. The statement sets out how we define, identify, analyse and respond to risk across all of our areas of responsibility. This approach allows the PSI to direct resources more efficiently and allows for a more proportionate response to an identified risk.

In 2022, we continued to embed our approach under this model, and our internal Regulatory Risk Analysis and Response Group has continued to drive analysis of information to assess risks, and to make recommendations on actions to be taken.

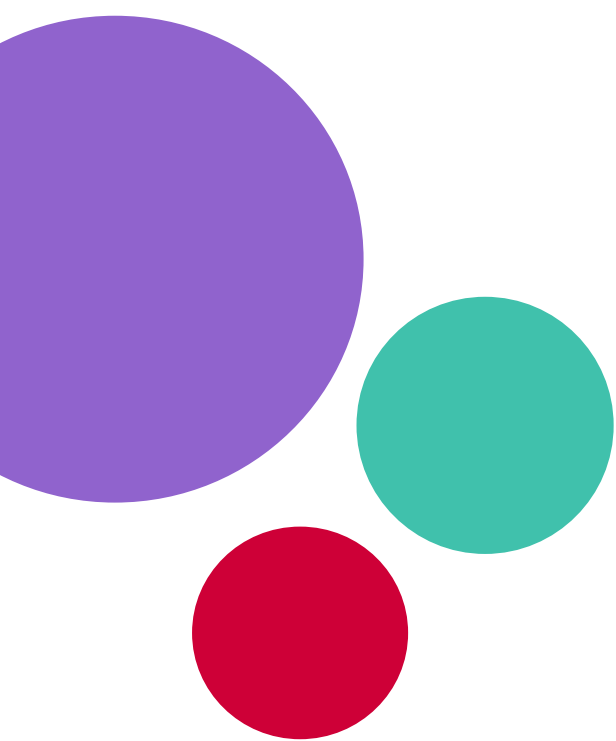
Contributing to the review of COVID-19 emergency legislation

In June, we met with the Department of Health, HSE and Medical Council to discuss the revocation of certain legislative provisions which were made specifically to address the continued availability of medicines for patients due to the circumstances arising from COVID-19 (as set out in S.I. 98 of 2020 amending the Medicinal Products (Prescription and Control of Supply) Regulations 2003 and S.I. 99 of 2020

amending the Misuse of Drugs Regulations 2017).

Following a Department of Health request, in August 2022 the PSI submitted a joint policy position statement with the Medical Council that sets out a rationale to support the introduction of an enabling mechanism in the legislation to allow a pharmacist to supply a controlled drug in certain emergency

circumstances, where it is safe, appropriate, and necessary for the continued treatment of the patient for the emergency supply to be made. At the request of the Department, a risk assessment was also developed from a pharmacy perspective to underpin the joint policy position statement. This was submitted to the Department for its consideration in November 2022.



Strategic Objective 3: Building our Capability and Performance as a Regulatory Organisation

Progressing our Business Transformation Programme

Our Business Transformation Programme (BTP) is intended to achieve better ways of working across the PSI, to ensure we optimise our use of technology and our people's time and expertise in the best way possible. A key deliverable of the BTP is a new digital platform to serve as our single customer view. This platform will streamline and modernise many of our processes in relation to registration, complaint, concern and query management, and inspections, and will deliver efficiencies for the PSI and registrants. The programme will also deliver improved data quality across all systems, supporting our risk-based approach to regulation. Phase one – the new registration system – was released in September 2021. Some of the benefits of the new registration system have already been realised so that we have an aggregated, consistent and holistic representation of the data known about our customers. The system is integrated with PSI's financial applications for fee processing. As more registration application processes have moved online, it has streamlined the process for registrants, with quicker turnaround times to process applications. There is also better dashboard reporting and analysis within the new system, which provides a clear view of the status of applications, throughput and enables better analysis of the data we hold.

In 2022, we built on the foundations of Phase one and made a chatbot (a computer programme that simulates human conversation to solve customer queries) available in September that provides 24/7 support for frequently asked questions for our registrants and registration applicants. The

chatbot adds to the supports already developed for the registration portal, such as FAQs and videos to support registrants and applicants. We analyse the queries we receive to update these support mechanisms to improve the information we make available.

Embedding our revised Organisation and Management Structures and implementing our HR Strategy

Together with the digital service changes we are progressing, we have also implemented a changed operating model and organisation structure, with the intent being to align with our strategy and future operating structure, and to support a more cross-functional work environment to meet the varied demands on our role as a health regulator. Work on this organisation development project commenced in 2020 with the new model going live in July 2021. While many aspects of the model are in place, other elements remain a work in progress which we will continue into 2023.

During 2022, progress was made towards establishing a programme delivery function (incorporating a Project Management Office approach) with the launch of standardised support documentation and the approach to project management to be used for all projects in the PSI. We were pleased to use the project management toolkit available to the public service via the Department of Public Expenditure and Reform, which we have tailored for our purposes.

Underpinning the new operating model and structure is our recommended expansion of staffing within the PSI. These proposals, approved by the PSI Council in 2021, were

made to the Department of Health in 2022, with the requested prioritisation of posts subsequently provided for sanctioning purposes. We hope to receive sanction from the Department for these new posts in 2023 and to commence open recruitment for this set of seven posts in 2023.

Aligning with our HR Strategy, staff support, development and training were provided throughout 2022 to assist with the organisational changes and for the continued development of our managers and all staff. Like most organisations, we have sought to balance the benefits and challenges of working from home and work in the office on a blended basis, to encourage team days together, as well as all-staff development days to enhance collegiality and collaboration. A blended working policy was developed in consultation with staff during 2022. This new policy, which is based on the framework proposed by the Department of Public Expenditure and Reform, will shape the PSI's ongoing approach to our people working both from home and the office environment, incorporating the Programme for Government's commitment to remote working, and the climate action plan to reduce emissions through reducing people's commuting.

Conducting the next phase of 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 mission to the standard expected by the public. In 2022, the Council approved a new reserves policy as part of the ongoing PSI Strategic Financing Review project. The new policy comprises a consolidated reserves approach, while ringfencing the legal reserve.

Continuing our EFQM Journey

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 2022, we continued our awareness-raising with staff of working within the EFQM model and made progress in planning our approach to maintaining and improving on our EFQM award as we prepare for submission in 2024.

Activity in support of our mission

As well as continuing and commencing strategic change and development projects in 2022, our key 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, policy and communication, and the effective governance of the organisation on an ongoing basis.

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 oversee the operation of 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).

Student placements at the PSI

In 2022, we continued our support of the MPharm programme and its experiential learning placements. Two Masters of Pharmacy students (one each from Trinity College Dublin and the Royal College of Surgeons in Ireland) joined the PSI on their 4th year, four-month statutory placement from September to December 2022.

During their placement, the students made valuable contributions to the work of the PSI through their involvement in initiatives such as the Review of the Core Competency Framework, the Emerging Risks to Future Pharmacy Workforce project and our Business Transformation Project. 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 staff.

Irish Institute of Pharmacy and the 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. All registered pharmacists must carry out appropriate CPD and maintain appropriate records of their CPD in the format set out in the PSI (Continuing Professional Development) Rules 2015. The required format is an ePortfolio on the IIOP website. Each year, a percentage of pharmacists are selected by the PSI so that an extract from their ePortfolio is submitted to the IIOP for review. Pharmacists are called once in every five years to submit this extract. Of the 964 pharmacists selected for ePortfolio Review in 2022, a total of 910 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 follows up, as appropriate, 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 an in-person clinical knowledge review and assessment against standardised pharmacy interactions.

Due to the COVID-19 pandemic, the PSI Council decided to suspend Practice Review in 2020, 2021 and April 2022. The Practice Review event recommenced in October 2022 with 61 pharmacists selected to participate. Of these, 58 pharmacists participated, and 57 pharmacists demonstrated competence. Pharmacists who do not demonstrate

competence initially are given a further opportunity to attend a subsequent Practice Review event. The PSI meets with pharmacists who fail to engage with the review process.

Consultation and engagement in the development of the IIOP Workplan

As part of the contract that oversees the operation of the Irish Institute of Pharmacy (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 2022, we held engagement meetings with the Department of Health and representatives from the Health Service Executive (HSE) including with its Quality Improvement Division, Primary Care Reimbursement Services, Antimicrobial Resistance and Infection Control, National Immunisation Office, Medicines Management Programme, and the National Cancer Control Programme. The purpose of the engagement meetings was to identify expected training needs for pharmacists for 2023. The Annual Work Plan for 2023 was subsequently approved by the PSI Council at its December meeting.

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 or undertakings given at a fitness to practise inquiry by a registrant. This means that the PSI monitors the registrant as they work to achieve the expected outcomes according to the undertakings given or the conditions attached to their registration. In 2022, we monitored seven individuals/pharmacies with High Court conditions imposed after findings being made at fitness to practise inquiries. We also monitored one individual who provided undertakings at a fitness to practise inquiry.

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. We continue to enhance our effectiveness as a regulator and to review how we regulate including adopting a risk-based approach which is being utilised within our range of regulatory tools.

Policy approach

The Council approved our revised Inspection and Enforcement Policy in June 2022 which reflects recent developments during the pandemic, and as we introduce a standards-based approach as an additional regulatory tool, in conjunction with our compliance focus.

