



The Pharmacy Regulator
An Rialtóir Cógaisíochta



Annual Report

2021

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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;
- 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 2021-2023 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 2021 is submitted to the Minister for Health in accordance with paragraph 17(1) of Schedule 1 to the Pharmacy Act 2007. The Report covers the period from 1 January 2021 to 31 December 2021.



Our Vision, Mission and Values

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.

Our Mission

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

Our Values

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

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

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 and timely.

Embrace change



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

Highlights of 2021

Corporate Strategy 2021-2023

We launched our current Corporate Strategy, which sets out our three key objectives until 2023. In this Report, we reflect on our progress against the Strategy to date.



Organisation and Management Structure Changes

As part of our organisation development project we implemented a new organisation structure with the changes designed to support us in achieving our strategic priorities, and in reflection of the digital changes that will impact the way we work.



New Registration Portal

Our programme of digital transformation continued with the launch of our new registration portal, to provide all registrants and registration applicants with a more efficient and streamlined way of engaging with us online.

Council Appointments

Five Council members completed terms in office during 2021 and the Minister for Health appointed new Council members in June and October.

COVID-19 Vaccinations

COVID-19 continued to dominate how we worked during 2021. We worked with others in ensuring pharmacists' participation in the national COVID-19 vaccination programme, the approval of training for pharmacist vaccinators, and the roll-out of the programme to community pharmacies.



COVID-19 Operational Standards Overview Report

We published an Overview Report documenting how we developed the COVID-19 Operational Standards and what we learned, on an initial basis, through assessing their impact and use in some pharmacies during the pandemic.

Regulated Professions (Health & Social Care)(Amendment) Act

We implemented the substantial changes arising from the Regulated Professions (Health & Social Care)(Amendment) Act. We updated all our policies, procedures and guidance documents related to our processes for formal complaints and disciplinary proceedings.

Introduction from the President

I am pleased to present the PSI Annual Report in accordance with the requirements of the Pharmacy Act 2007 for the period from 1 January to 31 December 2021. On behalf of the PSI Council, Registrar and staff, it is my pleasure to share in this report the details of our work during a busy and challenging year.

The PSI is a public body established with the purpose of protecting the health, wellbeing and safety of patients and the public by regulating pharmacies and pharmacists in Ireland. We undertake our mission in a variety of ways, focused on our commitment to assuring public trust through effective regulation. As this report outlines, last year, like the year before, demonstrated the ongoing ability of the PSI to adapt quickly and to collaborate extensively with others to ensure public health needs were met in the face of a global pandemic.

I will take this opportunity to commend all who played a key role in the fight against COVID-19 and acknowledge the sterling work of pharmacists, pharmacy owners and the whole pharmacy team, who ensured continuity of services under challenging conditions. In addition, to providing the “normal” and “expected” services associated with a pharmacy, pharmacists played a pivotal role in the national vaccine programme, demonstrating adaptability, capability and professionalism in their response, which was underpinned by a commitment to safeguarding public health. From January 2021, right through to the end of the year, the PSI was involved with the Department of Health, HSE, Irish Pharmacy Union and others in ensuring that the legislation, systems, guidance, training and governance was put in place to facilitate and support the roll-out of COVID-19 vaccines and boosters in national vaccination centres and through community pharmacies, for all cohorts

of the public. This was in addition to extensive collaborative efforts on contingency arrangements for pharmacies and adaptations around education, training and continuing professional development, all necessary in the face of a public health challenge to maintain standards of safety and quality for professional pharmacy services.

As in 2020, our work continued remotely, with staff, Council and Committees using technology to meet virtually and ensure we conducted our functions while limiting risks related to COVID-19. Statutory Disciplinary Committee meetings, including Fitness to Practice Inquiries, for example, and meetings before the PSI Council, continued to be held remotely during 2021, ensuring continuity, and most importantly, assuring a fair process for all involved. New legislation also came into force in early 2021, impacting the process of considering complaints and disciplinary proceedings against pharmacists and pharmacies under the Act. This brought changes in consideration of the publication of the outcomes of hearings and sanctions and our Council and Disciplinary Committee members undertook additional training in response to those changes.

In 2021, we continued to look to the future with our development agenda so that the PSI evolves and enhances our abilities as a public interest regulator. In conjunction with the Executive Leadership Team, the Council developed and launched our new Corporate Strategy 2021-2023, devised against the backdrop of the COVID-19 pandemic. The strategy recognises the critical importance of enhancing resilience within the sector and of building capacity so that the PSI can adapt and respond to the evolving needs of an integrated healthcare system.

The Council has committed and invested in several projects, which were continued during 2021, such as transitioning to a digital-first approach as part of the business transformation project. Ease of engagement and the availability of information is critical to successful regulation, and we are committed to making it easier for stakeholders to engage with the PSI and to streamlining the work of those within the PSI. This project is being delivered on a phased basis. Phase one saw the launch of a new registration platform, providing registrants with a single online point of contact with the PSI. The new system makes searchable online registers available to all wishing to access them, providing details of a range of matters, from a pharmacy's supervising pharmacist to its opening hours. The PSI will continue to enhance that service and move to the subsequent phases of our digital transformation project in 2022 and 2023.

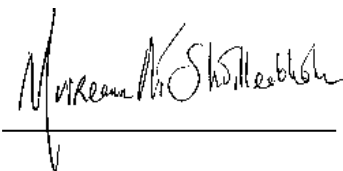
In 2021, aligned to our new Corporate Strategy, we continued developing our view for reform of pharmacy legislation, which must reflect the 21st-century healthcare and regulatory environment. The Pharmacy Act 2007 introduced many of the fundamentals of pharmacy regulation in Ireland, but it is now in operation for over 14 years. It is timely that we are engaging with the Department of Health in considering how we might progress a significant review of our regulatory framework to ensure it continues to be fit for purpose to protect the public interest and ensure patient safety.

As we look forward now with determination and energy for our task, and as restrictions start to ease concerning this devastating pandemic, I would like to thank members of Council for their dedication. We held ten Council meetings in 2021 and many other committee meetings. I thank the Council members who completed terms in office this past year and welcome those appointed to Council by the Minister for

Health. I also acknowledge outgoing President and Vice-President Joanne Kissane and Michael Lyons for their extensive efforts over two years, and I want to extend gratitude to the members of our statutory Disciplinary Committees, including those who completed their terms of service this year, for the detailed and careful work that they undertake.

Finally, I would like to pay a special tribute to the staff of the PSI. Under the expert guidance of Niall Byrne, Registrar, they brought energy, dedication, and a steadfast commitment to public service during a year that was often difficult. At the end of 2021, Niall stepped down from the helm of the organisation after five years, and we acknowledge his leadership and focus on an inclusive, collaborative regulatory approach. I also acknowledge Dr Lorraine Horgan, Head of Corporate Services with PSI, now filling the Interim Registrar role following Niall's departure and until a public recruitment process is completed to appoint a new Registrar.

Finally, on behalf of the Council, I would like to thank the Minister for Health and the officials within his department for their continued support and engagement with us at the PSI. This Annual Report represents the hard work and determination of all those who have committed themselves to the mission of the PSI, and together with the PSI Council, I look forward to our ongoing work with partners and stakeholders in the year ahead.



Ms Muireann Ní Shúilleabháin
President

Message from the Interim Registrar

While the year ended on a brighter note, COVID-19 continued to bear heavily on Ireland's healthcare system throughout 2021, and the delivery of all services, including those by pharmacists and pharmacies. It also impacted our work programme as the pharmacy regulator. Nonetheless, as this annual report details, notwithstanding the challenges the pandemic presented, our focus remained on carrying out our statutory functions effectively, delivering on our commitments to assure public and patient trust in continued safety of Ireland's pharmacy services.

The maintenance of registers of pharmacists, pharmaceutical assistants and pharmacies is among the core functions of the PSI along with ensuring the accuracy of the information available. There were 6,846 pharmacists and 1,981 pharmacies registered with the PSI by the end of 2021. This continues the year-on-year increase of registrants on both registers, and it is our role to ensure the suitability of the professionals and the pharmacy environments before they can provide health services to the public. Our establishment of a new registration system and portal for applicants and registrants, while not without its challenges, has introduced an improved system that will have great benefits for users, both internal and external, in the years ahead. We were delighted to see this system go-live in September and appreciate the inputs we had from pharmacists before its launch. Also on the registration front, after several years of preparation, January 2021 also marked the United Kingdom's (UK) departure from the European Union, and the agreed qualification recognition and registration process for applicants with qualifications obtained in the UK was therefore implemented.

Another significant aspect of our work is to respond to information that raises concern

about the conduct, professionalism or operation of a pharmacist or pharmacy. The public and patients, and indeed other pharmacists and healthcare professionals, all contribute to the effective regulation of pharmacists and pharmacies by reporting any concerns they may have regarding the safe delivery of pharmacy services. During 2021, 120 expressions of concern were received by the PSI. Separate to matters raised through our formal complaint process, a multi-disciplinary group of staff assessed each of the concerns to ensure these were followed up, if necessary, through the appropriate regulatory channel.

Furthermore, we received a total of 80 formal complaints resulting in 25 complaints referred for further action. The number of complaints was up in 2021 compared to 2020 and 2019, but these numbers also need to be considered in the context of the vast volume of pharmacy visits per annum, and additional services provided by pharmacists in community pharmacies during this pandemic. While there appear to be relatively low levels of concerns and complaints, the need for continued collective vigilance must be maintained, with all registrants having important roles to play and continuing to make available opportunities for feedback in pharmacies. The PSI will continue to raise awareness of our role so that people know how they can raise a complaint with the PSI when necessary.

Despite the impact of COVID-19 on field work (such as pharmacy inspections) and face-to-face interaction that continued during 2021, we utilised a range of methods to supervise and assess compliance with pharmacy legislation, enabling us to continue to fulfil our remit in assuring the safety of healthcare services as provided through community pharmacies. We adopted a hybrid approach to inspections, using both in-person and online visits.

Commencing the delivery of Council's new Corporate Strategy for the period to 2023 was also a significant part of our work this past year. Notwithstanding any changes necessitated by the pandemic, we continuously review how we regulate and started to implement our co-ordinated policy approach to risk-based regulation, which is now being utilised within our range of regulatory tools. This is part of how we make sure we can use our resources more efficiently and allow for a more proportionate response to an identified risk.

Aligning to our Business Transformation Programme (BTP), and our strategic objective to build our capability and performance, we have reviewed how we are structured as an organisation and implemented changes in 2021, with a view to enhancing how we can best work as a regulator and meet our strategic priorities. We are continuing to embed the agreed model to support a more cross-functional work environment, improving organisation capacity, planning and delivery and aligning how we work to our strategic approach.

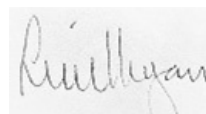
What we do is part of a greater healthcare and regulatory environment, and we are pleased to work with many others whose focus is on ensuring and providing safe and quality health services. We participated in, and lent our advice and expertise, to a broad range of discussions, meetings and working groups throughout the year, to represent public safety and pharmacy regulation. While our ability to meet many of our registrants in person has been curtailed since March 2020, we remain committed to direct engagement with pharmacists and those operating pharmacies, in our shared vision for the safe provision of pharmacy care and services, and we always welcome their input and feedback.

Throughout the year, we continued to participate in the National Safety Features Oversight Group around the phased implementation of the Falsified Medicines

Directive regarding medicine scanning and authentication. We have sought to encourage and support compliance in pharmacies as the end of the 'use and learn' period for this draws nearer. We have also been pleased to continue strong working relationships with our parent Department, with the HSE, and with other regulators, and representative bodies.

