

Annual Report 2020



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

The PSI Annual Report for 2020 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 2020 to 31 December 2020.

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.

Our Vision

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 support pharmacy practice development for the benefit of patients and the wider health system;
- We ensure compliance with pharmacy law and other requirements through programmes of inspection, quality assessment and, when necessary, enforcement, and we adjudicate formal complaints made against a pharmacist or a pharmacy, including imposing sanctions; and
- We provide advice 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 build on our strengths, engage more effectively and create impact for those we serve. Our Corporate Strategy 2018-2020 is designed to advance these objectives.

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 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 Values



Serve the public

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



Everyone counts

We value, appreciate and respect everyone we engage with



Work together

We work in partnership with our colleagues and all our stakeholders



Lead by example

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



Embrace change

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

Our Key Achievements in 2020

COVID-19

We established a COVID-19 response group to manage the PSI's external response during the COVID-19 pandemic and to coordinate the key strands of activity arising for the PSI

Operational Standards

In response to the COVID-19 pandemic, we developed new COVID-19 Operational Standards to apply across all pharmacies



Corporate Strategy

The PSI Corporate Strategy 2021-2023 was developed against the background of the COVID-19 global pandemic and the significant challenges it represented to society and healthcare services in Ireland, including for pharmacists and community pharmacies

PSI Branding

We completed the rollout of our new PSI logo



Equality, Diversity, and Inclusion

We established an Equality, Diversity, and Inclusion Working Group, which consists of staff drawn from every level of the organisation



Remote Hearings

Orders were made by the Minister designating PSI as a State body authorised to conduct remote meetings and hearings

Brexit

We continued to work to minimise any impact on the pharmacist workforce following Brexit

Falsified Medicines Directive

We continued to work closely with a number of partner organisations as part of the National Safety features Oversight Group

Business Transformation

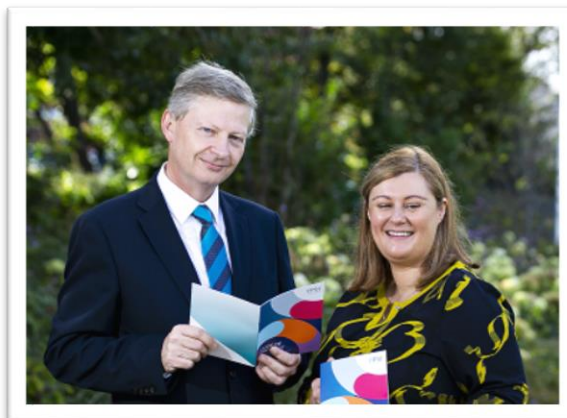
We carried out significant work on our digital transformation programme, including the development of a new registration system that provides registrants with a single online point of contact with the PSI. This will launch in 2021



Core Competency Framework

We commenced a review of the Core Competency Framework for pharmacists

Message from the President and Registrar/Chief Officer: 2020 in review



As the pharmacy regulator, the PSI's purpose and responsibility is to protect and promote the health, safety and wellbeing of patients and the public by regulating pharmacists and pharmacies in Ireland. Our intention is to clearly demonstrate through our work that we make a difference and that we create public value. Our Annual Report for 2020 provides an overview of the activities we carried out in 2020 to meet those commitments. Our Corporate Strategy 2018-2020 guided our activities and priorities and our Annual Report reflects progress on achieving our objectives during the final year of that three-year Strategy.

As with any other year, the PSI came into 2020 with extensive plans to further advance our objective of assuring public trust in pharmacy through effective regulation. That was our plan, and then the existential threat and rampant uncertainties of the COVID-19 pandemic materialised.

As the pharmacy regulator, the PSI had to pivot to ensure that we continued to deliver on our statutory remit while also recognising the challenging and disquieting environment in which we, together with everyone else in Ireland, found ourselves. While undertaking important initiatives in support of the public health response, we also developed new COVID-19 Operational Standards for community pharmacies. We did this in close collaboration with practising pharmacists, the Irish Pharmacy Union, the Health Service Executive, and the Department of Health. These Standards provide helpful guidance and support to those in leadership and governance positions in the retail pharmacy sector to ensure safe services and a safe environment for patients, the public and staff during the pandemic. They are also intended to inform patients and the wider public about what they can expect from their pharmacy and to provide assurance that their pharmacy is, indeed, a safe and supportive healthcare environment despite the risks arising from COVID-19.

The implementation of the Standards will continue into 2021 as we carry out visits to pharmacies to understand how pharmacy owners, superintendent and supervising pharmacists are reflecting on their own services and how they are adapting where needed. We are pleased with the positive response to the Standards and the evident commitment across the community pharmacy sector to their implementation.

In other work, we supported the widely welcomed expansion of pharmacy vaccination services to include children. This initiative, together with support for the provision of seasonal influenza vaccination by pharmacists off-site from the pharmacy, was a significant development in the onward evolution of pharmacy practice in response to public health need.

Despite the impact of COVID-19, it is very important to the public that the PSI continues to facilitate ongoing development within the pharmacy sector. This will help ensure continued high-quality and, where necessary, enhanced healthcare provision by pharmacists. This awareness underpinned the drafting of our new Corporate Strategy for 2021-2023, which incorporates feedback from extensive stakeholder engagement and public consultation.