We also submitted a position paper to the Department of Health mid-year, entitled Regulation of Retail Pharmacy Businesses: Current approach and future developments. This outlines our revised Inspection and Enforcement Policy and our ongoing work to move towards use of regulatory standards as an additional regulatory tool. We also set out the limits to the current legislative

framework, aligning to our proposals for broader reform of the Pharmacy Act 2007, so that the PSI can respond most effectively to patient needs and changing risks.

Inspection activity

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

During COVID-19, the PSI moved away from on-site new opening inspections in favour of a self-declaration process and further developed the remote inspection process by utilising a combination of photographic evidence, and video walkthroughs. In all, 78 first registrations were processed using self-declarations. Three virtual inspections also occurred. The PSI also conducted 12 onsite inspections.

Onsite inspections resumed in February 2022 as COVID-19 risks reduced. A total of 97 risk-based pharmacy inspections were conducted. 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 2022, this included professional cover, and the Falsified Medicines Directive.

Themed inspections accounted for 34 pharmacy visits under section 67 of the Pharmacy Act.

Compliance with requirements for internet supply of non-prescription medicines

The PSI has a role in ensuring that anyone (pharmacies and other retailers) selling non-prescription medicines online in Ireland is registered with the PSI and acts in accordance with the requirements of that registration. This aspect of our role saw increased activity in the previous two years, some of which related to a general increase in online retail sales due to the pandemic. At the end of 2022, 176 pharmacies and 157 other retailers were registered with the PSI on the internet supply list. In 2022, two enforcement actions were taken in relation to the internet supply of non-prescription medicinal products regarding compliance with the requirements. In conjunction with the HPRA, we also handled two enforcement actions pertaining to the illegal online advertisement of prescription-only medicines by a registered pharmacy and a non-registered premises.

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 retail pharmacy business (pharmacy) within these two key roles, in co-operation 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, as these are 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 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. The risks associated with vacancies are assessed on a continuous basis.

Implementation of the Falsified Medicines Directive

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. In preparation for the end of the ‘use and learn’ phase in June 2022, the PSI continued to engage with the Department of Health, the HPRA and the Irish Medicines Verification Organisation (IMVO), which is responsible for maintaining the national repository.

We continued to engage with pharmacies, and in particular with pharmacists in governance positions to explain and

encourage compliance with the Directive. We also used this engagement to explore broader issues regarding how the overall FMD approach works within Irish pharmacies and with the systems used in day-to-day work. We reported any issues raised to the National Safety Features Oversight Group. The Medicinal Products (safety features on packaging) Regulations 2022 (S.I. No. 270 of 2022) was signed into legislation by the Minister for Health on 1 June 2022. This legislation makes verification and decommissioning of medicinal products a legal requirement.

Engagement with the requirements across pharmacies improved as the year progressed. We issued, 1,409 emails to pharmacies outlining their 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 reported consistently by the European Medicines Verification Organisation, as above 60% with a peak of 70.8% in December 2022. This compliance rate is based on data determined by IQVIA that the Irish market stands at 105 million packs approximately for 2022. IQVIA data does not include medical devices or unlicensed medicines.

Specialist surveyor exercises

We undertook a specialist surveyor (mystery shopper) exercise across a sample of 100 pharmacies in September and October 2022 to assess compliance with our existing guidance for pharmacists on the safe supply of non-prescription codeine products to the public. The PSI guidance was published in 2010 as a public safety measure and as a support to pharmacists and pharmacies due to the known potential for misuse and harm with prolonged use. The intervention of a pharmacist is therefore important in the

provision of codeine products. At the end of 2022, the exercise was still in progress as engagement with the pharmacies visited was ongoing.

We carry out periodic exercises such as these across a sample of pharmacies as part of a suite of measures to ensure compliance with legislation and guidance. As well as our direct engagement with the pharmacies that were visited, we will share the findings of this exercise in the interest of promoting safe practice and maintaining standards in pharmacies and across the pharmacy profession. Awareness-raising and information provision remain vital to improve public understanding of the risks that medicines can pose when used incorrectly.

We also used specialist surveyors on five other occasions during 2022, where concern was raised, and information verification was required. These interventions provide an insight from a public perspective and allow the PSI to determine if more action is warranted. In all individual cases, no follow-up compliance actions were required.

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. Six investigations were commenced, and eight investigation files were closed during 2022. There were 15 investigation files open at the end of 2022.

Consideration by the Registrar of Authorised Officer 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

2022, the Interim Registrar considered 10 inspection reports and seven investigation reports.

Following consideration of the inspection reports actions were taken at the direction of the Interim Registrar, including meetings with registrants and the provision of undertakings by registrants, as well as re-inspections under Section 71(1)(d) of the Pharmacy Act.

Following consideration of the seven investigation reports:

- Four prosecutions were initiated (under Section 71(1)(d));
- Four pharmacists and four pharmacies were referred to the complaints process (under Section 71(1)(b));

- In three of these 8 complaints, the Council of the Pharmaceutical Society of Ireland (PSI) 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 or pharmacy pending further procedures under Part 6 the Pharmacy Act 2007; and
- Four other actions were taken at the direction of the Interim Registrar, including meetings with registrants and the provision of undertakings by registrants (under Section 71(1)(d)).

Pharmacy Quality and Safety in Numbers

97

Pharmacy compliance inspections conducted

15

New pharmacy opening inspections conducted by both onsite and virtual visits.
78 pharmacy registrations were also processed through a self-declaration process.

6

Investigations commenced in 2022

105

Specialist surveyor (mystery shopper) exercises completed

2

Enforcement actions taken in relation to the internet supply of non-prescription medicines

17

Authorised Officer Reports considered by the Registrar under section 17 of the Pharmacy Act 2007

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 ensuring the accuracy of the registers 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 contact management with our registrants and the wider public, we also deal with and address expressions of concern and general queries that we receive.

Register of pharmacists, pharmaceutical assistants, and pharmacies

All pharmacists, pharmaceutical assistants, and retail pharmacy businesses (pharmacies) must be registered with the PSI and where they meet the requirements to register 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 7,067 registered pharmacists on Part A of the PSI register at the end of 2022, a total increase of 222 pharmacists from 2021. There was an increase of 83% for pharmacists registered via the EU, UK and Non-EU routes of qualification recognition and registration in 2022 compared to those registered in 2021. This includes an increase of 57% in UK qualified pharmacists and over 150% in EU qualified pharmacists registering with PSI. There was one pharmacist on Part B of the PSI register at the end of 2022. There were 224 pharmaceutical assistants on the register at the end of 2022, down from 254 in 2021. 1,981 retail pharmacy businesses were named on the PSI Register at the end of 2022, the same as in 2021.

There were 130 cancellations from the Register of Pharmacists, with 18 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. At the end of 2022, 107 pharmacists had voluntarily cancelled their registration. In 2022, 23 pharmaceutical assistants voluntarily cancelled their registration. A total of three pharmaceutical assistants had their registration involuntarily cancelled. 32 pharmacists restored their registration under Section 61. This includes restoration following voluntary cancellation and involuntary cancellation.

The PSI has language competence requirements in place based on requirements in EU and national law. These apply to pharmacists who have completed their training outside of Ireland and who intend to register with the PSI. A pharmacist's language competence must enable them to communicate, understand and treat patients, and to discharge professional obligations as a pharmacist in Ireland. Following an updated benchmarking exercise, in June 2022, the PSI Council approved an adjustment to a lower minimum score for one component of the recognised tests. This adjustment replaced the discretion available to the Registrar over the period since the start of the COVID-19 pandemic.

The temporary register for pharmacists and pharmaceutical assistants, which was put in place to boost the available workforce during the peak COVID-19 pandemic period, was

ceased at the end of June in line with the revocation of national emergency legislation. During its operation, from March 2020, a total of 64 people were temporarily registered through this route.

In 2022, 20 new pharmacies were registered and opened, and 20 pharmacies cancelled their registration due to closure. We also dealt with the necessary re-application process for existing pharmacies that changed ownership or location during the year. We also include information about inspection activity related to pharmacy registrations under the Pharmacy Quality and Safety section of this report.

Certificates of current professional status

We issue Certificates of Current Professional Status on behalf of registrants accessing registration in other jurisdictions. In 2022, we issued 63 certificates.

European Professional Card (EPC)

The EPC mechanism is an electronic procedure, which 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 ten EPC applications were received in 2022, and all ten applications were approved and processed.

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 2022, we issued four pharmacist alerts to competent authorities in other EU countries regarding PSI-registered pharmacists. These alerts were issued due to substantial reasons concerning the practice of the professional involved.

Registration for internet supply of non-prescription medicines

We are responsible for the registration and maintenance of the Internet Supply List for registered pharmacies and other retailers who wish to supply non-prescription medicines online in Ireland. There were 176 pharmacies and 157 non-pharmacies on the internet supply list at the end of 2022. This was a decrease of 19 pharmacies and 13 other registered retailers compared to 2021. We have information about compliance activity related to this work under the Pharmacy Quality and Safety section of this report.

Query management

In line with our role, 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 as the pharmacy regulator. During 2022, we responded to 432 such queries in total, 111 (26%) from the public and 285 (66%) from registrants. 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. Of the queries received last year, 23% were general prescription and control of supply queries.

Assessment of concerns

We also take action to ensure that 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 at the PSI by a multidisciplinary panel to assess risk and determine what action is required. A total of 118 expressions of concerns were received in 2022. 39% of the concerns received related to pharmacy practice issues, and 86% of concerns received were reported by members of the public, followed by 11% from 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 118 concerns received in 2022, 6 resulted in formal complaints being made.