Like many organisations, 2021 was a challenging year for the PSI, where we strived to seek a balance between delivering on our core functions and strategy related activities, upholding good governance and the standards expected of a public body, and the demands presented by COVID-19. The PSI, with the support of the Council, continued to play an active role in the public health response to the pandemic, particularly prioritising support for the safe delivery of COVID-19 vaccination services by pharmacists across the country, ensuring the significant role pharmacists played in the national roll-out.

This Annual Report for 2021, and the accompanying financial statements, represent the commitment, hard work and ongoing professionalism of my colleagues across the organisation, of our Council, and of our Disciplinary Committee and Advisory Committee members, who continue to work collectively in the public interest despite working at a distance from each other over the past two years. I would like to thank Niall Byrne for his dedicated leadership and guidance in his role as Registrar and Chief Executive of the PSI, up until the end of December 2021. I would also like to acknowledge the many people outside the PSI who participate in our work and engage with us. This includes pharmacists, patients, advocacy groups, pharmacy teams and other healthcare professionals, as well as other regulatory and state bodies whose individual and collective contributions are greatly valued by the PSI.



Dr Lorraine Horgan
Interim 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 2021-2023 during its first year. There are three strategic areas under which we aim to deliver specific results.



Managing our response to COVID-19

The COVID-19 pandemic continued to play a large part in all our lives during 2021. Throughout this time pharmacists and pharmacy teams have continued to make an extraordinary contribution in ensuring the continuity of pharmacy services for patients and the public in the face of unprecedented difficulties, as well as making a significant and valuable contribution to public protection through their role in the National COVID-19 Vaccination Programme.

We continued to work in partnership with the pharmacy profession and other stakeholders to support pharmacy teams in their work to provide safe and effective care and services. We were in regular communication with PSI registrants throughout the year with updates on key developments and guidance.

For a second year, we outline in this section some of the COVID-19 related work that the PSI has been involved in.

HSE Community Pharmacy Contingency Planning Forum

The PSI continued to participate in the HSE Community Pharmacy Contingency Planning Forum during 2021. The forum was established by the HSE in 2020 to discuss contingency planning and issues arising for community pharmacy services during COVID-19. It includes members from the HSE, Department of Health, PSI, Irish Pharmacy Union (IPU), the Irish Institute of Pharmacy (IIOP) and several community pharmacists. The HSE also formed a subgroup comprising the HSE, PSI and IPU to address the roll-out of the COVID-19 vaccination programme to community pharmacies.

The National COVID-19 Vaccination Programme

The PSI worked in partnership with the pharmacy profession and other stakeholders to support the safe involvement of pharmacists in the COVID-19 vaccination programme and, in particular, its roll-out to community pharmacies.

During 2021, a total of 16 statutory instruments to amend the Medicinal Products (Prescription and Control of Supply) Regulations 2003 to provide for the COVID vaccination programme, and related changes to the programme, were drafted by the Department of Health with the PSI providing assistance and review.

Under that 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 by the PSI throughout 2021 to review and approve training for pharmacists to administer COVID-19 vaccines as new vaccines were authorised for use, and as the service was extended into community pharmacy. 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 and recommend for approval these training courses for pharmacists.

Through the subgroup of the HSE Community Pharmacy Contingency Planning Forum we worked closely with the HSE and the IPU to identify the key regulatory and operational components necessary to support the safe roll-out of vaccination services within community pharmacies. HSE operational guidance was developed together with the PSI

and the IPU, to give comprehensive and supportive guidance to pharmacists on how COVID-19 vaccination services should operate in community pharmacies. We also sent communications throughout the year to those in governance roles to highlight key aspects of governance and clinical leadership for the provision of a safe COVID-19 vaccination service in community pharmacies. The programme commenced in community pharmacies on 14 June 2021 and to year end community pharmacies provided a total of 606,394 COVID-19 vaccines as part of the national programme.

Pharmacists were central to the delivery of vaccination services within specialist centres and centralised vaccination centres throughout the country, taking up leadership, medicines management and vaccinator roles. In addition, many students of the five-year MPharm programme (the qualification for practice in Ireland as a pharmacist) made significant contributions to the success of the vaccination programme within centralised vaccination centres and community pharmacies.

COVID-19 Operational Standards for Pharmacies

PSI COVID-19 Operational Standards for Pharmacies were collaboratively developed with a range of stakeholders in 2020. The aim was to provide guidance and support during the pandemic to those in governance positions in pharmacies in continuing to ensure safe services and a safe environment for patients, the public and pharmacy teams. In 2021, PSI quality assessors continued to conduct fieldwork testing of the Standards during March and April. In the main these were virtual visits with pharmacies that had volunteered to participate through an expression of interest process.

The published Overview Report documents how we developed these Standards and what we learned, on an initial basis, through assessing the impact of the Standards in a small number of pharmacies. This report was published in June and sets out some important observations and findings from these initial assessments. It highlights a range of good practices found in pharmacies as well as noting some areas requiring improvement. Our learning to date will inform the development of a monitoring and an associated judgement framework that will assist us in carrying out assessments of performance against the Standards.

Testing for SARS-CoV-2 in Pharmacies

We engaged regularly in 2021 with the Department of Health, Health Products Regulatory Authority (HPRA) and the HSE on the provision of COVID-19 tests in pharmacies, as national policy and advice on COVID-19 testing continued to evolve. We communicated relevant information to registrants on this subject as the situation developed during the year.

COVID-19 Information Hub

Developed by the IOP at the request of the PSI, the COVID-19 Information Hub continues to provide a single source of up-to-date and comprehensive information on COVID-19 for pharmacists, supporting safe pharmacy practice. We have contributed to the development and review of useful content for the Hub since its inception. The IOP hosted 18 webinars in 2021 covering a wide range of topics of interest and benefit to pharmacists' work.

Student placements

In January 2021, following a public consultation, the Council approved the (Education and Training)(Integrated Course) (Amendment) Rules 2021. These Rules allowed for the recognition of a period of six months patient-facing experiential learning (as opposed to eight months) to be completed as part of the MPharm programme. This reduction in the length of the placement in the 5th year of the MPharm was provided for

on an exceptional basis in the context of the COVID-19 pandemic.

Remote meetings and hearings

As in 2020, our work continued remotely, with staff, Council and Committees making best use of suitable technology to ensure we conducted our functions to the fullest extent possible while limiting risks related to COVID-19. Further information on the online operation of fitness to practise Committees and hearings is outlined later in the report.

Progress on our strategy and improvement agenda

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

Reviewing the Core Competency Framework for Pharmacists

In 2021, we continued work on the review of the Core Competency Framework (CCF) for Pharmacists. This followed consideration of a report by Council in October 2020, which recommended an in-depth review of the CCF be carried out to ensure it is fit for purpose and can meet the needs of the public and the profession into the future. The CCF, in place since 2013, aims to reflect the practice of pharmacists in the early stages of their career, and it is intended to also be used to provide structure and guidance for continuing professional development (CPD) over the changing demands of a pharmacist's career. Activities in 2021 focused on the establishment of a Steering Group, which provided advice and guidance on the project throughout the year. A Working Group was also established by way of an expression of interest process and is made up of pharmacists working in different areas of practice such as community, industry, hospital, education and training and role emerging practice. It also includes representatives from the Schools of Pharmacy. During the year, we held three workshops with the Working Group where valuable input and feedback to help inform the review process was provided. The launch of a revised CCF is planned for 2022, following approval by Council and public consultation.

Reviewing the CPD Model for Pharmacists

In 2021, as part of our strategic commitment to Advancing the Role of Pharmacy and Pharmacists in the Future Integrated Healthcare System, we initiated a review of the statutory continuing professional development (CPD) system for pharmacists. In preparation for the review, feedback was gathered during workshops with PSI staff, a targeted consultation was carried out with pharmacists, and several meetings were held with relevant stakeholders. This project will continue in 2022, with a detailed review to be commissioned to inform the Council's consideration of the current and any future CPD model. Implementation planning for any new model will be commenced in 2023.

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

Actioning our Regulatory Risk Approach

Regulatory bodies, such as the PSI, have a duty to recognise and respond appropriately to risks and potential harms that relate to our area of accountability, with the purpose of protecting the health and safety of patients and the public. The PSI Council approved a Regulatory Risk Statement in 2019 and in adopting this Statement, the PSI made a public commitment to become a more risk-based regulator with the aim of controlling the risk of harm to the public. The statement sets out how we define, identify, analyse and respond to risk across all of our areas of responsibility. By implementing this strategic risk-based approach in our regulation of pharmacists and pharmacies, our work aims to prevent harm to patients by making pharmacy a safer environment.

Due to the COVID-19 pandemic and our available resources, we were unable to progress our application of the Statement at that time. Then, in 2021, a Regulatory Risk Analysis and Response Group was set up within the PSI. The Group met on four occasions during the year to analyse regulatory risks identified by PSI staff, to determine the severity of the risk, and to make recommendations on actions to be taken in relation to the risks identified.

In taking a risk-based approach to regulation, we are enhancing our organisational goal of 'assuring trust in pharmacy through effective regulation' and committing to address the risks that have the greatest potential to impact on patient safety, for example, where the behaviour of a pharmacist or pharmacy creates a serious risk to the public. This approach allows the PSI to direct resources

more efficiently and allows for a more proportionate response to an identified risk.

Advancing Reform of the Pharmacy Act

The aim of the Advancing Reform of the Pharmacy Act Project is to work in partnership with the Department of Health to advance the reform of the Act by developing a series of evidence-based policy proposals.

The Pharmacy Act 2007 introduced many of the fundamentals of pharmacy regulation in Ireland. The Act has now been in operation for over 14 years and the PSI considers that it is an important time to review the Act to ensure it continues to be fit for purpose in a changing regulatory and healthcare environment and can continue to support effective regulation into the future to protect the public interest and ensure patient safety.

During 2021, we undertook desk-based research on regulatory principles and practices as well as an exploration of the work of other healthcare and non-healthcare regulators, both nationally and internationally. We also carried out significant analysis to capture PSI's experience of the Act across our statutory functions, including with the PSI Council, as well as with some pharmacy stakeholders. An overview of our research and analysis was provided to Council in October. We also had regular engagement with the Department of Health on the development of PSI's position paper on the need for reform during 2021.

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

Progressing our Business Transformation Programme

We commenced a digital transformation journey in 2019 with the aim of bringing numerous benefits to the PSI and our registrants, and to deliver an effective and efficient digital service to members of the public. A key objective of the Business Transformation Programme (BTP) is to evolve our ways of working, and how we interact with registrants and the public, supported by a well-designed, reliable, and effective technology solution for the PSI and those who engage with us. This programme is giving effect to our Digital Policy Statement, which reflects the broader public service policy commitments to digital services and developments.

Our new online registration portal is the first part of this project, and it was launched in September 2021. The initial phase updated our current systems for registration, transitioning to a new, more secure and effective platform, and moved more processes online. As part of the user-testing phase, we met virtually with a number of superintendent pharmacists to show them how the portal would work and to gain their feedback. Significant supports were also put in place to help both internal and external users to use the new system on roll-out. We developed a range of videos to assist registrants with how to use the portal, and a helpline was in place to deal with queries. We continue to monitor feedback to ensure the system is as easy as possible to navigate. The remaining phases of the BTP will be rolled out under the Corporate Strategy 2021-2023.

Adopting a new Organisation Structure

Alongside the digital service changes we are making, we also reviewed how we are structured as an organisation, with a view to evolving how we can best work as a regulator and deliver on our strategic priorities.

As we become a more digitally capable workplace, with improved systems, this will have an impact inside and outside the PSI, and since the end of 2020 we have been examining with our staff how we can look afresh at the way we work, and we have commenced with some key changes. Our new organisation structure was implemented in July and is configured to support a more cross-functional work environment, to improve organisation capacity, planning and delivery, and to align how we work to our strategic approach. New developments for us include a programme delivery function (incorporating a Project Management Office approach) and establishing a customer service approach, along with finding ways to support staff workloads, cross-training and learning and development. We have reconfigured and renamed roles and teams, but our core functions and responsibilities are unchanged – meeting our statutory responsibilities and serving the public.