The Strategy, which was approved by the PSI Council at its December 2020 meeting, sets out our key priorities for the next three years. Our focus remains on assuring the continued provision of safe, quality healthcare within pharmacies and ensuring that pharmacists maintain high standards and enjoy the continued trust of the public.

Under our current Strategy, we committed to building the PSI as an agile and high-performing organisation. A key enabler of this is our Business Transformation Programme, which we pushed forward during 2020 through an extensive programme of work that will continue into 2021 and 2022. We are committed to making it easier for our stakeholders to engage with us through a 'digital-first' approach. Our transformation will be delivered on a phased basis, starting with the launch of a new streamlined registration platform in 2021. The new platform will provide registrants with a single online point of contact with the PSI. It will also make it easier, and quicker, for the public and patients to access information on the public register.

During 2020, we continued with our preparations for Brexit. We remain steadfast in our aim to ensure that we deliver on our responsibilities around pharmacist registration with minimal disruption and that we take steps to minimise any impact on the pharmacist workforce in Ireland following Brexit.

As we are all aware, we will be living with COVID-19 well into 2021. We in the PSI will continue to work to ensure that pharmacists and pharmacies are supported to make a full contribution to the public health response. We will also continue to work with others to ensure that pharmacists, across all healthcare settings, are facilitated to play a full role within the future integrated healthcare system as proposed under Sláintecare. In addition, we are committed to supporting other Government initiatives, such as the development of a new pharmacy contract that will serve the interests of the public into the future.

In a year that has been like no other and where COVID-19 framed much of our work programme, we would like to thank the members of the PSI Council and PSI staff for their dedication, support, and commitment across the year. We would also like to acknowledge, and thank, the many pharmacists, other stakeholders, and partners with whom we worked during 2020. As we look towards the challenges of 2021, we take confidence from the many positive collaborations during 2020, and we applaud the demonstrated commitment of pharmacists and pharmacy teams to serving patients during a long and difficult year. We look forward to continued engagement during 2021 with all involved in pharmacy in Ireland as we work to further strengthen and enhance the collective commitment to safety and quality within pharmacy services that was so evident during these past 12 months.



Niall Byrne
Registrar/Chief Officer
March 2021



Joanne Kissane
President

COVID-19

At the beginning of March 2020, we established a COVID-19 response group to manage the PSI's external response during the COVID-19 pandemic and to coordinate the key strands of activity arising for the PSI. This group was the primary mechanism to ensure that the multiple issues arising during the pandemic were addressed across the organisation. This involved extensive liaison with multiple stakeholders within the pharmacy and wider health sector, including the Department of Health and the Health Service Executive (HSE). The workstreams handled by the group are set out below.

HSE Community Pharmacy Contingency Planning Forum

The PSI was part of the HSE's Community Pharmacy Contingency Planning Forum, which was established to coordinate contingency planning for community pharmacy services in the context of the challenges arising from COVID-19. In 2020, the group met fortnightly and reported to the Office of the Chief Clinical Officer in the HSE. The forum continues to provide useful and relevant opportunities for community pharmacists to raise current issues relating to COVID-19.

Emergency legislative provisions

We worked with the Department of Health on the following emergency legislative provisions and developed associated guidance for consequent implementation in pharmacy.

Registration

In line with the Emergency Measures in the Public Interest (COVID-19) Act 2020, a restoration route was introduced to the Pharmacy Act, referred to as "Section 77 registration". This route enables former PSI registrants, who either voluntarily withdrew from the register or were removed due to non-payment of registration fees, to have their registration restored for a temporary period. In 2020, 42 pharmacists and 2 pharmaceutical assistants restored to the relevant registers under Section 77. The period of registration for any pharmacist re-registered under Section 77 of the Act was due to expire on 31 July 2020 but has since been extended by the Minister for Health to 30 June 2021.

We proposed changes to the existing statutory rules, which set out the fees payable by retail pharmacy businesses for continued registration. This amendment to the PSI (Fees) Rules 2014 was put in place to help mitigate any immediate cash flow issues at the individual pharmacy level. The amendment to the Fees Rules granted a deferral of continued registration fees, which were due to be paid by registered pharmacies for a specified period during 2020.

We also proposed changes to the existing statutory rules, which set out requirements for first time recognition and registration for applicants who first qualified in a Third Country. These provisions are intended to only be used in limited circumstances.

Education, training, and registration of pharmacy students

In the context of the COVID-19 pandemic, we proposed an amendment to the PSI (Education and Training) (Integrated Course) Rules 2014 to reduce the legislative requirement for the fifth-year pharmacy placement to be a period of six months – this applies in exceptional circumstances only and must be within the period of eight consecutive months provided for in the higher education institutions' calendar. Separately, guidelines under Rule 15 (1) of the PSI (Education and Training) (Integrated Course) Rules 2014 were developed to address the use of remote learning on experiential learning placements during the four month placement undertaken in the fourth year of the MPharm programme. We did this to help reduce the impact on experiential learning placements, where organisations require students to work remotely.

Changes to the regulations on the sale and supply of medicines

In 2020, changes were made to the Medicinal Products (Prescription & Control of Supply) (Amendment) Regulations 2020 and the Misuse of Drugs (Amendment) Regulations 2020. The key changes focused on ensuring the continued care and treatment for patients during the pandemic, including a national electronic prescription transfer, extensions to prescription validity, repeating prescriptions, and emergency supply provisions.