Registrant and Customer Relations in Numbers

7,067

pharmacists on Part A of the Register

6,845 in 2021 and **6,767** in 2020

1

pharmacist on Part B of the Register

349

pharmacists added to the Register

155 Irish trained
and

194 non-Irish trained

Country where new pharmacist qualification was obtained

5 Bulgaria	4 India	12 Romania
2 Croatia	1 Jordan	17 Spain
4 Egypt	2 Lithuania	4 South Africa
1 France	3 Malta	1 Sudan
2 Greece	2 Nigeria	88 UK
10 Hungary	6 Poland	
7 Italy	23 Portugal	



63

Certificates of Current
Professional Status issued

1,981

total pharmacies registered

1,981 in 2021 and **1,968** in 2020

Changes to the Register of Pharmacies included:

20 cancellations

20 new openings

6 new openings (relocations)

63 new openings (transfer of ownership)

224

Pharmaceutical assistants on the
Register

254 in 2021 and **285** in 2020



176 pharmacies and **157** non-pharmacies registered
on the internet supply list

Voluntary and involuntary cancellations

107 pharmacists voluntarily cancelled their registration

18 pharmacists had their registration involuntary cancelled

23 pharmaceutical assistants voluntarily cancelled their registration

3 pharmaceutical assistants had their registration involuntary cancelled



Q

A

432

responses given to regulatory and pharmacy practice queries from registrants and members of the public

118

expressions of concern received

120 in 2021 and

184 in 2020

86% of concerns from a member of the public

Categories of concerns raised

46 pharmacy practice issues

19 failure to supply

16 commercial, advertising or employment issue

9 behaviour (manner/attitude)

7 dispensing error (incorrect dose)

7 dispensing error (incorrect medication)

4 out of date medication

1 behaviour/ professionalism

1 generic substitution

1 multiple issues

1 emergency supply issues

1 dishonesty

4 other



Complaints, Inquiries 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 and 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.

The PSI received a total of 53 formal complaints in 2022, a reduction of 33% on the previous year.

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 disciplinary 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 2022, the PPC considered 58 complaints. Of these, 43% were considered within six months. Excluding one complaint, the balance was considered in under 13 months with any delay being due to either ancillary-related criminal prosecutions, or the complexity of the complaint.

Following review of the complaints considered, the PPC sent forward 13 complaints for further action, of which nine 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 40 complaints did not warrant further action and the Council agreed with the advice of the PPC. Five of the 58 complaints considered by the PPC were withdrawn by complainants.

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.

In relation to the five complaints withdrawn by complainants in 2022 after consideration by the PPC, the Council decided, on the advice of the PPC, to take no further action.

Professional Conduct and Health Committees overview

The Committees of Inquiry consist of the Professional Conduct Committee and Health Committee, and these hear complaints against pharmacists and pharmacies. In relation to the 17 inquiries held or commenced in 2022, 11 were held fully remotely, five took place in person at PSI House and one took place in a hybrid manner.

The Professional Conduct Committee (PCC), and the Health Committee, sitting with an independent Legal Assessor, also hold callovers. 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 timeline be complied with to ensure that a complaint is ready for hearing. In 2022, four PCC and five Health Committee callovers took place. The callovers took place remotely using video and audio technology.

Inquiry hearing outcomes

A total of 17 inquiries relating to 17 respondents were heard before a Committee of Inquiry in 2022, over a total of 18 hearing days. 14 of these were completed in 2022, with the remaining 3 being part-heard in 2022 and adjourned to be completed in early 2023. The PCC heard 13 inquiries and the Health Committee heard four inquiries.

Findings were made in almost all concluded inquiries, or an undertaking was accepted by the Committee. The findings by the Committee of Inquiry included professional misconduct and/or poor professional performance and/or impairment and some related to convictions against the respondents. The undertakings given were typically not to repeat the conduct which was the subject matter of the complaint, and some involved consents to sanction.

Sanctions and outcomes following fitness to practise hearings

A pharmacist or pharmacy may have one or more sanctions imposed following an inquiry. When an inquiry concludes, the PSI Council considers the Report of the Committee of Inquiry and formally imposes any sanction and makes any decision required for that complaint.

In 2022 the Council considered 16 Committee reports in relation to complaints, some of which had been heard before a Committee of Inquiry in 2021. 8 complaints involved undertakings, with consent to sanctions in five of those complaints. Two complaints were withdrawn by the complainants and the Council agreed that no further action was warranted. Two complaints resulted in no findings and were dismissed by the Council. The remaining five complaints contained findings against a pharmacist and/or

pharmacy, resulting in sanctions. These included (collectively) two cancellations of the pharmacist's registration, four censures, two admonishments, the imposition of two sets of conditions and a prohibition on restoration. Where required, the relevant sanctions were confirmed by the High Court.

In one complaint, an application was made to the High Court by a registrant to cancel the sanction imposed by Council. The judgment had not been received by 31 December 2022.

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 the registration of a registered pharmacist and/or a registered pharmacy against whom a complaint has been made. 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.

One interim suspension application was considered by the PSI Council in 2022 and the

Council decided to proceed to seek an order from the High Court suspending the registration of the pharmacist, (a pharmacy owner), and two retail pharmacy businesses. The High Court granted an Order suspending all three registrations pending further action in relation to the complaint.

Policy and Procedure Updates

In December 2022 an updated Publications and Disclosure Policy in relation to what the Council publishes in fitness to practise matters, and how it exercises its related statutory powers and obligations, was approved by the Council. The updated Policy reflects recent legislative changes which impacted the Council's powers and obligations and outlines the consequential policy changes. The Policy aims to provide clarity and transparency to registrants and members of the public also in relation to what information the Council will and will not publish following conclusion of a fitness to practise matter. The document is available on the PSI website.

Complaints and Fitness to Practise in Numbers

53

formal complaints
received

80 in 2021 and
46 in 2020

Formal complaints received by source

83% member of the public

13% Registrar

2% pharmacist

2% doctor



Categories of formal complaints raised

13 pharmacy practice issues

5 failure to supply

1 dispensing error

5 Dispensing error
(incorrect dose)

2 Dispensing error
(incorrect medication)

5 Breach of high court conditions

10 Behaviour (manner/attitude)

3 commercial, advertising or
employment issue

1 health impairment

1 other

1 behaviour/professionalism

1 conviction

2 dishonesty

1 out of date medication

5 professionalism



1 complaint referred to
mediation in 2022

17

inquiries commenced

13 before the Professional Conduct Committee

4 before the Health Committee

3 of these inquiries were adjourned to be completed in 2023

58 formal complaints considered by the PPC of which

13 referred for further action and

40 for no further action

5 complaints withdrawn

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.

Our Corporate Strategy 2021–2024 recognises the importance of effective communication and stakeholder engagement to underpin the achievement of our key strategic objectives. 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 is designed to ensure patient safety is core to our communications and to create awareness and understanding of the PSI's role.

Working with others

We continued to work in collaboration with our key stakeholder organisations throughout 2022, contributing to national health and social care consultations, working groups and other cross-organisational meetings. More than ever, the COVID-19 pandemic has highlighted the importance of collaboration and engagement across the health and social care sectors. The PSI regularly engages with include 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) and others.

Submissions to external consultations

In 2022, we made 12 submissions to many of

these organisations' public consultations and requests for input, where the subject matter was of relevance and significance to our role and that of our registrants. We make these submissions in the interest of strengthening the quality and safety of health and social care services for patients and the public and sharing information and knowledge across the health and social care system. The topic matters of these consultations ranged from the policy for open disclosure for the health service, antimicrobial resistance, national risk assessment and ICT enablement considerations for our health service.

Participation in external working groups

In addition to our participation in key consultations, the PSI is a regular contributor and participant in working groups. These include the National Near Patient Testing (NPT) Consultative Group which convenes under the auspices of the Faculty of Pathology of the Royal College of Physicians of Ireland (RCPI) and represents national laboratory medicine organisations and relevant regulatory bodies including the RCPI, the HPRA, the Association of Clinical Biochemists in Ireland and the Academy of Clinical Science and Laboratory Medicine.

The PSI continues to participate in the Medical Council stakeholder group on strategies to address overprescribing controlled drugs. The stakeholder group includes representatives from the Medical Council, HSE, HPRA, Department of Health, the PSI and the ICGP.

As mentioned in our COVID-19 related work, the PSI is a member of the HSE Community Pharmacy Planning Forum, which met during the year, chaired by the HSE. The forum aims

to facilitate ongoing engagement and consultation with the pharmacy sector to support consideration of the strategic direction for the future development of community pharmacy services in line with Sláintecare. The forum also aims to provide a process for ongoing strategic planning required for the future of community pharmacy in the longer term and in relation to the ongoing COVID-19 pandemic.

We continued frequent engagement with the National Safety Features Oversight Group throughout the year as matters progressed with assessing compliance with the Falsified Medicines Directive (FMD) in Ireland. We also engaged with the Department of Health and the HPRA in relation to proposed amendments to related legislation.

We maintained our engagement with the National ePrescribing Project through regular meetings with the ePharmacy team within the HSE. This multi-annual project, which will establish a National ePrescription Service for Ireland, will have significant implications for the PSI, those we regulate, the wider health system and the public.