Considerable work has gone into instigating change across the organisation in 2021, and we continue with the implementation phase into 2022, with the support of a resilient and supportive staff and management team. Some of the benefits of change will come as we progress our digital transformation and deliver on our current HR Strategy, and as we return to working together at PSI House.

Customer Services and Engagement with Key Stakeholders

In 2021 we developed a new Communications Strategy in response to feedback received as part of the consultation on the PSI's Corporate Strategy 2021-2023. We recognise that communication and engagement must underpin our work, and we will continue to approach that work with a focus on transparency and collaboration as indicated by the key elements of the strategy:

- **Engagement:** The need for continued improvement in levels of stakeholder engagement, and methods of communication between the PSI, the public, the pharmacy profession and pharmacy owners.
- **Collaboration:** The need for ongoing collaboration with key stakeholders, including a collaborative approach to the development of new initiatives, for example, new CPD model.
- **Information:** The need for greater awareness of the PSI's role in patient safety and presenting information in an accessible and user-friendly format.

An important aspect of the Communications Strategy will be to launch a new PSI website. We completed procurement for website redevelopment in 2021 and look forward to launching a new website during 2022.

Conducting a 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. A strategic review of these future financing needs was commenced in

2019 with assumptions underpinning the three phases of this project agreed in 2020.

The phases are:

- First phase: report on proposed expenditure models
- Second phase: core funding requirements for the PSI and fee modelling options
- Third phase: if required, this phase will focus on a review of registration fees

In 2021, the following activities were progressed as part of this review:

A detailed forecast of future income and expenditure was completed for the period 2022-2025. Council approved the adoption of a scenario-based modelling approach as a basis for future forecasting and financial modelling.

As part of the above exercise, various scenarios on the future utilisation of the PSI's reserves were prepared and considered by Council who adopted an approach that will form the basis of a new reserves policy.

Implementing our HR Strategy 2021-2023

A new HR Strategy 2021-2023 – Shaping our Future towards Better Ways of Working – was developed in consultation with our staff and approved by Council. This new strategy, designed to advance our people-focussed approach and underpin our Organisation Development Project, is based on three strands: People, Learning and Development, and the Future of Work. In 2021, we rolled-out a new Performance Development System providing a framework that supports continuous performance improvement within

the organisation and aligns individual and team performance with the PSI Corporate Strategy. Engagement also commenced on defining a new internal communications strategy and streamlining internal communication practices. This included the roll-out in 2021 of collaboration guidelines enabling staff to adapt to a new working environment and creating new organisational and cultural habits. These guidelines are compliant with the Code of Practice for Employers and Employees on the Right to Disconnect.

Continuing our EFQM Journey

We recognise the importance of quality in our work, in terms of how we carry out our functions, how we formulate our strategies and how we interact with our stakeholders. We made our submission to the European Foundation for Quality Management (EFQM) for external assessment in 2019 following which we received four-star recognition. We continue to promote EFQM throughout the organisation, embedding the quality management approach into our ways of working, and planning our approach to maintaining and improving on our EFQM award in 2022.



Activity in support of our mission

As well as continuing and commencing strategic change and development projects in 2021, 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 and the effective governance of the organisation on an ongoing basis.

Registrant and Customer Relations

We are responsible for managing the qualification recognition and registration processes for pharmacists and the registration processes for pharmacies and pharmaceutical assistants in Ireland, and for ensuring the accuracy of the registers, which we make available online to the public. We process complaints from the point of receipt so that they are considered by the Preliminary Proceedings Committee – 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 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 6,845 registered pharmacists on Part A of the PSI register at the end of 2021, an increase of 78 pharmacists from 2020. There was one pharmacist on Part B of the PSI register. There were 254 pharmaceutical

assistants on the register at the end of 2021, down from 286 in 2020. 1,981 retail pharmacy businesses were named on the PSI Register at the end of 2021, up from 1,968 in 2020.

There were 197 cancellations from the Register of Pharmacists, with 55 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. One pharmacist was removed from the Register following fitness to practise proceedings. Where a pharmacist indicated a reason for cancelling their registration, the reasons were as follows: 12 pharmacists emigrated, 36 pharmacists retired, 18 pharmacists returned abroad, three pharmacists took a career break, and three pharmacists cancelled their registration for study leave. In 2021, 24 pharmaceutical assistants voluntarily cancelled their registration, with 18 indicating that this was due to retirement. A total of six pharmaceutical assistants had their registration involuntarily cancelled. 18 pharmacists restored their registration under Section 61. This includes restoration following voluntary cancellation and involuntary cancellation. Twenty pharmacists returned to the Register under Section 77 of the Act, the temporary COVID-19 emergency restoration process.

In 2021, 13 new pharmacies were registered and opened, and 10 pharmacies cancelled their registration. 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 2021, we issued 52 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 seven EPC applications were received in 2021. Of these, three applications were approved and processed, one was withdrawn, and three refused due to non-production by the applicant of required documentation on time.

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 2021, we issued three 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.

Recognition and registration process changes due to Brexit

From 1 January 2021, with the UK leaving the European Union, we applied the planned changes to the recognition and registration process to take into account that pharmacists qualifying in Great Britain or in Northern Ireland must apply to practise with the PSI under the Third Country route. The changes had been considered over previous years in preparation for Brexit, and in coordination with the Department of Health. The process allows for a streamlined evidence-based assessment against the current provisions of the Professional Qualifications Directive, with similar processing timelines and criteria to be met as EU-qualified applicants for the current time.

Monitoring

We monitor compliance with any conditions imposed on an individual's registration due to findings made at a fitness to practise inquiry as well as any undertakings given at a fitness to practise inquiry by a registrant. This means

that the PSI monitors the registrant as they work to achieve the expected outcomes according to the undertakings given or the conditions attached to their registration. In 2021, we monitored eight individuals/pharmacies with High Court conditions imposed after findings being made at fitness to practise inquiries. We also monitored three individuals who provided undertakings at fitness to practise inquiries.

Internet supply of non-prescription medicines

We are responsible for the registration and maintenance of the Internet Supply List for registered pharmacies and non-pharmacy retailers involved in the internet supply of non-prescription medicinal products. There were 204 pharmacies and 160 non-pharmacies on the internet supply list at the end of 2021. We have information about compliance activity in this area 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 2021, we responded to 607 such queries in total, 147 (24%) from the general public and 411 (68%) 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, 32% were COVID-19 related and 14% were general prescription and control of supply queries.

Assessment of concerns

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

Expressions of concern arise where a person does not wish to make a formal complaint but wants to bring something to the attention of the PSI. All concerns are reviewed internally at the PSI by a multidisciplinary panel to assess risk and determine what action is required. A total of 120 expressions of concerns were received in 2021, representing a decrease of 35% since 2020. In 2021, 15% of the concerns received related to COVID-19 matters, which included operational standards in a pharmacy around social distancing, the use of facemasks, and the application of emergency supply legislation.

Sometimes a concern may become a complaint at which point it will be processed under Part 6 of the Pharmacy Act 2007. Of the 120 concerns received in 2021, 19 resulted in formal complaints being made. There is more information in the Complaints and Fitness to Practise section of the report.

Registrant and Customer Relations in Numbers

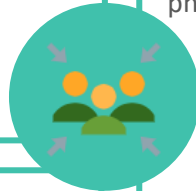
6,845

pharmacists on Part A of the Register

6,767 in 2020 and **6,506** in 2019

1

pharmacist on Part B of the Register



250

pharmacists added to the Register

144 Irish trained
and

106 non-Irish trained

70% of new registrants
were female



Country where new pharmacist qualification was obtained

2 Australia	1 Lebanon	4 Romania
1 Croatia	2 Malta	1 Saudi Arabia
1 Egypt	1 Moldova	8 Spain
1 France	1 Nigeria	1 South Africa
1 Ghana	1 Pakistan	2 Sudan
1 Hungary	1 Philippines	56 UK
6 Italy	4 Poland	
2 India	8 Portugal	



52

Certificates of Current
Professional Status issued

1,981

total pharmacies registered

1,968 in 2020 and **1,956** in 2019

10 cancellations

23 new openings

10 new openings (relocations)

80 new openings (transfer of ownership)



254

Pharmaceutical assistants on the
Register

285 in 2020 and **310** in 2019

204 pharmacies and **160** non-pharmacies on the
internet supply list



Voluntary and involuntary cancellations

197 pharmacists voluntarily cancelled their registration

56 pharmacists had their registration involuntary cancelled

24 pharmaceutical assistants voluntarily cancelled their registration

6 pharmaceutical assistants had their registration involuntary cancelled



607

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

32% related to COVID-19

120

expressions of concern received

184 in 2020 and
144 in 2019

Concerns received by source

85% member of the public

9% pharmacist

2% other pharmacy personnel

1% doctor

1% pharmacy

1% other health professional

1% other organisation



Categories of concerns raised

36 pharmacy practice issues

30 commercial, advertising or employment issue

22 behaviour (manner/attitude)

8 failure to supply

5 other

4 dispensing error (incorrect dose)

4 dispensing error (incorrect medication)

3 dishonesty

3 behaviour/ professionalism

2 out of date medication

1 Contravention of Section 63 or 64 of the Act

1 health impairment

1 emergency supply issues

Professional Standards

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

Accreditation matters - qualification for practice

The integrated Master's degree in pharmacy (MPharm) is a five-year programme which includes placements for students of varying lengths and at different points during the programme in the main areas of pharmacy practice, including community, hospital and industry.

We are tasked with approving and keeping under review the programmes of education and training leading to the professional qualification (MPharm), which allows graduates to apply for registration as pharmacists in Ireland. Training programmes are assessed against the PSI's approved accreditation standards to ensure programmes meet the relevant criteria as defined by the PSI Council. Schools of Pharmacy, as recognised institutions, are required by the Education and Training (Integrated Course) Rules 2014, to provide the Registrar with an annual report that includes matters relating to the MPharm. In 2020, in consultation with the Schools of Pharmacy, an annual reporting process was developed and implemented. Among other things, information on how the MPharm continues to align with the accreditation standards and any

changes made to the programme are included in the reporting process. Annual reports submitted by each School of Pharmacy in 2021 were considered and accepted by the PSI Council in December 2021.

As part of PSI's ongoing stakeholder engagement, meetings are held throughout the year with the Schools of Pharmacy, together with the Affiliation for Pharmacy Practice Experiential Learning (APPEL). APPEL manages the placing of students (from the three Schools of Pharmacy in Ireland) with relevant establishments.

Irish Institute of Pharmacy and the PSI CPD Model for Pharmacists

The Irish Institute of Pharmacy (IIOP) was established by the PSI in 2013 to oversee the development and management of the continuing professional development (CPD) system for pharmacists in Ireland. Pharmacists must maintain an ePortfolio documenting their CPD. Each year, those eligible for selection from the Register of Pharmacists, are selected by the PSI so that an extract from their ePortfolio is submitted to the IIOP for review. Of the 1,328 pharmacists selected for ePortfolio Review in 2021, a total of 1,227 met the standards. Pharmacists who fail to meet the standard are given one additional opportunity to complete the ePortfolio Review in the following year. The PSI meets with pharmacists who fail to meet the standard required for two consecutive years and with any pharmacists who fail to engage with the Review process.

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

assessment against standardised pharmacy interactions. Pharmacists who do not demonstrate competence initially are given a further opportunity to participate in a subsequent Practice Review.

Due to the COVID-19 pandemic, the PSI Council made a decision to suspend Practice Review during 2020 and 2021. It is scheduled to recommence in April 2022.