To support the pharmacy sector with the changes to these regulations and other challenges faced by pharmacies and the public during the pandemic, we developed the following guidance for pharmacies:

- The PSI, Medical Council and HSE published joint guidance setting out the amendments to the legislation for the supply of prescription-only medicines during the COVID-19 pandemic. Frequently asked questions and answers were also developed to assist pharmacists when supplying prescription-only medicines during the pandemic.
- The PSI and HSE published joint guidance to support patients, volunteers, and pharmacists with the safe delivery of medicines, particularly conscious of vulnerable people sheltering at home.
- The PSI and HSE issued joint guidance on business continuity planning for community pharmacies during the COVID-19 pandemic to help support the community pharmacy sector by providing a consistent and coordinated approach in dealing with changes in demand and capacity caused by the pandemic.

Changes to the regulations on vaccination services

To support influenza vaccinations by pharmacists at suitable locations, offsite from retail pharmacy premises, changes were made to the [Medicinal Products \(Prescription and Control of Supply\) \(Amendment\) \(No.5\) Regulations 2020](#).

To support these changes, we published addenda to the “PSI Guidance on the Provision of Vaccination Services by Pharmacists in Retail Pharmacy Businesses” to facilitate full participation of pharmacists in the national influenza vaccination campaign. These included the following:

- Guidance on the Provision of an Influenza Vaccination Service for Children Aged 6 Months and Older
- Practical Guidance when providing a Pharmacy Vaccination Service during the COVID-19 Pandemic
- Guidance to Support Pharmacies in Providing Safe Influenza Vaccination Services Offsite from the Pharmacy Premises

Fitness to practise matters during COVID-19

The PSI was mindful that dealing with a national health emergency had to be a priority for pharmacists and pharmacy owners. At the same time, when processing complaints against pharmacists and pharmacy owners, we have a duty to all parties to process complaints expeditiously and fairly. After due consideration, the processing of complaints against pharmacists and pharmacy owners was temporarily suspended between March and May 2020 to allow focus to be prioritised on patient safety and public health matters. The hearing of complaints before the PSI's Disciplinary Committees of Inquiry was also suspended to comply with Government Health guidelines, given that inquiries could no longer be held in person. The Disciplinary Committees were able to continue to conduct their other business by meeting remotely so that complaints could continue to be processed and prepared for inquiry in the normal way.

In November 2020, the PSI was designated as a State body for the purposes of holding remote meetings and hearings pursuant to Civil Law and Criminal Law (Miscellaneous Provisions) Act 2020 (Section 29) (Health) (Designation) Order 2020 (SI. No. 532/2020), and the Civil Law and Criminal Law (Miscellaneous Provisions) Act 2020 (Section 31) (Health) (Designation) Order 2020 (S.I. No. 533/2020). As a result, the PSI was able to resume the hearing of fitness to practice inquiries in December 2020, using new technology to do so remotely. We were pleased to embrace technology in this respect, recognising that an important aspect of any fitness to practice or disciplinary matter is that all parties can have finality to the matter. Given the PSI's overriding objective to deal with all complaints expeditiously and fairly, we will continue forward into 2021 using technology to hold inquiries by way of remote hearing.

COVID-19 Information Hub

Due to the evolving nature of the pandemic, we identified the need for a dedicated information resource for pharmacists. Together with the Irish Institute of Pharmacy (IIP), an online education and information signposting resource of up-to-date and comprehensive information on COVID-19 was created and hosted through the IIP website. The information hub aimed to ensure that pharmacists had access to resources to facilitate their ongoing CPD needs in this area and help facilitate safe practice on behalf of patients. The COVID-19 hub provides information and training on areas such as infection prevention and control, public communication, emergency medicines and vaccinations, supply and guidance on medicines, mental health and wellbeing resources, together with a return to practice resource for pharmacists restoring to the register in response to the pandemic.

Development of COVID-19 Operational Standards for Pharmacies

In August 2020, we published COVID-19 Operational Standards for Pharmacies. The Standards aim to provide guidance and support to those in leadership and governance positions in the retail pharmacy sector in continuing to ensure safe services and a safe environment for patients, the public, and staff. The Standards set out the safety and quality outcomes which the PSI expects pharmacies to deliver during COVID-19. The Standards were developed collaboratively with representatives from the community pharmacy sector and the Department of Health, the HSE and the Health Protection Surveillance Centre.

The Standards are currently in a 'use and learn' phase. During this period and into 2021, we will be engaging with and visiting pharmacies to gather feedback on the use of the Standards in practice and to see how they are being used to support safety and quality in pharmacies. Field-testing at pharmacies is being arranged on an appointment basis. In 2020, three virtual visits and 13 physical visits were conducted.

COVID-19 and the PSI's strategic results areas

As the scope and potential impact of the COVID-19 pandemic became apparent in early 2020, the PSI Council noted that COVID-19 would significantly impact on the strategic development process and on the PSI's operating environment. Due to this, a number of projects outlined in the PSI's Service Plan 2020 were postponed. These are as follows:

- Assess emerging risks to the continued availability of a professional pharmacy workforce within community pharmacy in Ireland
- Reducing the overuse of benzodiazepine medicines
- Assuring the safe supply of medicines from pharmacies into residential care settings
- Regulating for quality and safety in retail pharmacies
- Reform of the Pharmacy Act

We recognise that these significant objectives needed to be carried forward into the next strategic planning period, and they have been incorporated into the PSI's Corporate Strategy 2021-2023.