The PSI had significant engagement with the Department of Agriculture, Food and the Marine in regard to the Veterinary Medicinal Products Medicated Feed and Fertiliser Regulation Bill and also the National Veterinary Prescription System (NVPS), commenced at the end of January 2022 in an approach to tackling antimicrobial resistance in the European Union. We have raised with the Department of Health concerns about this new legislation so that it sufficiently addresses the role and responsibilities of pharmacies and pharmacists in the safe sale and supply of veterinary medicinal products.

We met with the National Cancer Control Programme (NCCP) and HPRA to discuss areas of mutual interest including contingency

arrangements in relation to extemporaneously compounded parenteral Systemic Anti-Cancer Therapy (SACT), Non-Medical Prescribing (NMP) and aseptic compounding. We also contributed to research commissioned by the National Patient Safety Office in the Department of Health for the Independent Patient Safety Council to explore the culture and principles underpinning the management of patient safety incidents.

At different points in the year, we were afforded the opportunity to present to students from each of the Schools of Pharmacy, a tradition now well established in our calendars. We were also pleased to participate at the APPEL Future of Pharmacie online event in October.

The PSI continues to be invited to attend a Controlled Drugs Cross-Border Group. Led by the UK Care Quality Commission, the Group shares information and concerns in regard to controlled drugs and illegal substances across the various jurisdictions of the UK and Ireland. We are also a member of the Committee of Experts on Quality and Safety Standards in Pharmaceutical Practices and Pharmaceutical Care through the European Directorate for the Quality of Medicines and Healthcare (EDQM). We were represented at meetings of this committee during 2022. The EDQM's mission is to contribute to the basic human right of access to good quality medicines and healthcare and to promote and protect human and animal health.

Ukraine Emergency Response Group

The outbreak of the war in Ukraine in March 2022, resulted in a need to engage across organisations to meet the demands expected to arise with the movement of people into Ireland, and in relation to any impact on our regulatory role. Between March and August, we established an internal Ukraine Emergency

Response Group to coordinate and address matters arising. Much of the work of the group involved engagement with stakeholders and improving knowledge and awareness of the issues involved. This included connecting with the HSE Primary Care Reimbursement Service (PCRS) regarding access to medicines and health advice from pharmacies for those arriving from Ukraine.

We also engaged with the Department of Health, national healthcare and non-healthcare professional regulatory bodies, the IPU and other key stakeholders in relation to providing a coordinated regulatory response, and to manage appropriately any applications for qualification recognition from Ukrainian qualified pharmacists. We also shared information, including on our website, for our registrants and for those coming from Ukraine. Finally, we also wrote to the Ambassador of Ukraine to Ireland, outlining PSI's role and how we may be involved in supporting Ukrainian pharmacists who considered working in their professional capacity while in Ireland, and with the aim of establishing a communication link for regulatory matters.

Communication channels

Our website is one important source of information supporting our mission and meeting stakeholder needs. We recognise that we have substantial work to do to provide a more effective website that is fit for a public sector body, and which that will align with other aspects of our digital transformation plans. We will implement a new, contemporary PSI website during 2023

and will engage with a variety of users as we do this to make it as useful and accessible a platform as possible.

We continued to engage through our social media platforms as an additional way of sharing information about our role and about regulatory and public health updates. We use the PSI newsletter to maintain regular contact with registrants and all those who subscribe to receive our updates. We issued four newsletters during 2022. 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 also sent email updates to our registrants on a range of topics as needed throughout the year. These included recognising the continued challenges of COVID-19 in the community for pharmacists and pharmacy teams, providing information about vaccination guidance and provision, compliance expectations, and opportunities to contribute to our work, such as for our pharmacist workforce survey in the latter part of the year. We also held one public consultation on the revised Core Competency Framework for Pharmacists during 2022.

We responded to media queries, supported media attendance at public Council meetings and public inquiries, issued press releases, wrote articles for external publications, answered 22 parliamentary questions, and responded to other requests for information from various stakeholders throughout the year.

Strategic Policy and Communication in Numbers

22

responses provided to
parliamentary questions



2 position papers submitted to the Department of Health

- The need for reform of the Pharmacy Act 2007
- Regulation of retail pharmacy businesses: current approach and future developments

4 updated guidance documents published to support pharmacist provision of vaccination services

4 PSI newsletters sent to our registrants and subscribers

3 press releases issued

1 public consultation held on a revised Core Competency Framework for pharmacists

12

Submissions to external consultations



- Mid-term review of Ireland's One Health National Action Plan on Antimicrobial Resistance 2021- 2025 (iNAP2)
- Draft Policy Framework for Open Disclosure in the Irish Health Sector to the National Patient Safety Office (NPSO), Department of Health
- National Risk Assessment 2023/24 for the Department of the Taoiseach
- Submission to inform the work of the Public Health Reform Expert Advisory Group
- Knowledge and Skills Framework for Healthcare Professionals Working with the Older Person developed by the Health Service Executive, Royal College of Physicians of Ireland and National Integrated Care Programme for Older Persons
- HSE draft National Clinical Guideline for Infection Prevention and Control
- HSE position paper on clinical governance for planning, oversight, and delivery of clinical care for older people in residential care services in Ireland
- HIQA draft recommendations on ICT enablement of Older Persons Services in Ireland.
- HIQA draft recommendations on a model for health information standards to support the delivery of health and social care services in Ireland
- Submission to inform HIQA recommendations on a consent model for the collection, use and sharing of health information
- HIQA draft National Standards for Information Management in Health and Social Care
- Medical Council revised draft standards and criteria for quality assuring medical education and training

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

We maintain a positive working environment for all our staff that encourages innovation and continuous improvement, with a strong focus on employee wellbeing, diversity, and inclusion.

In 2022, blended working was introduced and piloted with staff working from home a maximum of three days per week while the policy was in development. PSI's formalised Blended Working Policy was finalised towards the end of the year with roll-out commencing in Q1 of 2023. Related information is provided on page 17 about our implementation of our current HR Strategy.

Procurement of PSI's new HR information system was completed in 2022, with work commenced for its implementation towards the end of the year. The system will go live in Q1 of 2023. The benefits to be realised from this new system will be a reduction in the number of hours spent on manual HR administration tasks with the time saved dedicated to more value-add HR activities.

ICT

We 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 implemented a new telephone system that integrates with our existing collaboration software. The new system has reduced operating costs while increasing functionality. The increased functionality gives better self-service for support and reporting. This will assist the organisation to identify where resources are most needed.

We continue to review and implement measures to ensure that a suitable level of ICT systems security is in place, with a view to ongoing enhancement and increased security levels.

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 (BTP) and the Organisation Development Project (ODP). The outputs from these two initiatives will ensure that the PSI has the right organisational structure and technology to underpin our processes in order to maximise our resources as we evolve our regulatory reform model. Further information on the outputs in 2022 from the BTP and the ODP can be found earlier in this report.

Governance and Accountability

How we ensure standards of good governance

All PSI staff and officeholders have a role to play in assuring good governance of the PSI, including compliance with Government guidelines, and transparency about the way we carry out our statutory functions. The PSI is responsible to the public and is accountable to the Minister for Health and the Oireachtas in carrying out our role. We have a Corporate Governance Framework, Codes of Conduct for our Council, Committees and staff, and related governance policies and procedures to

support our compliance with the Code of Practice for the Governance of State Bodies. We meet our statutory governance obligations as set out in the Pharmacy Act 2007, the Ethics in Public Office Act 1995, and the Standards in Public Office Act 2001.

For public accountability and reporting purposes, the PSI is an aegis body of the Department of Health. In keeping with this obligation, three governance meetings were held with Department of Health officials during 2022, and the PSI Council was provided with the minutes of those meetings.

Council held ten meetings in 2022 of which seven were convened in public. The agenda and minutes of the seven public meetings of Council are published on the PSI website.

2022 marked the end of terms of office for some Council members, and following engagement with the Department of Health, new appointments were made to the Council by the Minister. The PSI Council also ensured the ongoing operation and good governance of the Advisory and Disciplinary Committees by making appointments where these fell due during the year. The work and commitment of current and past Council and Committee members is acknowledged.

PSI Council

The PSI is governed by a [21-member Council](#), with a non-pharmacist majority. Each member of the Council is appointed by the Minister for Health. The Council is accountable for the PSI's policy decisions, strategic direction, and overall performance of the organisation. Council members have a fiduciary duty in relation to the PSI. The PSI Council is also responsible for developing capacity and leadership within the PSI and is responsible for holding 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

PSI Council members, fees and expenses 2022

Council Member	Number of meetings attended¹	Fees paid in 2022²	Expenses paid in 2022³
Dr Paula Barry Walsh**	2/4	€4,173.06	-
Ms Geraldine Campbell**	8/10	€7,695.00	-
Ms Geraldine Crowley**	5/10	-	-
Mr Peter Dennehy**	4/4	€4,173.06	-
Ms Dorothy Donovan**	7/10	€7695.00	-
Mr Fintan Foy**	7/10	€7695.00	-
Mr John Given*	8/10	-	-
Mr Roy Hogan*	8/10	€7695.00	-
Mr Mark Jordan*	7/10	€7695.00	€892.92
Prof Brian Kirby*	9/10	€7695.00	-
Mr Graham Knowles**	9/10	€7695.00	€4,067.61
Dr Ann McGarry**	4/4	€4173.06	-
Ms. Katherine Morrow*	8/10	€7695.00	-
Ms Muireann Ní Shúilleabháin* President	10/10	€11970.00	€4,822.04
Mr Rory O'Donnell* Vice-President	10/10	€7695.00	€2,292.98
Ms Marie Louisa Power *	9/10	-	€694.00
Ms Grainne Power**	9/10	-	-
Mr Sean Reilly*	9/10	€7695.00	-
Ms. Avril Ryan*	1/1	€443.94	-
Ms Ann Sheehan**	7/10	€7695.00	-
Mr Paul Turpin**	8/10	€7695.00	-
Council Members in office for part of 2022 but no longer holding office:			
Dr Paul Gorecki**	4/5	€2811.63	-
Ms Joanne Kissane*	6/7	€5741.65	-
Dr Shane McCarthy**	4/5	€2811.63	-
Ms Fiona Walsh**	4/5	€2811.63	-

*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

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

² Fee payment is in line with the duration of term in office during 2022. Council Members employed in the public sector were not paid fees in 2022.