PSI Student Placement

In line with the PSI's continued support of the MPharm programme, a Master of Pharmacy student joined the PSI on her 4th year, four-month statutory placement.

During her placement, the student had the opportunity to engage in policy development, research, project work and communication activities which contributed significantly to the work of the PSI.

Pharmacy Quality and Safety

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

Inspection activity

Due to the health and safety concerns arising with the COVID-19 pandemic, routine inspection activity was suspended in line with government restrictions. This limited our in-person visits to pharmacies during 2021 in the interest of prioritising safe patient access to pharmacists and protecting PSI staff, pharmacists and pharmacy staff from in-person interactions during a pandemic. However, other methods have been used to engage with pharmacists and pharmacy owners and to seek assurance about the operation of pharmacies during this time. It has not limited any necessary action from being taken where required in the interest of

safeguarding the health and safety of the public.

Where we have registration applications for new pharmacies, or changes of ownership and relocations of pharmacies, we conduct pharmacy registration visits. During 2021, a total of 109 new opening registrations were carried out remotely using self-declarations along with a combination of the following, as required: photographs, video walkthroughs, submission of documents confirming calibration of equipment and additional confirmations and declarations. Four onsite new pharmacy registration inspections were carried out.

Due to COVID-19 risks, onsite inspection activity was limited. A total of 25 risk-based pharmacy inspections were conducted.

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 concern has been raised by a member of the public or an external body.

We also conduct themed inspections as may be required from time to time. These will assess certain other services provided by pharmacists. In 2021, this included professional cover, the Falsified Medicines Directive and inspections related to internet supply.

In addition, during 2021, we also conducted 29 exploratory visits to assess pharmacies in their application of the PSI COVID-19 Operational Standards. 25 of these exploratory visits were performed virtually.

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 was an area with increased activity for the PSI during 2021, some of which related to a general increase in online retail sales due to the pandemic. In 2021, 12 compliance actions were taken in relation to the internet supply of non-prescription medicinal products, including letters issued to pharmacies and non-pharmacies regarding compliance with relevant requirements.

Implementation of the Falsified Medicines Directive (FMD)

The Falsified Medicines Directive 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 has been in a 'use and learn' phase since 2019. In preparation for the end of the 'use and learn' phase in 2022, the PSI held meetings throughout 2021 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, during 2021 to explain and encourage compliance during the 'use and learn' period. We also used this engagement to explore broader issues as to how the overall FMD approach is working within Irish pharmacies and with the systems

they use in their day-to-day work. We reported any issues raised to the National Safety Features Oversight Group.

While engagement with the requirements was initially low in some pharmacies earlier in 2021, this improved as the year progressed. In 2021, we contacted 426 pharmacies regarding FMD registration issues. In addition, we issued an email to 597 superintendent pharmacists whose pharmacies did not detect or had limited FMD scanning and decommissioning activity on the relevant repository system during selected dates. As COVID-19 impacted pharmacy and the wider sector, we also sought to keep pharmacies advised of updates on implementation and the ending of the 'use and learn' period as it occurred.

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. A total of 10 investigations were commenced during 2021, and seven investigation files were closed during 2021. There were 17 investigation files open at the end of 2021.

Consideration by the Registrar of inspection reports

The Registrar considers significant issues identified during an inspection or an investigation under Section 71 of the Pharmacy Act 2007. This is a function designated to the Registrar by the Council. In 2021, nine reports were considered by the Registrar. Following consideration of these:

- 4 pharmacists and 3 pharmacies were referred to the complaints process (under Section 71(1)(b));
- 7 other actions were taken at the direction of the Registrar, including initiating prosecutions, meetings with

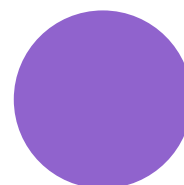
registrants, requiring undertakings, referral to other agencies and issuing enforcement letters (under Section 71(1)(d)); and

- no further action was required in 1 case (under Section 71(1)(a)).

Audit of Hospital Pharmacy

We continued work examining the provisions of the Pharmacy Act 2007 as they apply to pharmacies in a hospital setting that are

registered under the Act with us as retail pharmacy businesses. We explored the workings of hospital pharmacy through different surveys. The final survey, completed in 2021, invited all 75 registered hospital pharmacies to input, as we sought to quantify the percentage of medicines dispensed or supplied for administration, and therefore, quantify the percentage of medicine and activity which is outside the remit of the PSI. The PSI Council will further consider this matter in early 2022.



Pharmacy Quality and Safety in Numbers

109

new pharmacy opening registrations conducted by remote verification process, and

4

new pharmacy opening registrations conducted with onsite inspection visits

25

pharmacy inspections conducted



10

Investigations commenced in 2021

29

operational standard visits in 2021 and 16 in 2020



12

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



9

Reports considered by the Registrar

Note: In 2020, we reported that 124 pharmacy inspections were carried out in addition to pharmacy registration inspection visits. There was an error in the reporting description and 124 is the total of all pharmacy inspection activity (including for registration) carried out in 2020.

Complaints and Fitness to Practise

We address poor performance, practices and behaviours by considering formal complaints made against pharmacists and pharmacies, and impose sanctions, where appropriate. 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.

Impact of COVID-19 on remote meeting and hearings

In line with ongoing Government recommendations in relation to COVID-19, we continued to hold statutory Disciplinary Committee meetings including fitness to practise inquiries, and meetings before the PSI Council, remotely during 2021. We used a software platform suitable for hearings in a judicial and quasi-judicial environment. Although it was found that remote hearings take longer to conclude than in-person hearings, it was important that we could proceed to hear these matters in a fully remote environment, mindful of the PSI's statutory duty to process complaints as expeditiously as possible. We received no objections to operating online from the parties involved in complaints. We made sure to give time to support all those who used the online platform, making sure they were comfortable and capable of using and participating in the process online.

Impact of COVID-19 on complaint numbers and activities

In reviewing complaint related activity, where comparisons are made with previous years, it should be noted that activity levels in 2020 were not necessarily reflective of a typical year due to the initial impacts of the COVID-19 pandemic, which included the PSI

suspending for 10 weeks the processing of new complaints during the Spring of 2020.

Formal complaints

Formal complaints can be made to the PSI in writing about pharmacists and pharmacies. 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.

A total of 80 formal complaints were received in 2021 representing an increase of 74% in the number of complaints received by the PSI based on 2020 figures.

In 2021, 5% of the complaints received related to COVID-19 matters. These included issues in relation to the use of facemasks and operational standards in a pharmacy.

There has generally been a significant increase in the number of complaints made to the PSI in 2021 in comparison to 2020 and 2019, including 15 complaints made by the PSI Registrar in 2021. In 2020 the Registrar made five complaints. Of the complaints made by the Registrar in 2021 five related to non-compliance/engagement with CPD on the part of a pharmacist. Complaints of the Registrar are mostly brought under section 71 of the Pharmacy Act 2007 and on foot of an Authorised Officer's report pursuant to section 67 of the Pharmacy Act 2007.

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 route set out in legislation. 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 the complaint. The PPC can refer the complaint to either mediation or for hearing before a statutory Fitness to Practise Committee of Inquiry.

In 2021, the PPC considered 59 complaints. Of these, 85% were considered within six months. The balance was considered in under 15 months, with any delay being due to either ancillary-related criminal prosecutions, or the complexity of the complaint. In 2021, the PPC considered 59% more complaints than in 2020.

Following review of the complaints considered, the PPC sent forward 25 complaints for further action, of which 15 were referred to the Professional Conduct Committee, five were referred to the Health Committee and five were referred to mediation. Of the five complaints referred to mediation, three were resolved by mediation before year-end and the remaining two mediations will take place in early 2022.

Of the complaints considered, the PPC advised the Council that 28 complaints did not warrant further action and the Council agreed with the advice of the PPC. Six of the 59 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 six complaints withdrawn by complainants after consideration by the PPC, the Council decided, on the advice of the PPC, to take no further action.

Professional Conduct and Health Committees – Fitness to Practise Inquiries and Hearings

The Committees of Inquiry consist of the Professional Conduct and Health Committees, and these hear complaints against pharmacists and pharmacies. During 2021 all the meetings of the Committees of Inquiry took place remotely using video and audio technology.

Callovers

A callover is a meeting where the Professional Conduct Committee (PCC), and the Health Committee, sitting with an independent legal assessor, can 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 2021, five PCC and three Health Committee callovers took place, with the final Health Committee callover being adjourned from December 2021 to January 2022.

Inquiry hearing outcomes

A total of 12 inquiries relating to 19 respondents were heard before a Committee of Inquiry in 2021. Eleven of these were completed in 2021, with the remaining part-heard inquiry having been adjourned to be completed in early 2022. The PCC heard 10 inquiries and the Health Committee heard two.

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 imposed 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 2021 the Council considered 11 complaints, some of which had been heard before a Committee of Inquiry in 2020. Four complaints involved undertakings with consent to sanctions in two complaints. Two complaints were withdrawn by the complainants and the Council agreed that no further action was warranted. One complaint resulted in no findings and was dismissed by the Council. The remaining four complaints involved the consideration of Committee reports, which contained findings against a pharmacist and/or pharmacy, resulting in sanctions. These included one cancellation of the pharmacist's registration (on grounds of impairment), censures, admonishment and the imposition of two sets of conditions. The sanctions were confirmed by the High Court. An application was made to the High Court to cancel the sanction imposed by Council in relation to one complaint.

Interim suspension

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 or registered pharmacy against whom a complaint has been made. This is done if there is a risk to the health and safety of the public, which is of such magnitude that registration should be suspended pending the conclusion of the complaint process. Two interim suspension applications were considered by the PSI Council in 2021.

The Council decided not to proceed to seek an order from the High Court suspending the registration of a pharmacist in one case. In relation to the other, the Council applied to the High Court, which made an Order suspending the registration of a pharmacist and the pharmacy pending further action in relation to the complaint.

Regulated Professions (Health and Social Care) (Amendment) Act 2020

On 13 February 2021 the Minister for Health commenced most of the sections of the Regulated Professions (Health and Social Care) (Amendment) Act 2020 pursuant to S.I. 54/2021 Regulated Professions (Health and Social Care) (Amendment) Act 2020 (Commencement of Certain Provisions) Order 2021.

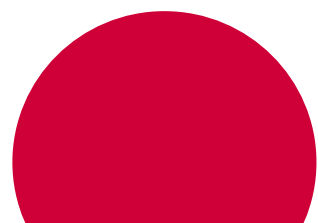
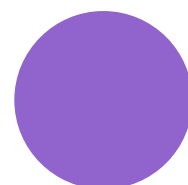
This applied legislative reform across most healthcare regulators and amended the Pharmacy Act 2007 in a substantive way. There were over 40 distinct amendments and new provisions, which impacted the process of considering complaints and disciplinary proceedings against pharmacists and pharmacies under the Act. This resulted in a significant body of work being undertaken by the PSI to consider and incorporate the legislative changes into PSI processes, documentation, and related training for Council and Committee members once the

relevant provisions of the amended legislation commenced.

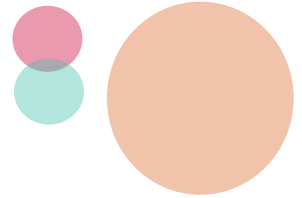
The main amendments affecting the PSI under Part 6 of the Act related to new grounds for complaints, enhanced powers of communications with regulators outside the jurisdiction regarding complaints and their outcomes, changes to the composition of the Disciplinary Committees when hearing complaints, enhanced powers and rights in relation to appeals to the High Court following decisions by the Council, as well as a new power to publish reports of Committees of Inquiry and transcripts of inquiry hearings if it is in the public interest to do so.