Results and Activity

Progress on our strategic change and improvement agenda in 2020

Assuring trust in pharmacy through effective regulation is our commitment in our 2018-2020 Corporate Strategy. There are four distinct strategic areas under which we aim to deliver specific results.

Promoting professionalism and quality in pharmacy

We will act to support professionalism within pharmacy and the delivery of safe and reliable pharmacy services.



Impacting through deeper collaboration and engagement

We will deepen our engagement and communications with stakeholders to ensure our work is making an impact and that we are focused on key outcome areas.

Regulating effectively for better health outcomes and patient safety

We will regulate in ways that are proportionate, effective and risk based, with a focus on the key areas relevant to patient health and safety.



Building an effective organisation and benchmarking our performance

We will build an agile and high-performing organisation, capable of delivering on our mission and have our performance independently assessed.

Strategic results area 1: Promoting professionalism and quality in pharmacy



Core Competency Framework for Pharmacists

One of our responsibilities is to ensure that all key elements are in place to ensure a high-quality of pharmacy practice in Ireland. The Core Competency Framework is one of these key elements. The Framework describes the competencies and behaviours of pharmacists in their daily practice and aims to reflect the practice of pharmacists in the early stages of their career. The Framework was developed to assist pharmacists to enhance their practice and, thereby, patient outcomes through self-reflection, self-assessment and self-identification of learning needs.

The outcomes from a review of the Framework were brought before the PSI Council at its meeting in October 2020. The review process included a series of early engagement meetings with key stakeholders, an examination and benchmarking exercise of international developments in competency frameworks, and a targeted consultation with registered pharmacists and various other stakeholders. The recommendations of the report outlined the need for a deeper consideration of the Framework to assure that it is fit for purpose and that it is capable of meeting the needs of the public and profession into the future. The review and development of a revised Core Competency Framework have been included in the PSI Service Plan for 2021 as a two-year strategic project, commencing in January 2021 and concluding in December 2022. The PSI will work in conjunction with its stakeholders through steering groups, working groups and public consultations throughout this project.

Brexit

From 1 January 2021, all applicants holding a qualification from Great Britain or Northern Ireland must apply for recognition and registration under the Third Country route if they hold a qualification obtained in those States. In 2020, we instituted a process under this route, a more streamlined evidence - based assessment, congruent with the current provisions of the Professional Qualifications Directive in processing timelines, documents to be provided and fees applied. Further work will take place in 2021 to rationalise the Third Country Qualification Recognition route for all applicants holding qualifications obtained in countries outside of the European Economic Area.

Code of Conduct for Pharmacists

The updated Code of Conduct for pharmacists, which sets out the principles, standards and ethics for pharmacists, came into effect on 21 October 2019. To provide information and support to pharmacists in the roll-out of the new Code of Conduct, we held two information events in early 2020. Further planned events were deferred due to the pandemic.

Strategic results area 2: Impacting through deeper collaboration and engagement



Engaging with stakeholders and the public

The PSI's Communications Strategy focuses on the importance of effective communication and meaningful engagement to create and enhance awareness and understanding of the role of the PSI as the pharmacy regulator. It aims to build and improve our existing engagement with our stakeholders by strengthening vital relationships to ensure that the regulation of pharmacy and the provision of safe and effective pharmacy services appropriately contribute to the continuing improvement of health services. To realise our objectives and to drive the achievement of positive public health outcomes, the PSI recognises the importance and necessity, of working with a wide range of external stakeholders to deliver our central organisational goal of assuring trust in pharmacy through effective regulation.

To support the pharmacy sector during the COVID-19 pandemic, we communicated with the pharmacy profession on an ongoing basis by issuing statements and regular updates. The aim of these communications was to ensure that the pharmacy profession had access to reliable information during the initial and rapidly evolving stages of the pandemic. This involved working with many of the agencies involved, including the HSE, Health Protection Surveillance Centre (HPSC) and the Health Products Regulatory Authority (HPRA). A designated COVID-19 section on the PSI website was also developed, containing information and updates to further assist pharmacists and the public.

In 2020, the PSI continued its engagement with Quality and Qualifications Ireland (QQI), other professional and regulatory bodies in the State, and higher education institutions. The purpose of this engagement, coordinated by QQI, is for all relevant stakeholders to work together to agree on a set of accreditation principles that will ultimately decrease the accreditation burden on higher education institutions. This engagement also provides a platform, through meetings and hubs, for professional and regulatory bodies to meet regularly, share information, best practice and issues that may arise, etc. In 2020, the PSI was invited to present to other professional and regulatory bodies on its experiences with accreditation report writing. This engagement will continue in 2021.

The PSI Council and Executive adapted to remote working over the year. Significant effort was devoted to maintaining communication with our stakeholders, including PSI registrants, patients and healthcare advocates, the Department of Health, representative organisations, the PSI Council and Committee members.

Corporate Strategy 2021-2023

The PSI Corporate Strategy 2021-2023 was developed against the backdrop of the COVID-19 global pandemic and the significant challenges to society and healthcare services in Ireland, including for pharmacists and community pharmacies.