³ Aggregate expenses paid up to 31 December 2022.

PSI Committees

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 by 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 Committees 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 opportunities throughout 2022, including training in relation to new legislative provisions amending the Pharmacy Act 2007, recent case law in professional regulation, and equality, diversity and inclusion issues in decision-making.

PSI Advisory Committee members' attendance 2022

Audit and Risk Committee

Committee member	Meetings attended
Dr Paul Gorecki	1/1
Ms Fiona Walsh	1/1
Mr Liam Burke	3/4
Mr John Given	2/4
Mr Peter Dewhurst	3/4
Ms Niamh O'Regan	2/3
Ms Geraldine Campbell	4/4
Mr Graham Knowles	3/3
Dr Paula Barry Walsh	1/1

Special Purposes Committee

Committee member	Meetings attended
Ms Muireann Ní Shúilleabháin	5/5
Mr Rory O'Donnell	5/5
Mr Graham Knowles	1/1
Ms Joanne Kissane	3/4
Mr Paul Gorecki	2/2
Mr Paul Turpin	4/4
Ms Geraldine Campbell	3/3

Performance and Resources Committee

Committee member	Meetings attended
Mr Graham Knowles	2/2
Ms Geraldine Crowley	2/5
Ms Dorothy Donovan	3/5
Mr Fintan Foy	5/5
Mr Roy Hogan	3/5
Mr Mark Jordan	3/5
Dr Shane McCarthy	1/2
Ms Katherine Morrow	5/5
Mr Paul Turpin	5/5
Dr Ann McGarry	1/1

Regulatory and Professional Policy Committee

Committee member	Meetings attended
Mr Sean Reilly	5/6
Ms Ann Sheehan	3/6
Prof Brian Kirby	4/6
Mr Paul Turpin	3/3
Ms Marie Louisa Power	4/6
Ms Grainne Power	6/6
Ms Joanne Kissane	4/4
Mr Peter Dennehy	1/1

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 members of PSI staff 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 staff. This is based on the twelve principles of quality customer service used by Government Departments. In 2022, 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 26 data sharing requests, and 8 subject access requests in 2022.

Energy Efficiency and Conservation

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 2022, the PSI consumed 366,877 kWh of energy, consisting of 170,850 kWh of electricity and 194,005 kWh of gas. In comparison, the PSI consumed 388,517 kWh of energy in 2021, consisting of 154,850 kWh of electricity and 231,646 kWh of gas.

This is a 10% increase in electricity and a 16% reduction in gas in 2022. The increase in electricity can be attributed to staff working on a hybrid basis starting in March 2022 having worked remotely for the previous year due to the COVID-19 crisis. The decrease in gas can be attributed to energy saving measures implemented during 2022, in support of the 2030 public sector energy and CO2 targets.

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.

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 2022, we ensured compliance with the legislation by responding in a timely manner to FOI requests and reporting on our engagement with the legislation. In 2022, we received 9 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. 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.

In line with the Government's Work Safely Protocol, we maintained the COVID-19 Response Plan and worked with the Lead

Worker Representative to ensure staff and visitor safety at all times. The Response Plan and mitigation measures were kept under review during the year.

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 2022, 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. In 2022, two protected disclosures were received by the PSI in relation to the Registrar's role as the prescribed person for pharmacies and pharmacists in the jurisdiction. The PSI received one protected disclosure in relation to our role as an employer.

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 2022, 32% of our creditors had been paid

within 15 days and a further 46% within 30 days.

Equality, Diversity, and Inclusion Working Group Report

The PSI's Equality, Diversity, and Inclusion (EDI) Working Group comprises staff drawn from every level of the organisation, and 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 EDI.

The Group promotes awareness amongst PSI staff of our EDI obligations as a public body and assists the PSI in becoming a more inclusive and diverse workplace. In 2022, the Group organised a programme of talks, inviting a range of guest speakers who presented on topics such as attitudes to ageing and older people, dyslexia, and lived experiences of racism in pharmacy. These presentations raised awareness within the PSI and assisted us in exploring how we create a dyslexia-friendly workplace, counter age discrimination, and inform us of the racism faced by pharmacists, and pharmacy students from minority ethnic backgrounds in their work and educational environments.

The Group undertook the first of a programme of annual surveys of PSI staff on diversity and inclusion. The purpose is to better understand staff diversity levels in the PSI as well as levels of inclusion. The results of this survey led to recommendations being made by the EDI Group that will be implemented by the organisation in 2023.

The Group continues to work 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

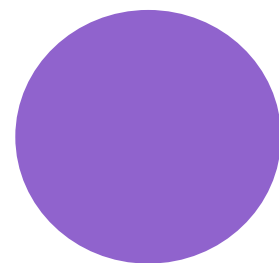
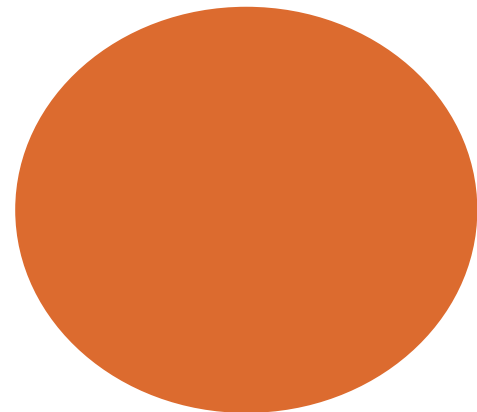
The Public Sector Duty is provided for under Section 42 of the Irish Human Rights and Equality Act 2014 and requires that public bodies seek to eliminate discrimination, promote equality of opportunity and treatment, and protect the human rights of its staff, and its stakeholders.

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, Delivering Equality in Public Services: An Introduction for Front-line Staff. 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, training was provided during 2022 to the Council of the PSI

and its Disciplinary Committees in relation to equality, diversity, and inclusion in fitness to practise decision-making.

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 2022, the PSI maintained the minimum 3% target of employment for people with disabilities. In meeting 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 detailed in the Code of Practice for the Governance of State Bodies, the Committee acts independently to ensure the interests of the PSI's stakeholders are protected. It does this by ensuring the PSI's business, financial reporting, and internal controls are robust and its assurance framework is fit for purpose. It also monitors the PSI's compliance with the law as it applies to public bodies, and the provisions of the Code of Practice.

The PSI's assurance framework includes a programme of internal audits presented to the Committee for consideration and approval. In 2022, the Audit and Risk Committee considered internal audit reports on the following operational areas:

- Governance and Programme Delivery
- Business Transformation Programme

In 2022, 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 was 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, which ensure risks are identified,

- Strategic Planning, and Monitoring Systems and Procedures

- Payroll, Travel and Allowances Policies and Procedures.

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 briefings on the PSI's quarterly financial position and the management of current regulatory risks.

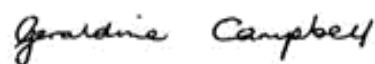
The Committee continues to monitor the implementation of the Protected Disclosures (Amendment) Act 2022 across the organisation, as the PSI seeks to bring its policies and standard operating procedures into compliance with the requirements of the Act.

At each of its meetings, the Committee reviewed the PSI's corporate risk register, and in 2022 conducted a deep dive on the following Business Area/programme risk registers:

- Strategic Policy and Communication
- Practitioner Assurance

mitigated, and controlled, and that the PSI is meeting its legal obligations.

On a personal note, I would like to thank my predecessor, Dr. Paul Gorecki, for his hard work and commitment, from which both the PSI and the Audit and Risk Committee has benefitted enormously.



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 with PSI staff and stakeholders to identify and assess those risks and agree on mitigating measures to manage them. These 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.

A summary of the PSI's principal risks and uncertainties as of 31 December 2022 is provided below:

1. The PSI relies on technology as a significant enabler for the delivery of

our functions. The PSI is also cognisant of government strategy to enhance online and digital access to services for the public and our registrants. The PSI carries risks related to operational effectiveness and service user access and experience owing to aging 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 that ensure ongoing systems updates and testing take place, a business continuity plan is established, and antivirus software and cybersecurity infrastructure are in place.

2. The PSI Council has deliberated extensively on the absence of rules in relation to the matter of temporary absence of 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 Minister 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 2022 they continued to keep this matter under review.
3. 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. There are risks identified in relation to the current legislative framework, and in seeking to mitigate those risks the PSI is engaged with the Department of Health with a view to reforming the legislative framework. The PSI has also examined the model of regulation that applies to the regulated element of hospital pharmacies and is seeking to bring clarity to this matter.