New Procedures for PSI Council consideration of Committee of Inquiry reports regarding sanctions

On 7 October 2021, the PSI Council adopted new written procedures for considering reports from Committees of Inquiry and where recommendations are made as to sanctions. The aim of the procedures is to streamline and make most effective the process and to allow for fairness to both sides in terms of the time taken to present any oral submissions before the Council. It involves a requirement for parties to a matter to file written submissions in advance of the Council meeting, outlining points of difference and any particular arguments about sanctions and proposed publication of outcomes, and provides for short oral hearings if required.



Complaints and Fitness to Practise in Numbers



80

formal complaints
received

46 in 2020 and
61 in 2019

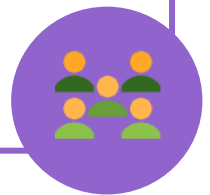
Formal complaints received by source

79% member of the public

19% Registrar

1% pharmacist

1% pharmacy



Categories of formal complaints raised

21 pharmacy practice
issues

15 failure to supply

11 behaviour
(manner/attitude)

11 dispensing error

5 education/Registration
compliance

4 commercial, advertising or
employment issue

4 health impairment

3 behaviour/professionalism

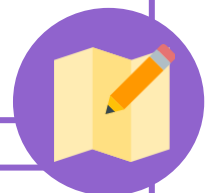
2 conviction

1 dishonesty

1 out of date medication

1 other

1 professionalism



5 complaints referred to
mediation, of which 3
successfully concluded in
2021

12

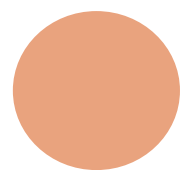
inquiries

10 completed before the Professional Conduct Committee

1 completed before the Health Committee

1 inquiry adjourned

59 formal complaints considered by the PPC of which
25 for further action and
28 for no further action
6 withdrawn



Strategic Policy and Communication

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

Keeping our registrants informed and promoting safe, quality practice

Due to the COVID-19 pandemic, we were required to re-orient our work to continue to support the public health response to the pandemic and the unprecedented challenges faced in the pharmacy sector. As part of our COVID-19 external response, we issued regular communications and updates to our registrants throughout the year about the changing landscape in relation to public health advice, medicines, and pharmacy practice issues. We did this, as relevant, in partnership and in consultation with the health authorities and others with whom we worked.

Communication channels

Our Corporate Strategy 2021–2023 recognises the importance of effective communication in underpinning 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 create awareness and understanding of the PSI's role.

Our website is an 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 fitting of a public sector body, and which will align with other aspects of our other digital transformation plans, for example, the new registration portal. We completed procurement for website redevelopment in 2021 and we will implement a new, contemporary PSI website during 2022.

We continued to use 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. The newsletter provides the latest pharmacy practice guidance, advice, and relevant professional and public health updates, and we issued four of these in 2021. All newsletters are archived on the PSI website so that they can be referenced. We updated registrants on a range of topics by email throughout the year and ensured information was available about other ways of engaging with us.

Informing and enabling policy decisions or informing public and political debate is also part of our work. We responded to parliamentary questions, media queries, issued press releases, wrote articles for external publications, and responded to other requests for information from various stakeholders throughout the year.

Working with others

As Ireland's pharmacy regulator, we recognise the importance of working collaboratively with others, and we contribute to many public

health and safety initiatives. We engage with Departments, agencies, academic institutions, and other organisations on a range of issues, including through working groups, formal meetings and consultations where we can share our knowledge and expertise.

During 2021, our external engagement was considerably focused again on working with other agencies and stakeholders on the COVID-19 response, including joint initiatives with the Department of Health, HSE, HPRA, IPU, IIOIP and others. We provide more information about this earlier in the report.

At the same time, reflecting on the range of our role, we were involved in a variety of working groups and collaborations with a public health and safety focus. This included continuing to contribute to the Medical Council stakeholder group on strategies to reduce the overprescribing of benzodiazepines. We were also invited to participate in a Department of Health and HSE Working Group that was established to prevent Paracetamol-related intentional drug overdose, set up as part of Ireland's National Strategy to Reduce Suicide (2015-2024). We were also delighted to participate in a stakeholder engagement process hosted by the National Patient Safety Office of the Department of Health on the development of a draft policy on supporting and facilitating patient representatives. We continued to participate in the Royal College of Physicians of Ireland (RCPI) National Near Patient Testing Consultative Group, which convenes under the auspices of the Faculty of Pathology and represents national laboratory medicine organisations and regulatory bodies with an interest in this topic. We opened discussions during the year too with the National Standards Authority of Ireland and met about legal metrology.

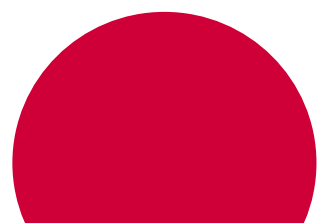
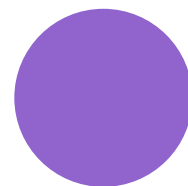
As outlined in this report, we have a role in the implementation of aspects of the Falsified Medicines Directive (FMD) in Ireland. We continued frequent engagement with the National Safety Features Oversight Group throughout the year as matters progressed with assessing compliance during the 'use and learn' phase, and as we move towards full implementation of the legislation. The Oversight Group comprises the Irish Medicines Verification Organisation, the Department of Health, the HPRA, the HSE and the Private Hospitals Association. We met with the HSE across a variety of issues and areas of responsibility during 2021, including to discuss the issues pertaining to the development of an ePharmacy system. We also met with the Department of Agriculture and the Marine around the establishment of a National Veterinary Prescription System (NVPS), part of the implementation of the new EU Veterinary Medicinal Products (VMP) and Medicated Feed Regulation commencing at the end of January 2022 in an approach to tackling antimicrobial resistance in the European Union.

As part of our development of a standards-based approach to regulation, and our creation of the COVID-19 Operational Standards for Pharmacies, we are appreciative of the engagement we had with the General Pharmaceutical Council, Great Britain and the Mental Health Commission in 2021 on their experience of using healthcare standards. We had several engagements with HIQA on areas of shared interest, including on the development of their draft Overarching National Standards for the Care and Support of Children using Health and Social Care Services. We also made a submission to the National Patient Safety office to inform the development of Ireland's second National Action Plan on Antimicrobial Resistance 2021-2025, to be called iNAP2.

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.

We are part of a cross-border UK and Ireland Controlled Drugs Group, led by the Care Quality Commission, the independent regulator of health and social care in England. Together with other regulators and public bodies we participated in meetings of the Group during the year. The Group shares information on concerns, monitoring and investigative risks associated with legislated controlled drugs and illegal substances. We

continue to be 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, and at a joint meeting between this committee and the Committee of Experts on Minimising Public Health Risks Posed by Falsification of Medical Products and Related Crimes, during 2021. 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.



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 2021, working from home remained the norm with about 20% of staff going to the office on a regular basis. Guidelines for effective interactions and collaboration were introduced to support new habits in the way we work with colleagues. The guidelines were established following a test period of four months and consultation with all staff.

The Employee Experience Consultative Forum was set up to foster a high level of employee participation in advancing the HR agenda in the PSI and to inform the effective implementation of our new HR Strategy. Other working groups, including the Equality, Diversity and Inclusion Working Group and the Workplace Wellbeing Group, have continued their engagement with the HR Team in 2021, contributing to the ongoing focus on maintaining the conditions that allow for an open and dynamic culture in the workplace.

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 ensured that all necessary security tests were in place before the launch of our new registration portal in September 2021. All new systems are added to the scheduled security audits and testing to ensure our systems are robust. The ICT Team assisted in the testing of the new registration system before the launch and helped transition the system from the project team through to business as usual. We continue to explore and implement measures to ensure that an appropriate level of ICT systems security is in place, with a view to the 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 2021 from the BTP and the ODP can be found on page 15.

Governance and Accountability

How we ensured high standards of internal 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. The PSI complies with the Code of Practice for the Governance of

State Bodies and meets its 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 2021.

PSI Council

The PSI is governed by a 21-member Council, with a non-pharmacist majority. Each member of Council is appointed by the Minister for Health. The Council is accountable for the PSI's policy decisions, strategic direction, and the 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 Council held a total of ten meetings in 2021, and the agenda and minutes of the public meetings of Council are published on the PSI website.

2021 marked the end of terms of office for some Council members, and following engagement with the Department of Health, and an election process, new appointments were made to the Council by the Minister in June and in October. 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, including opening a public expression of interest process to recruit to the Disciplinary Committees. The work and commitment of current and past Council and Committee members is acknowledged.

All PSI Council members who held office during 2021 are listed below on page 40, along with records of attendance, fees and expenses paid.

PSI Council members 2021

Council Member (as at 31 December 2021)	Number of meetings attended¹	Date of first appointment	Fees paid in 2021²	Expenses paid in 2021³
Ms Geraldine Campbell**	2/2	19 October 2021	€ 1,598.20	-
Ms Geraldine Crowley**	6/10	18 June 2019	-	-
Ms Dorothy Donovan**	10/10	16 May 2018	€ 7,695.00	-
Mr Fintan Foy**	8/10	17 June 2015	€ 7,695.00	-
Mr John Given*	6/6	21 June 2021	-	-
Dr Paul Gorecki**	9/10	31 January 2014	€ 7,695.00	-
Mr Roy Hogan*	7/10	18 June 2019	€ 7,695.00	-
Mr Mark Jordan*	8/10	18 June 2019	€ 7,695.00	-
Ms Joanne Kissane*	10/10	17 June 2015	€ 9,684.52	-
Prof Brian Kirby*	7/10	18 June 2019	€ 7,695.00	-
Mr Graham Knowles**	7/10	17 June 2015	€ 7,695.00	-
Dr Shane McCarthy**	7/10	13 March 2014	€ 7,695.00	-
Ms Katherine Morrow*	6/6	21 June 2021	€ 4,084.27	-
Ms Muireann Ní Shúilleabháin* President	10/10	17 June 2015	€ 9,980.48	-
Mr Rory O'Donnell* Vice-President*	6/6	17 June 2015	€ 4,084.27	-
Ms Marie Louisa Power *	8/10	21 June 2017	-	-
Ms Grainne Power**	6/6	21 June 2021	-	-
Mr Sean Reilly*	10/10	21 June 2017	€ 7,695.00	€ 41.80
Ms Ann Sheehan**	6/10	17 June 2015	€ 7,695.00	-
Mr Paul Turpin**	10/10	17 June 2015	€ 7,695.00	-
Ms Fiona Walsh**	4/10	16 May 2018	€ 7,695.00	-
Council Members in office for part of 2021 but no longer holding office:				
Mr Hugo Bonar**	4/4	29 October 2015	€ 3,610.73	-
Ms Nicola Cantwell*	4/4	18 June 2013	€ 3,610.73	-
Mr Michael Lyons*	4/4	21 June 2017	€ 3,610.73	-
Dr Ailis Quinlan**	4/4	21 June 2017	€ 7,458.23	€ 659.10
Ms Veronica Treacy*	4/4	21 June 2017	€ 3,610.73	-

*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 2021. Council Members employed in the public sector were not paid fees in 2021.

³ Aggregate expenses paid up to 31 December 2021.

PSI Committees

PSI Advisory Committees advise and support the Council on the performance of its functions. There are four Advisory Committees: the Audit and Risk Committee, the Performance and Resources Committee, the Regulatory and Professional Policy Committee and the Special Purposes Committee. In general, the Advisory Committees are made up of Council members, except the Audit and Risk Committee, which also includes external members who are appointed to contribute their expertise in the areas of compliance, finance, risk management and governance. Each Committee meets throughout the year and reports to the PSI Council on the work they have undertaken. The agenda and minutes of Advisory Committee meetings are published on the PSI website.