The process commenced with the appointment of a subgroup of the PSI Council and Executive on the development of the Corporate Strategy. A public consultation process was opened in July and August 2020, and more than 150 submissions were received. The strategy was adopted by the PSI Council at its December 2020 Council meeting.

Strategic results area 3: Regulating effectively for better health outcomes and patient safety



Falsified Medicines Directive

The Falsified Medicines Directive came into operation on 9 February 2019. Implementation of the Directive aims to ensure that medicines continue to be provided to patients without delay and ensure that all stakeholders, manufacturers, wholesalers, pharmacists and other healthcare professionals work to build confidence in operating the new safety system. To assist with its implementation, we continued to work closely with the Department of Health, HPRA, Irish Medicines Verification Office (IMVO), HSE and the Private Hospitals Association as part of the National Safety Features Oversight Group. Throughout 2020, the PSI met with the IMVO regularly to share information on the implementation of the Directive within pharmacies. Due to the challenges of COVID-19 and Brexit, the use and learn phase is being reviewed.

Regulatory remit in hospital pharmacies

As part of the PSI Service Plan 2020, the PSI sought further information to complete our review of the regulation of retail pharmacy business in hospital pharmacy. We continued to examine the provisions of the Pharmacy Act 2007 as they apply to hospital pharmacy departments registered under the Act as retail pharmacy businesses. All 75 registered hospital pharmacies were invited to participate in a survey, which allowed further analysis of the nature of the pharmacy services provided and the extent of their provision. The objective was to bring clarity for all involved as to the precise regulatory remit of the PSI in respect of these registered entities. To date, a total of 68 pharmacies have participated in the survey.

Regulated Professions (Health & Social Care) Amendment Act 2020

Significant legislative reform took place in 2020 across most healthcare regulators in the form of the Regulated Professions (Health & Social Care) Amendment Act 2020, which in the context of the PSI, amends parts of the Pharmacy Act 2007 and introduces a number of new provisions. The amendments to Part 6 of the 2007 Act will bring in new grounds for complaints against pharmacists and pharmacy owners and will make some procedural changes in relation to sanctions and publication. There will also be greater obligations and entitlements in relation to publishing transcripts and reports following a fitness to practice inquiry before a Disciplinary Committee, the sharing of information with other regulators regarding the existence and outcome of other disciplinary and certain other legal proceedings, and enhanced powers to obtain information from An Garda Síochána and the Courts Service.

The Regulated Professions (Health & Social Care) Amendment Act 2020 will commence in early 2021, and we have commenced delivering training to the PSI's Disciplinary Committees concerning the relevant changes. We will also update our complaints guidance documents for complainants, pharmacists and pharmacy owners, and our website.

Strategic results area 4: Building an effective organisation and benchmarking our performance



Business transformation

A core component of our Business Transformation Programme is a digital services transformation project focused on the design and development of a new, improved, secure and effective ICT system. This project will also give effect to the PSI's Digital Policy Statement; Digital First 2018-2021. This statement reflects the broader public service context within which the PSI operates and reflects many of the key policy commitments published by the Department of Public Expenditure and Reform relating to digital developments in public bodies.

We commenced our digital transformation journey at the end of 2019, and we continued this project throughout 2020. The design and testing of the first phase of this new technology solution – a new registration system - was a major feature of work carried out in 2020. This will deliver benefits for PSI, registrants and the public when implemented in 2021.

Future funding strategy

A key focus for the PSI is the requirement to determine the alignment of our funding streams and our development strategy, including our workforce development strategy, to support the delivery of our statutory and other functions into the future. The focus of this alignment exercise is to demonstrate that we are carrying out our regulatory mission to the standard expected by the public and that we have the requisite resources available. A strategic review of the future financing of the PSI was agreed as an objective for the PSI to progress in 2020. Its overriding purpose is to lay the basis for financial stability and sustainability, utilising available resources effectively and ensuring structural deficits are addressed.

There are three broad phases to this review which will span several years:

- 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

At its December 2020 meeting, the PSI Council agreed on the broad assumptions that will underpin the first phase of the Strategic Financing Review, which will be undertaken in 2021. Council agreed to keep these assumptions under regular review. These assumptions include:

- general economic assumptions based on Irish Government macroeconomic indicators
- minimal growth in numbers registered with PSI
- PSI to continue to be primarily funded from current income streams and supplemented by the accumulated reserves.

Activity in support of our mission

As well as the strategic change and development projects undertaken in 2020, we continued to deliver on our key functions, with operational activity taking place across registration, inspection, investigation, consideration of complaints and disciplinary matters, practice development and the effective governance of the organisation.

Registration

Register of pharmacists, pharmaceutical assistants, and pharmacies

All pharmacists, pharmaceutical assistants and retail pharmacy businesses must be registered with the PSI and entered in the relevant register in order to provide pharmacy care, treatment or services to the public. Registrants must apply for their continued registration each year to maintain registered status.

The number of registered pharmacists on Part A of the register in 2020 was 6,767, and one pharmacist on Part B of the register. There were 285 pharmaceutical assistants on the register at the end of 2020, down from 310 in 2019. There were 1,968 retail pharmacy businesses on the PSI Register at the end of 2020, up from 1,956 in 2020.