4. The ramifications in relation to the global COVID-19 pandemic continued in 2022 to impact the PSI's ability to fulfil all of its statutory and regulatory responsibilities, given the need to adhere to Government guidelines on safe working and remote-working. The PSI sought to adapt and mitigate this risk by holding fitness to practise inquiries remotely and carrying out online pharmacy assessments, where this was practical, and moved to in-person inspections and inquiries, where it became practical. The efficiencies identified while carrying out our statutory activities online were harnessed to evolve new processes. The ramifications in relation to the pandemic, in addition to increasing levels of staff turnover also impacted our ability to implement agreed strategies and plans within relevant timeframes, as well as impacting the

delivery of the PSI's Business Transformation Project given its foundational nature, and the scale of change across both people and processes in the organisation. The PSI mitigated the risk by putting additional supports in place for staff during remote working through our HR function, weekly Team Briefs and the input of our Wellbeing Group and an ongoing review of our capacity to deliver projects under the Service Plan 2022.

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, in order to put mitigation measures in place, the Council commissioned a project to be carried out to look at factors impacting the pharmacy workforce. Indications are that pharmacists are moving away from full time working within retail pharmacy businesses and this situation will have a further impact on the continuity of patient care and the clinical governance arrangements within pharmacies. In addition, PSI also implemented an escalation process for pharmacies that failed to comply with the Pharmacy Act 2007.

Our Financial Report

The 2022 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 2022.

Income

The total income in 2022 was €8.058m, which is an increase of €145k compared to the income received in 2021 of €7.913m. 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 (IOP) services.

The total fee income for 2022 is €7.458m, which is an increase of €145k compared to the fee income received in 2021. The increase was driven by the rise of €84k relating to applications for the recognition of pharmacist qualifications and continued registration fees of pharmacists of €77k.

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 2022 was €6.024m (€5.819m in 2021) and is reflected in the cash held at that date in the Statement of Financial Position.

In 2022, funding of €0.600m was received from the Department of Health with respect to the IOP. The drawdown of €0.600m represents the full allocation of funds from the Department of Health for 2021.

Cost of operations

The total cost of operations increased by €460k in 2022 to €8.029m, compared to €7.569m in the previous year. This was due to a variety of factors, including the lifting of COVID-19 restrictions, the continued investment in the new registration system 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 2021–2022*, as well as increased energy costs. The most significant increases in expenditure were in the Legal, Facilities, ICT, business transformation and pay costs.

The Council authorised the use of the Income and Expenditure Reserve to fund a number of projects amounting to €439k, of which €281k was spent in 2022. Of the €281k, €39k was spent on the Organisation Development Project and €242k on the Business Transformation project. €185k of fitness to practise related expenditure was funded by the Fitness to Practise Rolling Reserve.

In 2022, €22k was spent on the judicial review, taken by the Pharmaceutical Assistants Association, which has now concluded, and which was funded from the Designated Legal Reserve.

Pay costs

The level of permanent whole-time staff approved by the Department of Health in 2022 was not exceeded. The average number of staff on payroll during the year was 43. In 2022, 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 2022, were €3.589m, an increase of €0.065m on the 2021 cost of €3.524m. Direct pay costs amounted to €2.894m for the year, which is an increase of €0.052m on the 2021 cost of €2.842m.

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 and Reform, are disclosed in the annual financial statements.

The fees and travel expenses paid to Council members, Committee members, and employees of the PSI are also subject to scrutiny by the Internal Auditors and the Audit and Risk Committee and are formally approved by the Registrar. Travel expenses and subsistence, including international travel

expenses, are disclosed in the annual financial statements.

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 and Reform for health sector and civil sector grades. No bonuses, overtime, or performance payments were paid by the PSI in 2022, in accordance with the directive of the Department of Public Expenditure and Reform.

The level of absenteeism amongst PSI staff in 2022 was c. 2.6%. It is an increase compared to the figure of 1.51% in 2021. The commitment and dedication to work of PSI staff is highly valued by the Registrar and Council, particularly in view of the complex and expanding services required to be carried out in changed circumstances due to the COVID-19 restrictions at the start of 2022 followed by the introduction of blended working in Q2 2022.

Non-pay costs

The total non-pay costs in 2022 were €4.439m (2021: €4.045m). The major elements were:

	2022 €m	2021 €m
• Legal fees	0.895	0.824
• Tax and financial advisory fees	0.019	0.029
• Public affairs / marketing fees	0.033	0.028
• Energy costs	0.085	0.047
• Consultancy & Professional fees	0.031	0.013
• ICT costs	0.631	0.562
• Printing, postage, and stationery	0.097	0.070

• Repairs, maintenance, and other property costs	0.188	0.150
• Depreciation	0.279	0.121
• Insurance	0.099	0.091
• Institute of Pharmacy (IIOP)	1.172	1.136

The IIOP operated for a full calendar year in 2022 and drew down €1,171,993 of its full operating budget allocation of €1,300,000. This amount was offset by €600,000 from Department of Health funding received.

The PSI continued to use its approved Procurement Policy and the 2022 annual procurement plan to ensure that best value for money was achieved and costs were contained to the best of our ability.

Financial results 2022 against budget

The table below outlines the operating income and expenditure results for 2022 against the original 2022 budget. These figures exclude capital-related transactions, which are accounted for in the Balance Sheet.

Outturns for the year 2022 from operating activities against original budget

	Original Budget €	Outturn €	Variance €	Variance %
Total income	8,024,803	8,057,712	32,909	0.41%
Expenditure				
Pay costs	4,360,974	3,589,083	771,891	17.70%
Non-pay costs	4,742,561	4,439,418	303,143	6.39%
Total expenditure	9,103,535	8,028,501	1,075,034	11.81%
(Deficit) surplus from operating activities	(1,078,732)	29,211	1,107,943	102.71%
Interest income	-	5,878	5,878	-
(Deficit) / surplus	(1,078,732)	35,089	1,113,821	103.25%
Funding from reserves	726,021	486,688	(239,333)	(32.97)%

Adjusted (deficit) / Surplus for the year	(352,711)	521,777	874,488	247.93%
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Statement of financial position

The PSI's Statement of Financial Position as at 31 December 2022 shows that total assets exceeded total liabilities by €25.023m

compared to €24.988m at 31 December 2021.

This is the net assets of the PSI including PSI House. It is represented in the Statement of Financial Position as follows:

	2022	2021
	€m	€m
Consolidated reserves	11.109	11.074
Revaluation reserve	11.414	11.414
Designated legal reserve	2.500	2.500
Closing reserves	25.023	24.988

The cash balance in the Statement of Financial Position at 31 December 2022 was €7.177m. This amount excludes €12m 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 €6.024m (€5.819m in 2021).

The cash and investment assets balance include the following commitments:

	2022	2021
	€m	€m
Deferred income (prepayment of fees)	6.024	5.819
Statutory staff superannuation scheme funds	5.586	5.357
Designated legal reserve	2.500	2.500
Consolidated reserves minimum level – 50% of fee income	3.729	2.124
Total cash committed	15.339	15.800
Unrestricted cash	1.338	2.391
	19.177	18.191

The PSI's statutory staff superannuation scheme fund of €5.586 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 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 2022, and of its results for the year 2022. 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 with 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 2022 were undertaken for the PSI by the firm Crowleys DFK, 5 Lapps Quay Cork, T12 RW7D.

The PSI's appointed external auditors in 2021 were 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 2022

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Council Information

President

Ms. Muireann Ní Shúilleabháin

Vice President

Mr. Rory O'Donnell

Council Members

Dr. Paula Barry Walsh (appointed on 16 June 2022)

Ms. Geraldine Campbell

Ms. Geraldine Crowley

Mr. Peter Dennehy (appointed on 16 June 2022)

Ms. Dorothy Donovan (appointed on 16 May 2022)

Mr. Fintan Foy

Mr. John Given

Dr. Paul Gorecki (until 15 May 2022)

Mr. Roy Hogan

Mr. Mark Jordan

Prof. Brian Kirby

Ms. Joanne Kissane (until 28 September 2022)

Mr. Graham Knowles

Dr. Shane McCarthy (until 15 May 2022)

Dr. Ann McGarry (appointed on 16 June 2022)

Ms. Katherine Morrow

Ms. Grainne Power

Ms. Marie Louisa Power

Mr. Sean Reilly

Ms. Avril Ryan (appointed on 12 December 2022)

Ms. Ann Sheehan

Mr. Paul Turpin

Ms. Fiona Walsh (until 15 May 2022)

Registrar

Dr. Lorraine Horgan (Interim Registrar to 8th January 2023)

Ms. Joanne Kissane (appointed on 9th January 2023)

Head Office	PSI House, 15-19 Fenian Street, Dublin 2
Auditors	Crowe Ireland, 40 Mespil Road, Dublin 4
Bankers	Ulster Bank, 166a Shelbourne Road, Ballsbridge, Dublin 4 Bank of Ireland, College Green Dublin 2 Allied Irish Bank plc, 18 Eyre Square, Galway Allied Irish Bank plc, 1-4 Baggot Street Lower, Dublin 2 KBC Bank, Sandwith Street Upper, Dublin 2
Solicitors	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 2022

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 and Council 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 six members, which met on four occasions during 2022. 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 2022 show an operating surplus of €29,211 (2021: €343,544) which contributed to the total surplus for the financial year of €35,089 (2021: €344,418). The income for the year at €8.058m is a 1.8% increase on 2021 income of €7.913m.