The PSI also has three Disciplinary Committees as required under the terms of

the Pharmacy Act 2007. These are the Preliminary Proceedings Committee, the Professional Conduct Committee, and the Health Committee. Each Disciplinary Committee has a particular remit in relation to the PSI complaints and disciplinary process. Their work is outlined in the Complaints and Fitness to Practise section of this report.

Disciplinary Committees comprise a membership of people who can bring a range of experience to the role, and this includes people who are and are not pharmacists. 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 2021, including training in relation to new legislative provisions amending the Pharmacy Act 2007.

PSI Advisory Committee members 2021

Audit and Risk Committee

Committee member	Meetings attended
Dr Paul Gorecki (Chair)	5/5
Mr John Given	1/2
Ms Fiona Walsh	4/5
Mr Liam Burke	5/5
Ms Niamh O'Regan	5/5
Mr Peter Dewhurst	5/5
Ms Veronica Treacy	3/3
Ms Marie Louisa Power	2/3

Performance and Resources Committee

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

Special Purposes Committee

Committee member	Meetings attended
Ms Muireann Ní Shúilleabháin (Chair)	7/7
Ms Joanne Kissane	6/6
Dr Paul Gorecki	4/4
Mr Graham Knowles	4/7
Mr Michael Lyons	3/3
Mr Rory O'Donnell	3/4
Ms Veronica Treacy	3/3

Regulatory and Professional Policy Committee

Committee member	Meetings attended
Ms Joanne Kissane (Chair)	1/1
Mr Hugo Bonar	4/4
Ms Nicola Cantwell	2/4
Dr Paul Gorecki	2/2
Mr Brian Kirby	3/5
Ms Muireann Ní Shúilleabháin	4/4
Ms Marie Louisa Power	1/1
Ms Grainne Power	1/1
Dr Ailis Quinlan	3/4
Mr Sean Reilly	5/5
Ms Ann Sheehan	4/5
Mr Paul Turpin	3/3

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 person, 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 which 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 2021, we continued to monitor performance against the standards set out in the Customer Charter and identify areas for improvement.

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 40 data sharing requests and five subject access requests in 2021.

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 2021, the PSI consumed 386,496 kWh of energy, consisting of 145,850 of electricity and 231,646kWh of gas. In comparison, the PSI consumed 471,763 kWh of energy, consisting of 196,300 kWh of electricity and 275,463 kWh of gas in 2020. This is a 21% reduction in electricity and a 15% reduction in gas in 2021. We can attribute this mainly to the ongoing COVID-19 crisis, which meant that our staff worked remotely all year with limited onsite presence. This resulted in the reduction of lighting, heat, and hot water as compliance with Government guidance meant there was very limited attendance by staff at PSI House during the year.

Ethics in Public Office Act

The provisions of the Ethics in Public Office Act 1995 and the Standards in Public Office Act 2001 are implemented in full by the PSI. Council members, office holders and PSI staff are required to disclose material interests on appointment and update disclosures of their interests when there is any relevant change. PSI Council members' disclosures of interest are published on the PSI's website. Annual statements of interest for those holding designated positions are submitted to the Standards in Public Office Commission.

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 2021, we ensured compliance with the legislation by responding in a timely manner to FOI requests and reporting on our engagement with the legislation. In 2021, we received seven 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, both onsite at PSI House or when working remotely and meeting our responsibilities for others, including members of the public who access PSI House or who may be affected by our operations. An independent staff-led Health, Safety and Sustainability Committee is in operation, which serves to advise the PSI Executive Leadership Team on health and safety matters and act 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 regularly reviewed and updated as necessary. The Response Plan extends to staff working onsite at PSI House or on official PSI business travel, including visits to retail pharmacy businesses

as part of our regulatory functions, as well as third party visitors to PSI House. Specific training on measures to prevent the spread of COVID-19 was part of the induction for new starters in 2021. In addition, all staff working from home underwent an assessment of their home working station, and corrective measures were implemented to meet health and safety standards.

Official Languages Act

In accordance with its legal obligation under the Official Languages Act 2003, the PSI endeavours to publish documents setting out public policy proposals, and our annual report and financial statement, in Irish and will engage in the Irish language with those who wish to do so.

Protected Disclosures

The Protected Disclosures Act provides for the protection of persons from action being taken against them in respect of disclosures made by them in the public interest. In 2021, seven protected disclosures were received by the PSI under section 7 of the Act, which relates to the Registrar's role as the prescribed person for pharmacies and pharmacists. No protected disclosures were received under section 6 of the Act, which relates to the PSI's 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 2021, 61% of our creditors had been paid within 15 days and a further 33% within 30 days.

Equality, Diversity, and Inclusion Working Group Report

The PSI's Equality, Diversity, and Inclusion (EDI) Working Group is made up of staff drawn from across the organisation and was established to support, through action, the values outlined in the [PSI Equality Diversity & Inclusion Statement](#).

The Group promotes awareness amongst PSI staff of our EDI obligations as a public body. In 2021 the Group organised a programme of talks, inviting a range of guest speakers to address colleagues on the issues faced by the lesbian, gay, bisexual, transgender, and intersex community, as well as hosting a workshop on the use of inclusive language.

The Group welcomed the appointment of two PSI Access Officers with responsibility for providing, arranging for and co-ordinating assistance or guidance to persons with disabilities in accessing the range of services provided by the PSI.

The Group noted that in gender diversity terms, the PSI registers reflect a female majority, with 63% of all pharmacists and 96% of pharmaceutical assistants identifying as women.

With regard to meeting the 40% gender balance requirement as set out in the Code of Practice for the Governance of State Bodies: Annex on Gender Balance, Diversity and Inclusion, the Group noted that the level of gender diversity in the pharmacy profession, was reflected within the PSI. At the end of December 2021, of the 21 members of the PSI Council, 10 were women, and 11 were men. 65% of the PSI's Executive Leadership Team, which comprises the Registrar and five senior managers, were women.

The Group continues to work to enhance diversity of representation across all levels of the PSI, in terms of gender, marital status, family status, age, disability, sexual orientation, race, religion, and membership of the Traveller community.

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 all the people to whom it provides services. As part of our ongoing commitment to meeting this 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 make a demonstrable effort to embed equality and human rights throughout our work and our engagement with all our stakeholders.

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 2021, the PSI achieved 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 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 PSI 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, 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 March 2021 the Committee agreed an internal audit plan for the period March 2021 to August 2022 to ensure, insofar as is possible, that all key risk management, governance and internal control systems were reviewed. In 2021, the Audit and Risk Committee considered internal audit reports on the following;

- High level review of the PSI System of Internal Control in operation in 2020;
- Review of the PSI's fitness to practise procedures, systems, and controls;
- Review of PSI purchasing, procurement and payments; and
- Review of PSI ICT systems.

The Committee received regular reports from the PSI's Executive Leadership Team on progress regarding the implementation of recommendations of previous internal audit

reports, as well as briefings on the PSI's quarterly financial position and the management of staffing, resources, and superannuation.

The Committee noted that the PSI continued to meet the challenges posed by COVID-19 in 2021, and it was the Committee's view that the organisation was successful in mitigating the risks posed by the pandemic, and commends PSI staff for their efforts in this regard.

At each of its meetings, the Committee reviewed the PSI's corporate risk register, and in 2021 conducted a deep dive of the following PSI departments' risk registers:

- Corporate Governance and Public Affairs
- Regulation
- Corporate Services
- Education and Registration

In 2021 the Committee was satisfied with the integrity of the PSI's assurance framework and believe it sufficient to provide the PSI Council with a basis for informed decision-making.

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

As I was appointed Chair of the Committee in 2021, I would like to acknowledge the hard work and commitment of the former Audit & Risk Committee Chair, Ms. Veronica Treacy.



Dr Paul Gorecki
Chair, PSI Audit & Risk Committee

Our Risk Management Report: Principal Risks and Uncertainties

The Pharmaceutical Society of Ireland (PSI), in common with all organisations, manages a range of risks, by means of its Risk Management Framework. The Framework seeks to minimise risks to ensure we meet our strategic objectives, core processes, and functions, as well as our stakeholders' expectations, in a timely manner.

The PSI Council is responsible for the PSI's system of internal control, including risk management, and is advised by the Audit and Risk Committee with regard to its efficacy.

The Council is responsible for approving the organisation's Risk Management Framework, including setting its risk appetite, and with the assistance of the Audit and Risk Committee, monitoring the effectiveness of the organisation's risk management strategy.

As a public body tasked with acting in the interests of public and patient safety, the PSI seeks to manage and mitigate risks that have the potential to affect the organisation's ability to carry out its 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 to identify and assess those risks and agree mitigating measures to be put in place to manage them. These are reviewed by both the Audit and Risk Committee, and the Council.

The Council has considered the nature and extent of the risks it is willing to take, in order to achieve the PSI's strategic objectives and reviews the corporate risk register at Council meetings.

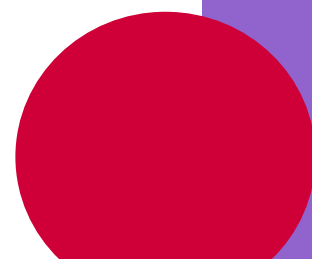
A summary of the PSI's principal risks and uncertainties as of 31 December 2021 is provided below:

1. The PSI relies on technology as a significant enabler to 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 is 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. The Council is clear that the absence of rules remains a risk for the public and for the PSI.
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 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 global COVID-19 pandemic continued in 2021 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. The pandemic also impacted on our ability to implement agreed strategies and plans within relevant timeframes, as well as impacting on 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 2021.



Our Financial Report

The 2021 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 2021.

Income

The total income in 2021 was €7.913m, which is in line with income received in 2020 of €7.885m. The PSI is mainly self-funded, currently with two main sources of income: registration and administration fee income and funding from the Department of Health for the Irish Institute of Pharmacy (IIOP) services.

The total fee income for 2021 of €7.313m, which is in line with fee income received in 2020.

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 at 31 December 2021 was €5.819m (€5.844m in 2020) and is reflected in the cash held at that date in the Statement of Financial Position.

In 2021, funding of €0.600m was received from the Department of Health in respect of the IIOP. 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 €583k in 2021 to €7.569m, compared to €6.986m in the previous year. This was due to a variety of factors, including the ongoing

impact of COVID-19 and the implementation of new systems and organisation structures. The most significant increases in expenditure were in the Legal, ICT, business transformation and other organisation projects.

The Council authorised the use of the Income & Expenditure Reserve to fund a number of projects amounting to €501,096, of which €229,760 was spent in 2021. Of the €229,760, €76,875 was spent on the Organisation Development Project, €73,160 on a software upgrade for the outsourced Irish Institute of Pharmacy services, €73,405 on the Business Transformation project and €6,320 on seed-funding for the Affiliation for Pharmacy Practice Experiential Learning (APPEL).

In 2021, €21,157 was spent on the judicial review, taken by the Pharmaceutical Assistants Association, which was funded from the Designated Legal Reserve.

Pay costs

The level of permanent whole-time staff approved by the Department of Health in 2021 was not exceeded. The average number of staff on payroll during the year was 44. In 2021, 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 2021, were €3.524m, a decrease of €0.142m on the 2020 cost of €3.666m. Direct pay costs amounted to €2.842m for the year, which is a decrease of €0.096m on the 2020 cost of €2.938.

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 2021, in accordance with the directive of the Department of Public Expenditure and Reform.

The level of absenteeism of PSI staff in 2021 was at 1.51%. It is an increase compared to the figure of 0.45% in 2020 that was, however, exceptionally low. The commitment and dedication to work by PSI staff is highly valued by the Registrar and Council, particularly viewing the complex and expanding services required to be carried out and in changed circumstances due to home working throughout 2021.