There were 102 cancellations from the Register of Pharmacists, with 15 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. Where a pharmacist indicated a reason for cancelling their registration, the reasons were as follows: 18 pharmacists emigrated, 16 pharmacists retired, 16 pharmacists were moving abroad, and four pharmacists cancelled their registration for study leave. The remaining 33 pharmacists did not provide a reason. In 2020, 17 pharmaceutical assistants voluntarily cancelled their registration, with 14 indicating that this was due to retirement and the remainder not giving a reason. A total of eight pharmaceutical assistants had their registration involuntarily cancelled. Twenty-three pharmacists restored their registration under Section 61, and 42 pharmacists and two pharmaceutical assistants were restored to the Register under Section 77 (temporary COVID-19 emergency restoration process).

Certificates of current professional status

We issue Certificates of Current Professional Status on behalf of registrants accessing registration in other jurisdictions. In 2020, we issued 45 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 state, the home state facilitates the verification of the applicant's Internal Market Information 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 14 EPC applications were received in 2020, and one application was carried over from 2019. Of these, 13 applications were processed, one was withdrawn, and one was 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 on a daily basis and are recorded by the PSI. We investigate these alerts if they relate to pharmacists. In 2020, we issued five 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.

Education remediation

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 to the Council by a registrant. This means that the PSI monitors the registrant as they work to achieve the expected outcomes and demonstrate the relevant competencies as per the undertakings given or the conditions attached to their registration. In 2020, we monitored seven education remediation cases. All are still ongoing in 2021.

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 128 pharmacies and 78 non-pharmacies on the internet supply list at the end of 2020.

Registration in numbers



6,767

pharmacists
on Part A of the Register



6,506
in 2019

6,246
in 2018

1

pharmacist
On Part B of the Register

320

pharmacists added to the register

161
Irish
trained

154
EU/EEA
trained

5
Non-EU/EEA
trained



68%
of new
registrants
were female

Country where new pharmacist qualifications were obtained



161
Ireland



106
UK



11
Portugal



11
Italy



6
Romania



5
Poland



5
Spain



4
Hungary



2
Croatia



2
Lithuania



1
Germany



1
Belgium



1
Australia



1
Egypt



1
India



1
South Africa



1
Sudan



45

Certificates of
Current
Professional Status
issued by PSI

30 UK
8 Australia
2 Canada
2 Spain

1 New Zealand
1 Switzerland
1 United States

285



pharmaceutical assistants
registered

310
in 2019

330
in 2018

pharmacists

87 voluntarily
cancelled their
registration

15 involuntary
cancellations of
registration

pharmaceutical
assistants

17 voluntarily
cancelled their
registration

8 involuntary
cancellations of
registration

1,968



pharmacies registered

1,956
in 2019

1,945
in 2018

81
cancellations

6
new openings
(relocations)

29
new openings

58
new openings
(transfer of ownership)



Education and Training

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, standards and arranging for the accreditation of educational programmes for pharmacists. We also monitor the system of continuing professional development for pharmacists through the Irish Institute of Pharmacy.

MPharm Programme

The integrated MPharm involves the integration and dispersal of practice placements for students throughout the five years of the course and facilitates placements of varying durations in the many areas of pharmacy practice, including community, hospital and industry. In 2020, we welcomed the first cohort of graduates from the five-year integrated MPharm programme in pharmacy, which commenced in 2015.

Accreditation matters- qualification for practice

The PSI is 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. In 2020, accreditation visits took place at each of the three Schools of Pharmacy: The Royal College of Surgeons in Ireland, Trinity College Dublin, and University College Cork. Subsequently, the MPharm at all three Schools of Pharmacy was approved for five years by the PSI Council, without condition, following the recommendation of the accreditation teams. Accreditation reports for each School of Pharmacy have been published on our website.

Irish Institute of Pharmacy (IIOp) and the PSI CPD Model

The 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. The ePortfolio Review operates by the PSI randomly selecting a group of pharmacists from the Register of Pharmacists each year to submit an extract from their ePortfolio to the IIOp for review. 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 the Practice Review process. Of the 1,352 pharmacists selected for ePortfolio Review in 2020, a total of 1,317 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. In 2020, the decision was made to make a formal complaint under the Pharmacy Act against three pharmacists who did not complete their ePortfolio Review or did not adhere to their CPD obligations.

Due to the ongoing global COVID-19 pandemic, the two face-to-face Practice Review events scheduled to take place in 2020 were cancelled.

Education and training in numbers



1,317

of the **1,352**
pharmacists
selected for
ePortfolio
Review
met the
standards



We welcomed
two pharmacy
students to PSI
as part of their
four-month
placement

Inspection and Enforcement

We provide public assurance of safe standards of pharmacy practice, promote good and safe practice within pharmacies and work to ensure compliance with legislative requirements, guidelines, best practice, and the Code of Conduct for pharmacists. 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.

Inspections

A total of 124 pharmacy inspections were conducted, including systems inspections, risk-based inspections and re-inspections.

Systems inspections review the quality systems and governance arrangements of the pharmacy; examine the way prescription-only medicines and controlled drugs are supplied; assure there is a legitimate and safe basis for the supply of medicines; assess the pharmacy premises and pharmacy workflow.

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.

Themed inspections are conducted to assess certain other services provided by pharmacists. In 2020, these included flu vaccination inspections and internet supply inspections.

Re-inspections are conducted to verify the implementation of any confirmations and assurances of compliance after the previous inspection of the pharmacy.