In terms of annual reported expenditure, operating expenditure increased by €459k to €8.029m in 2022 compared to 2021 €7.569m. 2022 was marked by the lifting of COVID-19 restrictions and the start of the war in Ukraine. 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. 2022 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 2021–2022 and the resulting increase in pay costs.

Principal Risks and Uncertainties

In the current year, the PSI continued to be faced with high levels of change as we emerged from the pandemic across the year, adapted to changing work practices as blended working was introduced and addressed the uncertain economic conditions that prevailed.

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

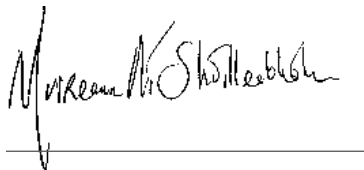
Each of the persons who is a Council Member at the date of approval of this report confirms that:

- 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

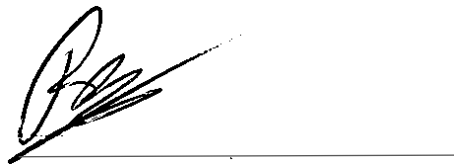
Crowe Ireland was appointed as the organisation's auditor in 2021, in accordance with Schedule 1, para 16(2) of the Pharmacy Act 2007.

This report was approved by the Council on 23 March 2023 and signed on its behalf.



Ms Muireann Ní Shúilleabháin

President



Mr Rory O'Donnell

Vice President



Statement of Council's Responsibilities for Year Ended 31 December 2022

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

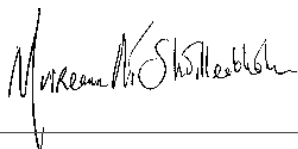
Schedule 1, paragraph 16, of the Pharmacy Act 2007 requires the Council to prepare the financial statements for each financial year. Under the law, the Council has elected to prepare the financial statements in accordance with Financial Reporting Standard 102 'The Financial Reporting Standard applicable 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 23 March 2023:



Ms. Muireann Ní Shúilleabháin
President



Mr. Rory O'Donnell
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

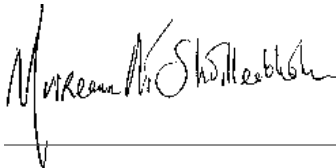
In compliance with the Department of Public Expenditure and Reform's Code of Practice for the Governance of State Bodies 2016, I would like to confirm that:

- i. There were no commercially significant developments affecting the ongoing operations of the PSI in 2022.
- ii. All appropriate procedures for financial reporting, internal audit, travel, procurement and asset disposals are being carried out.
- 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.
- x. 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 2022 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 2021-2023 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 2022:
The Council had [10] 47.6% female and [11] 52.4 % 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.
- Five appointments were made to the Council in 2022.
- The following measures are used to maintain and support gender balance on the Council:
 - The Council's annual evaluation process will incorporate a detailed analysis 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 23 March 2023 and signed by the President:



Ms Muireann Ní Shúilleabháin

23 March 2023

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 performances.
- 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 2022 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 Corporate Strategy 2021-2023.
- 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 2022, the following controls were reviewed:

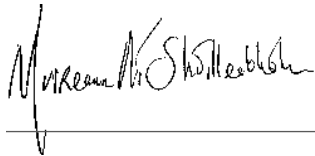
- Quarterly management accounts were reviewed by the Audit and Risk Committee, the Performance and Resources Committee, and the Council with an explanation of significant deviations from budget.
- Annual Accounts for 2021 were reviewed, approved and published by Council with explanation of significant 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:
 - Review of Strategic Planning, Scoping and Monitoring
 - Review of PSI Payroll, Travel and Allowances

No weaknesses in internal control were identified that 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 2022. All elements of the control system were operational. No material losses or frauds were identified in 2022.

The PSI complies with current procurement rules and guidelines set out by the Office of Government Procurement.

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. I confirm that the Council conducted an annual review of the effectiveness of the internal controls for 2022.

This statement of internal control has been formally reviewed and approved by the PSI Council on 23 March 2023 and signed on its behalf by the President:



Ms Muireann Ní Shúilleabháin

23 March 2023



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 2022, 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 2022 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 7 to 9 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 skepticism 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 Councils' 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
23 March 2023

Statement of Comprehensive Income for Year Ended 31 December 2022

	Notes	2022 €	2021 €
Income	3	8,057,712	7,912,632
Operating expenses		<u>(8,028,501)</u>	<u>(7,569,088)</u>
Operating surplus		29,211	343,544
Interest Receivable	9	<u>5,878</u>	<u>874</u>
Surplus before taxation		35,089	344,418
Taxation	11	<u>-</u>	<u>-</u>
Surplus for the financial year		<u>35,089</u>	<u>344,418</u>

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

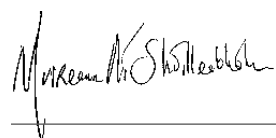
The notes on pages 77 to 94 form part of these financial statements.

Statement of Financial Position for Year Ended 31 December 2022

	Notes	2022 €	2021 €
Fixed assets			
Tangible assets	12	18,805,196	18,827,163
Investment assets	13	12,000,000	7,200,000
		<u>30,805,196</u>	<u>26,027,163</u>
Current Assets			
Debtors	15	192,400	180,568
Cash at bank and in hand	16	7,176,843	10,990,855
		<u>7,369,243</u>	<u>11,171,423</u>
Creditors: amounts falling due within One year	18	<u>(13,151,681)</u>	<u>(12,210,917)</u>
Net current assets		<u>(5,782,438)</u>	<u>(1,039,494)</u>
Total assets less current liabilities		<u>25,022,758</u>	<u>24,987,669</u>
Reserves			
Revaluation Reserve	19	11,413,635	11,413,635
Designated Legal Reserve	19	2,500,000	2,500,000
Consolidated Reserves	19	11,109,123	11,074,034
Closing Reserves		<u>25,022,758</u>	<u>24,987,669</u>

The financial statements were approved and authorised for issue by the Council on 23 March 2023.

Signed on behalf of the Council:



Ms Muireann Ní Shúilleabháin
President



Mr Rory O'Donnell
Vice President

Statement of Cash Flows for Year Ended 31 December 2022

	2022	2021
	€	€
Cash flows from operating activities		
Surplus for the financial year	35,089	344,418
Depreciation on tangible assets	278,790	120,976
Interest received	(5,878)	(874)
Decrease/(increase) in debtors	(11,832)	17,782
Increase/(decrease) in creditors due within one year	940,764	273,310
Net cash flows from operating activities	1,236,933	755,612
Cash flows from investing activities		
Payments for tangible fixed assets	(256,823)	(582,966)
Payments for investment assets	(4,800,000)	(7,200,000)
Interest received	5,878	874
Net cash flows from investing activities	(5,050,945)	(7,782,095)
Net decrease in cash and cash equivalents	(3,814,012)	(7,026,483)
Cash and cash equivalents at beginning of financial year	10,990,855	18,017,338
Cash and cash equivalents at end of financial year	7,176,843	10,990,855
Relating to:		
Cash at bank and in hand	7,176,843	10,990,855

The notes on pages 77 to 94 form part of these financial statements.

Notes to the Financial Statements for Year Ended 31 December 2022

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 cost includes 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:

1.3. Tangible fixed assets (continued)

Depreciation

Depreciation is provided on the following basis:

Freehold property	-	Not depreciated
Office equipment & fittings	-	12.5% straight-line
Computer equipment & software	-	33.3% straight-line
Portraits, medals and badges	-	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 resultant revaluation is recognised in the Statement of Comprehensive Income. The last revaluation took place on the 18 January 2019.

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 re-valuation 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 current year value at 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 Income Statement.

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 instruments 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 at call 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 10th March 2016, SI 136 of 2016 was signed by Minister for Health with the consent of 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 the 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 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 is 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 judgement.

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.

	2022	2021
	€	€
Registration of pharmacists	2,710,217	2,645,408
Registration of retail pharmacy business (RPB)	4,478,206	4,483,106
Administration charges and other registration costs	228,604	123,378
Other fees	40,685	60,740
Department of Health funding for Irish Institute of Pharmacy (IIOP) services	600,000	600,000
	<u>8,057,712</u>	<u>7,912,632</u>

4. Operating surplus

Operating surplus for the year is calculated after charging:

	2022	2021
	€	€
Depreciation of tangible assets	278,790	120,976
Other pension costs	442,426	440,086
Audit Remuneration (including VAT)		
-Audit Fees	31,094	13,537
	<u>752,310</u>	<u>574,599</u>

5. Employees

5.1. Average Numbers

The average monthly number of employees during the year was as follows:

	2022	2021
Office and management	<u>43</u>	<u>44</u>

5.2. Aggregate remuneration

Their aggregate remuneration comprised:

	2022	2021
	€	€
Wages and salaries	3,058,915	3,058,140
Social insurance costs	254,208	242,239
Pension costs	442,425	440,086
	3,755,548	3,740,465

Analysed as follows

Capitalised into assets	165,308	216,585
Expensed in the year	3,590,240	3,523,880
	3,755,548	3,740,465

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:

	2022	2021
€60,000 to €70,000	4	10
€70,000 to €80,000	7	3
€80,000 to €90,000	3	-
€90,000 to €100,000	2	-
€100,000 to €110,000	-	2
€110,000 to €120,000	2	-
€120,000 to €130,000	-	1
	18	16

5.4. Key Management Personnel

The remuneration of key management personnel was as follows:

	2022	2021
	€	€
Wages and salaries	474,423	547,472
Allowances	12,197	-
Other pension costs	109,131	134,455
	595,751	681,927

5.5. Registrar remuneration

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

	2022	2021
	€	€
Niall Byrne	4,506	128,090
Other pension costs	751	32,022
Lorraine Horgan	114,881	-
Other pension costs	28,720	-
	<u>148,858</u>	<u>160,112</u>

6. Other Staff Costs

6.1 Staff Travel and Subsistence

	2022	2021
	€	€
Domestic	12,635	8,835
International	7,177	-
	<u>19,812</u>	<u>8,835</u>

6.2 Hospitality Expenditure

	2022	2021
	€	€
Staff hospitality	861	948
	<u>861</u>	<u>948</u>

7. Council/Committee Members' Remuneration

	2022	2021
	€	€
Council/Committee members' remuneration	206,889	224,225
	<u>206,889</u>	<u>224,225</u>

8. Council/Committee Members' Travel & Subsistence

	2022 €	2021 €
Domestic	28,586	3,181
International	6,117	-
	<u>34,703</u>	<u>3,181</u>

9. Interest Receivable

	2022 €	2021 €
Bank interest receivable	5,878	874
	<u>5,878</u>	<u>874</u>

10. Consultancy and Legal Costs

10.1 Consultancy Costs

Consultancy costs include the cost of external advice to management and exclude outsourced 'business as usual' functions.

	2022 €	2021 €
General legal advice	38,176	82,205
Financial advice	17,712	4,469
Public Affairs	30,996	26,090
Procurement	22,506	12,745
Other	20,225	21,489
	<u>129,615</u>	<u>146,998</u>
Consultancy costs capitalised	-	-
Consultancy costs charge to the Income and Expenditure and Retained Earnings Reserves	129,615	146,998
	<u>129,615</u>	<u>146,998</u>

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 and 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 which is disclosed in Consultancy costs above.

	2022 €	2021 €
Legal Fees	856,819	741,891
Conciliation and arbitration payments settlements	-	-
	<u>856,819</u>	<u>741,891</u>

Legal costs 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 2022 legal fees amounted to €856,819 (2021: €741,891) 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.

All fees incurred in 2022 in the Judicial Review proceedings, which has now concluded, and which concerned proposed statutory rules dealing with the temporary absence of pharmacists in registered Retail Pharmacy Businesses, have been accounted for in the Financial Statements.

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 & buildings €	Premises Improvements €	Portraits, medals & badges €	Office fixture & fittings €	Computer equipment & software €	Total €
Cost						
At 1 st January 2022	17,700,000	35,579	10,431	258,955	1,403,557	19,408,522
Additions	-	5,229	-	10,404	241,190	256,823
Cost of Disposal	-	-	-	-	-	-
At 31 st December 2022	17,700,000	40,808	10,431	269,359	1,644,747	19,665,345
Depreciation and impairment						
At 1 st January 2022	-	16,790	-	232,834	331,735	581,359
Depn. eliminated on disposals	-	-	-	-	-	-
Depn. charged in the year	-	4,679	-	6,751	267,360	278,790
At 31 st December 2022	-	21,469	-	239,585	599,095	860,149
Carrying amount						
At 1 st January 2022	17,700,000	18,789	10,431	26,121	1,071,822	18,827,163
At 31 st December 2022	17,700,000	19,339	10,431	29,774	1,045,652	18,805,196

13. Investment Assets

Investment Assets

	2022	2021
	€	€
Exchequer Notes	12,000,000	7,200,000
	<u>12,000,000</u>	<u>7,200,000</u>
	2022	2021
	€	€
Cost		
At the beginning of the year	7,200,000	-
Purchased during the year	4,800,000	7,200,000
Disposed during the year	-	-
At the end of the year	<u>12,000,000</u>	<u>7,200,000</u>

The PSI purchased €4,800,000 of Exchequer Notes during the year with a maturity date of 19th June 2023. The fair value at 31st December 2022 was €12,000,000 (2021: €7,200,000). The investment assets included €4,800,000 of Superannuation funds.

14. Financial Instruments

	2022	2021
	€	€
Financial assets		
Bank and Cash Balances	7,176,843	10,990,855
Investment assets	12,000,000	7,200,000
	<u>19,176,843</u>	<u>18,190,855</u>
Financial liabilities		
Trade creditors	<u>572,918</u>	<u>247,297</u>

15. Debtors	2022	2021
	€	€
Trade Debtors	65,359	45,448
Prepayments and accrued income	118,854	123,249
Other Debtors	8,187	11,871
	192,400	180,568
16. Cash and cash equivalents	2022	2021
	€	€
Cash at bank and in hand	7,176,843	10,990,855
17. Cash	2022	2021
	€	€
Cash at hand	309	273
Current accounts	5,398,038	5,094,280
Superannuation funds deposit account	536,964	5,357,056
Fixed term deposits	1,241,532	539,246
	7,176,843	10,990,855

Cash held in fixed term deposits and current accounts contains part of the Consolidated Reserves.

€4,800,000 of Superannuation funds held in Superannuation funds deposit accounts were invested in Exchequer Notes during 2022. The Designated Legal Reserve funds of €2,500,000 was also invested in Exchequer Notes.

18. Creditors: amounts falling due within one year

	2022 €	2021 €
Trade creditors	572,918	247,297
Other creditors	12,827	11,026
PAYE/PRSI	162,244	120,300
VAT	-	443
PSWT	29,353	33,555
Deferred income	6,023,678	5,818,928
Accruals	764,838	622,312
PSI Superannuation scheme	5,585,823	5,357,056
	13,151,681	12,210,917

19. 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 is 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 will be kept under annual review to ensure they remain fit for purpose.

19.1 Revaluation reserve

The freehold property was valued by Murphy Mulhall Chartered Surveyors, on the 18th January 2019 to a fair value of €17,700,000. The PSI reflected this revised valuation in the accounts for the year ended 31st December 2018. No revaluation of this asset has been undertaken in the interim and therefore no change in the valuation at 31st December 2022.

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 reserve of €200K taken from the Income and Expenditure Reserve on an annual basis dedicated to funding strategic projects identified as such as part of the annual planning process. 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 and so as to off-set year-on-year peaks and troughs. This is a rolling reserve with a limit of €300K.

19.4. Movements in reserves

The movements in reserves are detailed below:

	At 1st January 2022	Income	Expenditure	Transfers	At 31 December 2022
Income & Expenditure Reserve	11,074,034	8,063,590	(7,772,989)	(3,221,652)	8,142,983
Strategic Objectives Reserve	-	-	(48,364)	200,000	151,636
Future Technology Investment Reserve	-	-	-	1,200,000	1,200,000
Building Maintenance Reserve	-	-	-	1,500,000	1,500,000
FTP Rolling Reserve	-	-	(185,496)	300,000	114,504
Total Consolidated Reserves	11,074,034	8,063,590	(8,006,849)	(21,652)	11,109,123
Revaluation Reserve	11,413,635	-	-	-	11,413,635
Designated Legal Reserve	2,500,000	-	(21,652)	21,652	2,500,000
Total Reserves	24,987,669	8,063,590	(8,028,501)	-	25,022,758

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 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 2022, superannuation benefits were payable in respect of three members. Total benefits paid amounted to €10,973 (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

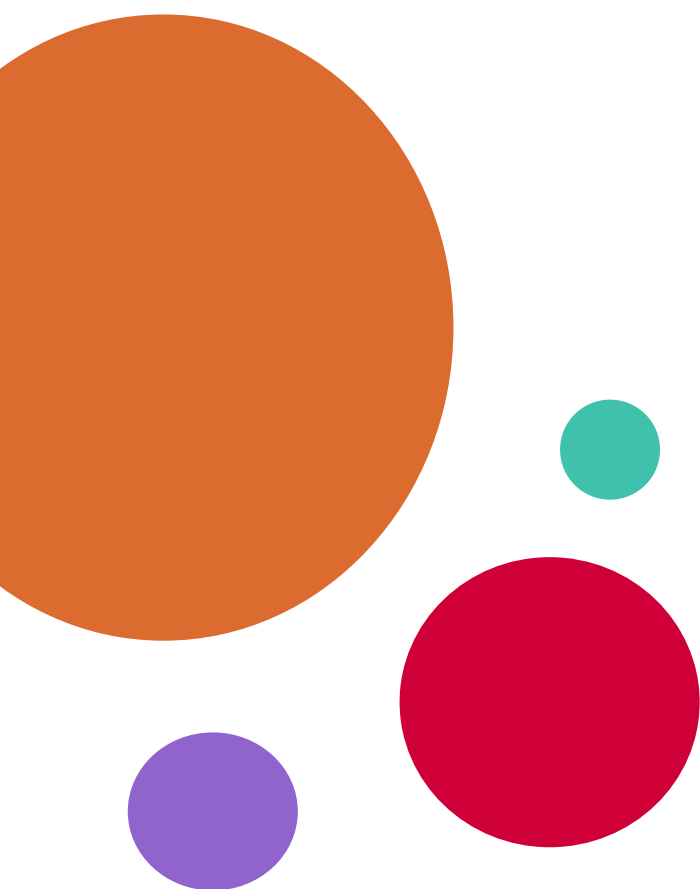
There were no transactions with related parties that require disclosure.

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 23rd March 2022.





The Pharmacy Regulator

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