Non-pay costs

The total non-pay costs in 2021 were €4.045m (2020: €3.320m). The major elements were:

	2021	2020
	€m	€m
• Legal fees	0.824	0.466
• Tax and financial advisory fees	0.029	0.017
• Public affairs / marketing fees	0.028	0.028
• Pensions and human resources	0.005	0.012
• Consultancy and professional fees	0.013	0.035
• ICT costs	0.562	0.410
• Printing, postage, and stationery	0.070	0.090
• Repairs, maintenance, and other property costs	0.150	0.149
• Depreciation	0.121	0.072
• Other education costs	0.001	0.045

• Institute of Pharmacy (IOP)	1.136	1.202
• Affiliation for Pharmacy Practice Experiential Learning (APPEL)	0.006	0.002

The IOP operated for a full calendar year in 2021 and drew down €1,136,467 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 2021 annual procurement plan to ensure that best value for money was achieved and costs contained to the best of our ability.

Financial results 2021 against budget

The table below outlines the operating income and expenditure result for 2021 against the original 2021 budget. These figures exclude capital related transactions, which are accounted for in the Balance Sheet.

Outturns for the year 2021 from operating activities against original budget

	Original Budget €	Outturn €	Variance €	Variance %
Total income	7,993,800	7,912,632	(81,168)	-1.02%
Expenditure				
Pay costs	4,190,085	3,523,880	666,205	15.90%
Non-pay costs	4,657,628	4,045,208	612,420	13.15%
Total expenditure	8,847,713	7,569,088	1,278,625	14.45%
(Deficit) surplus from operating activities	(853,913)	343,544	1,197,457	140.23%
Interest income	-	874	874	-
(Deficit) / surplus	(853,913)	344,418	1,198,331	140.33%
Funding from reserves	501,096	276,673	224,423	44.79%
Adjusted (deficit) / Surplus for the year	(352,817)	621,091	973,907	276.04%

Statement of financial position

The PSI's Statement of Financial Position as at the 31 December 2021 shows that total assets exceeded total liabilities by €24.988m

Income and expenditure account
Revaluation reserve
Designated legal reserve
Closing reserves

compared to €24.643m at 31 December 2020. This is the net assets of the PSI including PSI House. It is represented in the Statement of Financial Position as follows:

	2021 €m	2020 €m
Income and expenditure account	11.074	10.729
Revaluation reserve	11.414	11.414
Designated legal reserve	2.500	2.500
Closing reserves	24.988	24.643

The cash balance in the Statement of Financial Position at 31 December 2021 was €10.991m. This amount excludes €7.200m 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

reached a peak as most registrants had prepaid their fees (deferred income) for the following year. The value of this deferred income was €5.819m (€5.844m in 2020). The cash and investment assets balance include the following commitments:

Deferred income (prepayment of fees)
Statutory staff superannuation scheme funds
Designated legal reserve
Income and expenditure reserve minimum level – circa 30% of registration fees
Total cash committed
Unrestricted cash

2021

€m

5.819
5.357
2.500
2.124
15.800
2.391
18.191

The PSI's statutory staff superannuation scheme fund of 5.357 million relates to the 'Pharmaceutical Society of Ireland Superannuation Scheme 2016', which was formally established on 10 March 2016, when SI 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. No. 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 two designated deposit accounts pending approval of the funding mechanism for the scheme. The PSI is liaising 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 2021, and of its results for the year 2021. 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 Generally Accepted Accounting Practice in 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 2021 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 2021

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Council Information

President	Ms Muireann Ní Shúilleabháin
Vice President	Mr Rory O'Donnell (appointed 21 June 2021)
Council Members	Ms Geraldine Campbell (appointed 19 October 2021) Ms Geraldine Crowley Ms Dorothy Donovan Mr Fintan Foy Mr John Given (appointed 21 June 2021) Dr Paul Gorecki Mr Roy Hogan Mr Mark Jordan Prof Brian Kirby Ms Joanne Kissane Mr Graham Knowles Dr Shane McCarthy Ms Katherine Morrow (appointed 21 June 2021) Ms Grainne Power (appointed 21 June 2021) Ms Marie Louisa Power (appointed 21 June 2021) Mr Sean Reilly (appointed 21 June 2021) Ms Ann Sheehan Mr Paul Turpin Ms Fiona Walsh
Registrar	Mr Niall Byrne (resigned 31 December 2021) Dr Lorraine Horgan (appointed 1 January 2022)
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, Co. Galway

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 31st December 2021.

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.

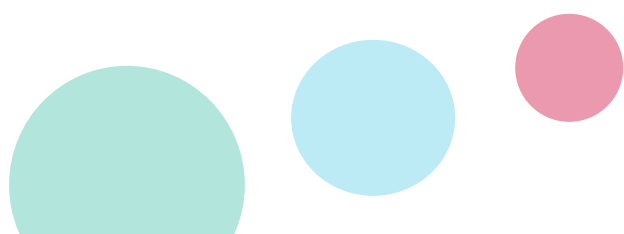
Audit and Risk Committee

The PSI has an Audit and Risk Committee comprising seven members, which met on five occasions during 2021. 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 the Department of Health consolidated salary scales and the Civil Service salary scales.



Financial Results

The financial results for 2021 show an operating surplus of €344,418 (in 2020, the surplus was €898,717). The income for the year at €7.913m is a 0.3% increase on 2020 income of €7.885m.

In terms of annual reported expenditure, operating expenditure increased by €583k to €7.569m in 2021 compared to 2020 €6.986m. Changes to the way that PSI operated during the Covid-19 global pandemic resulted in some cost savings throughout the year, but the PSI's redirected focus to respond and adapt to ensure it met its regulatory obligations under the Pharmacy Act 2007 and a renewed focus in achieving its strategic objectives, as outlined in the Corporate Strategy 2021-2023, contributed to the increase in operating expenditure in 2021.

Principal Risks and Uncertainties

In the current year the PSI has been faced with unprecedented change as a result of the pandemic. Work practices have changed and economic conditions are uncertain.

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:

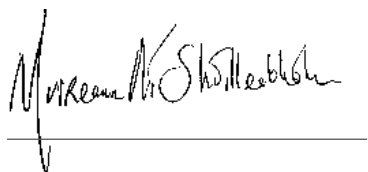
- i. so far as the Council Member is aware, there is no relevant audit information of which the PSI auditors are unaware; and

- 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 were 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 24th March 2022 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 2021

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

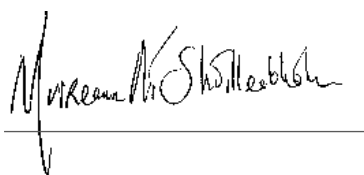
Schedule 1, paragraph 16, of the Pharmacy Act 2007 requires the Council to prepare the financial statements for each financial year. Under the law, the Council has elected to prepare the financial statements in accordance with Financial Reporting Standard 102 'The Financial Reporting Standard applicable 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 24 March 2022:



Ms Muireann Ní Shuilleabháin

President



Mr Rory O'Donnell

Vice President

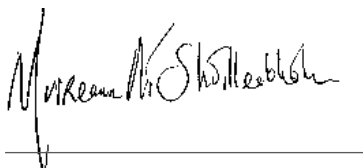
Report from the President in line with the Code of Practice for the Governance of State Bodies for the Year Ended 31 December 2021

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 2021.
- ii. All appropriate procedures for financial reporting, internal audit, travel, procurement and asset disposals are being carried out. In 2021 there was one instance where a non-competitive process was used for a contract above €25,000 (exclusive of VAT). This arose out of the Covid-19 global pandemic and the need for the PSI to carry out fitness to practise hearings remotely through a secure online portal that mirrored the experience of a courtroom or tribunal setting and there was only one suitable product available on the market at the time that offered this functionality. This derogation from procurement principles was deemed to be justifiable due to the exceptional circumstances and the need to maintain the operation of PSI's fitness to practise system on public protection grounds.
- 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 (IIOIP). Detailed oversight procedures are in place between the PSI and Department, and contract and governance arrangements in place between the PSI and the IIOIP 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 2021 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 2021:
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.
 - Seven appointments were made to the Council in 2021.
 - 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 24 March 2022 and signed by the President:



Ms Muireann Ní Shúilleabháin

24 March 2022

Statement on the Systems of Internal Control for the Year ended 31 December 2021

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 fulfill 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 2021 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 2021 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 2020 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:
 - High-level review of the System of Internal Control relating to 2020
 - Review of the PSI's Fitness to Practise Procedures, Systems, and Controls
 - Review of PSI Purchasing, Procurement and Payments
 - Review of PSI ICT Systems

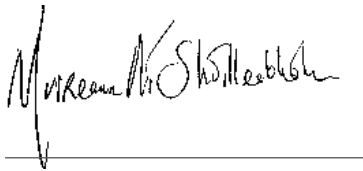
No weaknesses in internal control resulted in material losses, contingencies or uncertainties which require disclosure in the financial statements or the Auditor's Report on the financial statements. Appropriate steps recommended by the Internal Auditors are being undertaken and responsibility for the implementation of all audit recommendations is attributed to the relevant manager and a

timeline of implementation assigned. Implementation of internal audit recommendations are reported to the Audit and Risk Committee at each meeting. No breaches were reported for 2021. All elements of the control system were operational. No material losses or frauds occurred in 2021.

The PSI complies with current procurement rules and guidelines set out by the Office of Government Procurement. In 2021 there was one instance where a derogation from the rules and guidelines was considered justifiable and is outlined in more detail in the Report from the President in the Financial Statements.

PSI's monitoring and review of the effectiveness of the system of internal control is informed by the work of the Internal and External Auditors, the Audit and Risk Committee and senior management within PSI who are responsible for the development and maintenance of the internal control framework. I confirm that the Council conducted an annual review of the effectiveness of the internal controls for 2021.

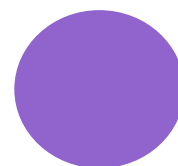
This statement of internal control has been formally reviewed and approved by the PSI Council on 24 March 2022 and signed on its behalf by the President:



Ms Muireann Ní Shúilleabháin

President

24 March 2022



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 2021, 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 31 December 2021 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 64 -66 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 21 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 of Going Concern

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

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

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

Other Information

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

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

We have nothing to report in this regard.

Matters on Which we are Required to Report by Schedule 1, Paragraph 16, of the Pharmacy Act 2007

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

Matters on Which we are Required to Report by Exception

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

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

Respective Responsibilities of the Council and Auditors

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

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

Auditor's Responsibilities for the Audit of the Financial Statements

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

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

- Identify and assess the risks of material misstatement of the financial statements, whether due to fraud or error, design and perform audit procedures responsive to those risks, and obtain audit evidence that is sufficient and appropriate to provide a basis for our opinion. The risk of not detecting a material misstatement resulting from fraud is higher than for one resulting from error, as fraud may involve collusion, forgery, intentional 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 on 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.

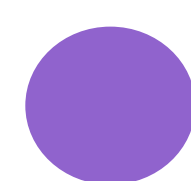
Shaw McClung

for and on behalf of



Crowe Ireland
Chartered Accountants and Statutory Audit Firm
40 Mespil Road
Dublin 4

24 March 2022



Statement of Comprehensive Income for Year Ended 31 December 2021

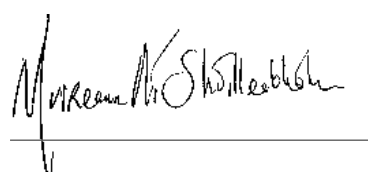
	Notes	2021 €	2020 €
Income	3	7,912,632	7,885,037
Operating expenses		<u>(7,569,088)</u>	<u>(6,986,320)</u>
Operating surplus		343,544	898,717
Interest Receivable	9	<u>874</u>	<u>4,532</u>
Surplus before taxation		<u>344,418</u>	<u>903,249</u>
Taxation	11	<u>-</u>	<u>-</u>
Surplus for the financial year		<u>344,418</u>	<u>903,249</u>

Statement of Financial Position for Year Ended 31 December 2021

	Notes	2021 €	2020 €
Fixed assets			
Tangible assets	12	18,827,163	18,365,170
Investment assets	13	7,200,000	-
		26,027,163	18,365,170
Current Assets			
Debtors	15	180,568	198,350
Cash at bank and in hand	16	10,990,855	18,017,338
		11,171,423	18,215,688
Creditors: amounts falling due within one year	18	(12,210,917)	(11,937,607)
Net current assets		(1,039,494)	6,278,081
Total assets less current liabilities		24,987,669	24,643,251
Reserves			
Revaluation Reserve	19	11,413,635	11,413,635
Designated Legal Reserve	19	2,500,000	2,500,000
Income and Expenditure Reserve	19	11,074,034	10,729,616
Closing Reserves		24,987,669	24,643,251

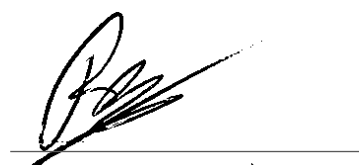
The financial statements were approved and authorised for issue by the Council on 24 March 2022.