In 2020, 100 registration related inspections were carried out to assess compliance with the Retail Pharmacy Business Regulations (S.I. No. 488 of 2008)(as amended) and PSI guidelines. Twelve of the 100 new pharmacy inspections involved a physical visit to the pharmacy premises. This was a combination of new openings, changes of ownership and relocations of pharmacy premises.

Due to COVID-19 restrictions, routine inspection activity was suspended in line with government restrictions. Eighty-eight out of the 100 registration related inspections that were carried out remotely used 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. These were a combination of new openings, changes of ownership and relocations.

A total of 22 inspections and two focus visits were conducted to assess compliance with declarations provided at registration.

Falsified Medicines Directive (FMD)

In 2020, the PSI contacted 28 pharmacies regarding FMD registration issues. In addition, the PSI issued an email to 353 pharmacies whose FMD scanning activity was not detected on the relevant repository system during selected dates. The email also contained a survey to better understand issues surrounding FMD non-compliance. A total of 217 survey responses and 152 phone calls were received from the survey cohort.

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 seven investigations were commenced during 2020, and eight investigation files were closed during 2020. There were 14 investigation files open at the end of 2020.

Internet supply of non-prescription medicines

In 2020, 10 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.

Consideration by the Registrar of inspection reports under Section 71 of the Pharmacy Act

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 2020, 21 reports were considered by the Registrar. Following consideration of these:

- 11 pharmacists and six pharmacies were referred to the complaints process (under Section 71(1)(b));
- 13 other actions were taken at the direction of the Registrar, including initiating prosecutions, re-inspections, 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 eight cases (under Section 71(1)(a)).

Inspection and enforcement in numbers



100

registration
related
inspections

114	109
in 2019	in 2018

124

pharmacy
inspections

161	149
in 2019	in 2018



653

responses to
pharmacy practice
queries

28% related to
COVID-19

7 investigations commenced in 2020



21 reports
considered by the
Registrar



10 compliance actions taken in
relation to the internet supply of non-
prescription medicinal products

Pharmacy practice development, advice and guidance

We promote good practice standards and the improvement of pharmacy through the development of guidance and information resources on pharmacy practice, medication, and patient safety. We also provide advice, support and guidance to the public, the pharmacy profession, and the Government on pharmacy care, treatment and services in Ireland.

PSI guidance

In the interest of the safety of patients and the public the PSI issues guidance to facilitate compliance with pharmacy and medicines legislation and support good practice in the supply of medicines and the operation of a pharmacy. In 2020, we issued three PSI guidance documents on vaccinations. We also provided guidance to the profession during COVID-19. Further information on this can be found on page 7.

Pharmacy practice updates

Due to the COVID-19 pandemic, we were required to pivot our work to respond to the pandemic and the unprecedented challenges faced in the pharmacy. As part of our COVID-19 external response, we issued regular communications and updates to the profession on the rapidly changing landscape in relation to public health advice, medicines, and pharmacy practice issues.

Working with others

As Ireland's pharmacy regulator, we contribute to many public health and safety initiatives. In 2020, our collaborations were mainly focused on working with other agencies and stakeholders on the COVID-19 response, including joint initiatives with HSE, HPSC and HPRA.

Concerns, Formal Complaints & Fitness to Practise

We address poor performance, practices and behaviours by considering 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. We also take action to ensure concerns reported to us are reviewed and actioned, as appropriate.

Concerns

Expressions of concern arise where a person does not wish to make a formal complaint but wants to bring something to the attention of the PSI. All concerns are reviewed internally by a multidisciplinary panel to assess risk and determine what action is required. A total of 184 concerns were received in 2020, representing an increase of 28% since 2019. In 2020, 19% of the concerns received related to COVID-19 matters, which included issues in relation to operational standards in a pharmacy, the use of facemasks, patient safety, emergency supply legislation, and pricing of COVID-19 related products.

Sometimes a concern may become a complaint. Of the 184 concerns received in 2020, 16 resulted in formal complaints, which were then processed under Part 6 of the Pharmacy Act 2007. Those concerns which are unresolved as of 31 December 2020 are carried forward into 2021 and remain under review.

Formal complaints

Formal complaints are received 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 in line with the Pharmacy Act 2007. A total of 46¹ formal complaints were received in 2020.

Due to the COVID-19 pandemic, we temporarily suspended the processing of formal complaints between 19 March 2020 and 22 May 2020, as healthcare professionals, including pharmacists, focused their efforts on responding to the emergency, which included adapting to new legislative changes and government guidelines around medicines, delivering healthcare, and patient, employee and public safety.

In 2020, 11% of the complaints received related to COVID-19 matters. These included issues in relation to operational standards in a pharmacy, patient safety, emergency supply legislation and pricing of COVID-related products.

¹ Where a complaint relates to the same allegations/incident but is against multiple respondents, it is counted for reporting purposes as a single complaint.

Preliminary Proceedings Committee

Once the PSI has received and processed a complaint, it is referred to the Preliminary Proceedings Committee (PPC) for consideration under Part 6 of the Pharmacy Act 2007. The PPC, upon reviewing the complaint, decides whether there is sufficient cause to warrant further disciplinary action being taken in relation to the complaint. Where the PPC decides that there is a case for further action, the complaint is referred to either mediation or to a fitness to practise committee of inquiry for hearing.