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 2021

	€	2021 €	€	2020 €
Cash flows from operating activities				
Surplus for the financial year	344,418		903,249	
Depreciation on tangible assets	120,976		72,228	
Interest received	(874)		(4,532)	
Decrease/(increase) in debtors	17,782		(23,029)	
Increase/(decrease) in creditors due within one year	273,310		292,325	
	<hr/>		<hr/>	
Net cash flows from operating activities		755,612		1,240,241
Cash flows from investing activities				
Payments for tangible fixed assets	(582,966)		(521,213)	
Payments for investment assets	(7,200,000)		-	
Interest received	874		4,532	
	<hr/>		<hr/>	
Net cash flows from investing activities		(7,782,095)		(516,681)
		<hr/>		<hr/>
Net (decrease)/increase in cash and cash equivalents		7,026,483		723,560
		<hr/>		<hr/>
Cash and cash equivalents at beginning of financial year		18,017,338		17,293,778
		<hr/>		<hr/>
Cash and cash equivalents at end of Financial year		10,990,855		18,017,338
		<hr/>		<hr/>
Relating to:		10,990,855		18,017,338
Cash at bank and in hand		<hr/>		<hr/>

The notes on pages 74 to 89 form part of these financial statements.

Notes to the Financial Statements for Year Ended 31 December 2021

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

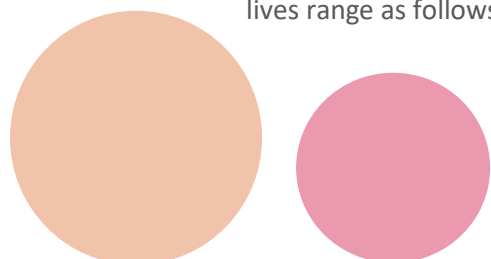
Income is recognised in the financial statements in the year to which the income relates to. To the extent income is received in advance, it is deferred and recognised in the relevant period for which services for these registrations or fees are given.

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 as follows:



Depreciation

Depreciation is provided on the following basis:

Freehold property	- Not depreciated
Office equipment and fittings	- 12.5% straight-line
Computer equipment and software	- 33.3% straight-line
Portraits, medals and badges	- Not depreciated
Electrical	- 5% straight-line
Mechanical and 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 18th 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. Investment assets

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

1.6. Debtors

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

1.7. 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.

1.8. 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.

1.9. 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.

1.10. Pensions

The Pharmaceutical Society of Ireland Superannuation Scheme 2016

On 10 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 1 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.

1.11. 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.

1.12. Interest income

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

1.13. Income and expenditure reserve

The Council recommends the minimum level of the Income and Expenditure Reserve be maintained at 30 per cent of the PSI's annual registration fee income receivable and that the Reserve be used only for specific activities. The activities must meet the following criteria:

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

1.14. 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.

1.15. Taxation

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

2. Judgements and key sources of estimation uncertainty

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

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

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

Going Concern

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

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

3. Income

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

	2021	2020
	€	€
Registration of pharmacists	2,645,408	2,630,633
Registration of retail pharmacy business (RPB)	4,483,106	4,507,532
Administration charges and other registration costs	123,378	113,583
Other fees	60,740	33,289
Department of Health funding for Irish Institute of Pharmacy (IIOP) services	600,000	600,000
	7,912,632	7,885,037

4. Operating surplus

Operating surplus for the year is calculated after charging:

	2021	2020
	€	€
Depreciation of tangible assets	120,976	72,228
Other pension costs	440,086	485,285
Audit remuneration (including VAT)	13,537	11,378
-Audit fees	<u>574,599</u>	<u>568,891</u>

5. Employees

5.1. Average Numbers

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

	2021	2020
	€	€
Office and management	44	43

5.2. Aggregate remuneration

Their aggregate remuneration comprised:

	2021	2020
	€	€
Wages and salaries	3,058,140	3,120,501
Social insurance costs	242,239	242,424
Pension Costs	440,086	485,285
	3,740,465	3,848,210
Analysed as follows		
Capitalised into assets	216,585	182,437
Expensed in the year	3,523,880	3,665,773
	3,740,465	3,848,210

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

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

	2021	2020
€60,000 to €70,000	10	11
€70,000 to €80,000	3	3
€80,000 to €90,000	-	1
€90,000 to €100,000	-	1
€100,000 to €110,000	2	2
€110,000 to €120,000	-	-
€120,000 to €130,000	1	1
	<u>16</u>	<u>19</u>

5.4. Key Management Personnel

The remuneration of key management personnel was as follows:

	2021	2020
	€	€
Wages and salaries	547,472	610,062
Other pension costs	134,455	138,352
	<u>681,927</u>	<u>748,414</u>

5.5. Registrar remuneration

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

	2021	2020
	€	€
Niall Byrne	128,090	122,959
Other pension costs	32,022	28,855
	<u>160,112</u>	<u>151,814</u>

6. Other Staff Costs

6.1 Staff Travel and Subsistence

	2021	2020
	€	€
Domestic	8,835	13,847
International	-	3,193
	<u>8,835</u>	<u>17,040</u>

6.2 Hospitality Expenditure

	2021	2020
	€	€
Staff hospitality	948	245
	<u>948</u>	<u>245</u>

7. Council/Committee Members' Remuneration

	2021	2020
	€	€
Council/Committee members' remuneration	224,225	193,070
	<u>224,225</u>	<u>193,070</u>

8. Council/Committee Members' Travel & Subsistence

	2021	2020
	€	€
Domestic	3,181	16,103
International	-	-
	<u>3,181</u>	<u>16,103</u>

9. Interest Receivable

	2021	2020
	€	€
Bank interest receivable	874	4,532
	<u>874</u>	<u>4,532</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.

	2021	2020
	€	€
General legal advice	82,205	27,510
Financial advice	4,469	12,522
Public Affairs	26,090	25,509
Procurement	12,745	34,291
Other	21,489	6,587
	<u>146,998</u>	<u>106,419</u>
Consultancy costs capitalised	-	-
Consultancy costs charge to the Income and Expenditure and Retained Earnings Reserves	<u>146,998</u>	<u>106,419</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.

	2021	2020
	€	€
Legal Fees	741,891	438,270
Conciliation and arbitration payments settlements	-	-
	<u>741,891</u>	<u>438,270</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 2021, legal fees amounted to €741,891 (2020: €438,270) 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.

As at 31 December 2021, the PSI is involved in Judicial Review proceedings concerning proposed statutory rules dealing with the temporary absence of pharmacists in registered Retail Pharmacy Businesses. All fees incurred in this case to 31 December 2021 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 January 2021	17,700,000	35,579	10,431	255,139	824,404	18,825,553
Additions	-	-	-	3,816	579,153	582,969
Cost of Disposal	-	-	-	-	-	-
At 31 December 2021	17,700,000	35,579	10,431	258,955	1,403,557	19,408,522
Depreciation and impairment						
At 1 January 2021	-	12,342	-	223,200	224,841	460,383
Depn. eliminated on disposals	-	-	-	-	-	-
Depn. charged in the year	-	4,448	-	9,634	106,894	120,976
At 31 December 2021	-	16,790	-	232,834	331,735	581,359
Carrying amount						
At 1 January 2021	17,700,000	23,237	10,431	31,939	599,563	18,365,170
At 31 December 2021	17,700,000	18,789	10,431	26,121	1,071,822	18,827,163

13. Investment Assets

Investment Assets

	2021	2020
	€	€
Exchequer notes	7,200,000	-
	<u>7,200,000</u>	<u>-</u>
	<u><u>7,200,000</u></u>	<u><u>-</u></u>

	2021	2020
	€	€
Cost		
At the beginning of the year	-	-
Purchased during the year	7,200,000	-
Disposed during the year	-	-
	<u>-</u>	<u>-</u>
At the end of the year	<u>7,200,000</u>	<u>-</u>
	<u><u>7,200,000</u></u>	<u><u>-</u></u>

The PSI purchased €3,700,000 and €3,500,000 of exchequer notes during the year with maturity dates on 19th October 2022 and 22 December 2022, respectively. This represents the fair value at 31 December 2021 (2020: N/A)

14. Financial Instruments

	2021	2020
	€	€
Financial assets		
Bank and Cash Balances	10,990,855	18,017,338
Investment assets	7,200,000	-
	<u>18,190,855</u>	<u>18,017,338</u>
Financial liabilities		
Trade creditors	247,297	184,588

15. Debtors	2021	2020
	€	€
Trade Debtors	45,448	-
Prepayments and accrued income	123,249	180,792
Other Debtors	11,871	17,558
	<u>180,568</u>	<u>198,350</u>

16. Cash and cash equivalents	2021	2020
	€	€
Cash at bank and in hand	<u>10,990,855</u>	<u>18,017,338</u>

17. Cash	2021	2020
	€	€
Cash at hand	273	273
Current accounts	5,094,280	4,911,049
Superannuation funds deposit account	5,357,056	5,019,092
Fixed term deposits	539,246	8,086,923
	<u>10,990,855</u>	<u>18,017,338</u>

18. Creditors: amounts falling due within one year

	2021	2020
	€	€
Trade creditors	247,297	184,588
Other creditors	11,026	34,341
PAYE/PRSI	120,300	119,718
VAT	443	40
PSWT	33,555	7,255
Deferred income	5,818,928	5,844,686
Accruals	622,312	727,887
PSI Superannuation scheme	5,357,056	5,019,092
	12,210,917	11,937,607

19. Reserves

17.1. Revaluation reserve

The freehold property was valued by Murphy Mulhall Chartered Surveyors, on the 18 January 2019 to a fair value of €17,700,000. The PSI reflected this revised valuation in the accounts for the year ended 31 December 2018. No revaluation of this asset has been undertaken in the interim and therefore no change in the valuation at 31 December 2021.

17.2. 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.

17.3. 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.

The Council recommends the minimum level of the Income and Expenditure Reserve be maintained at 30 per cent of the PSI's annual registration fee income receivable and that the Reserve be used only for specific activities. The activities must meet the following criteria:

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

20. Movements in reserves

The movements in reserves are detailed below:

	Revaluation Reserve €	Designated Legal Reserve €	Income & Expenditure Reserve €	Total Reserves €
At 1 January 2021	11,413,635	2,500,000	10,729,616	24,643,251
Surplus for the year	-	-	344,418	344,418
		2,500,000		
At 31 December 2021	11,413,635		11,074,034	24,987,669

21. 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 31 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.

The Single Public Service Pension Scheme

The Single Public Service Pension Scheme came into effect on the 1 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 are two benefits 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.

22. 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.

23. Related Parties

There were no transactions with related parties that require disclosure.

24. Controlling Party

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

25. Approval of the Financial Statements

The Council approved and authorised these financial statements for issue on 24 March 2022