In 2020, 37 complaints were considered by the PPC. Of these, 95% were considered within six months.

During 2020, the PPC sent forward 15 complaints for further action, of which 13 were referred to the Professional Conduct Committee and two were referred to mediation. As one complainant later withdrew consent to mediation, and the other complaint could not be resolved by mediation, both complaints were ultimately referred on for inquiry to bring the total back to 15.

The PPC advised the Council that 22 complaints did not warrant further action. The Council agreed with the advice of the PPC in relation to all these complaints.

No complaints were referred to the Health Committee.

Withdrawal of Complaints

It is possible that once a complaint process has started, a complainant may later choose to withdraw that complaint.

Under Section 44 of the Pharmacy Act 2007, a complainant may withdraw their complaint at any stage of the complaint process, and where that occurs, the relevant Committee (in this case the PPC) may nonetheless consider that complaint and may, subject to subsequent Council agreement:

- decide that no further action is required, or
- proceed as if the complaint has not been withdrawn.

A total of nine of the 37 complaints considered by the PPC were withdrawn by complainants. The PPC decided, with Council's agreement, to take no further action in relation to all these complaints.

Mediation

Mediation is a confidential process where a neutral third party (a mediator) facilitates both sides to the complaint in trying to resolve the matter and arrive at an appropriate outcome and agreement. Both parties on either side must consent to the matter being dealt with by mediation.

As reported above, in 2020, two complaints were referred by the PPC to mediation.

- In one complaint, a mediation took place; however, it did not result in a mediated outcome. As a result, the complaint was referred forward for inquiry.
- In one complaint, both parties did not consent to the complaint being dealt with by mediation, so as a result, it was referred forward for inquiry.

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

Callovers

A callover is a meeting where the Professional Conduct Committee, and the Health Committee, in conjunction with advice from an independent legal assessor, can consider matters such as setting dates for inquiries, applications for adjournment, privacy applications and/or other preliminary applications. The Committees may also direct that specific timelines be complied with in order to ensure that a case is ready for hearing.

In 2020, four callovers took place, of which three took place remotely using video technology.

Inquiry hearing outcomes

COVID-19 had a significant impact on the ability to conclude fitness to practise matters by inquiry before a Disciplinary Committee. As a result, a lower number of inquiries were dealt with in 2020 than in previous years. We had to suspend the hearing of inquiries at PSI House due to Government travel restrictions and public health guidelines. Following the enactment of legislation in August to provide for remote (virtual) hearings by State bodies and the introduction of the Civil Law and Criminal Law (Miscellaneous Provision) Act 2020 in November designating the PSI as a State body for the purposes of the new legislation, the hearing of inquiries resumed on a remote basis in December 2020.

Before the end of March, seven inquiries relating to eight respondents were heard before a Committee of Inquiry. All were heard by the Professional Conduct Committee.

Findings were made, or undertakings were provided for 75% of the respondents who were the subject of an inquiry. The findings include professional misconduct and/or poor professional performance and/or convictions against the respondents. The undertakings included not to repeat the conduct, which was the subject matter of the complaint.

Sanctions imposed following fitness to practise hearings

A pharmacist or pharmacy may have one or more sanctions imposed following an inquiry. In 2020, four censures were imposed, and four sets of conditions were attached to the registration of the respondents. A number of the sanctions imposed by the PSI Council in 2020 related to inquiries which concluded in 2019. The four sets of conditions imposed on the respondents were confirmed by the High Court.

Interim suspension

The PSI may apply to the High Court for an order to immediately suspend the registration of a registered pharmacist or registered pharmacy against whom a complaint has been made 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 inquiry process. The PSI made one interim suspension application to the High Court in 2020. The Court made an Order suspending the registration of the pharmacist pending further procedure in relation to the complaint.

Concerns, Formal Complaints & Fitness to Practise in numbers



184

concerns received

144
in 2019

133
in 2018



Categories of concerns raised

81.5% member of the public

11% pharmacist

2% other pharmacy personnel

1% nurse

1% doctor

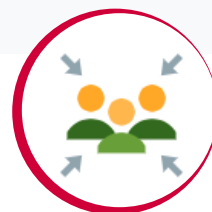
1% HSE

1% Registrar

0.5% other health professional

0.5% other organisation

0.5% pharmacy



Categories of concerns raised

52 pharmacy practice issues

41 commercial, advertising or
employment issue

31 behaviour (manner/attitude)

21 failure to supply

15 other reasons

6 dispensing error (incorrect
medication)

4 dispensing without valid
prescription

3 generic substitution

2 contravention of section 63/64
of the Pharmacy Act

2 health impairment

2 emergency supply issues

2 dispensing error (incorrect
medication)

1 dishonesty

1 out of date medication

1 breach of voluntary undertaking
to Registrar/Council



Formal complaints received by source

- 72%** member of the public
- 20%** Registrar
- 2%** other organisation
- 2%** pharmacist
- 2%** pharmacy
- 2%** HSE



Categories of formal complaints raised

- 12** pharmacy practice issues
- 8** behaviour (manner/ attitude)
- 8** failure to supply
- 5** commercial, advertising or employment issue
- 3** dispensing without valid prescription
- 3** dispensing error (incorrect dose)
- 1** contravention of Section 63 or 64 of the Act
- 1** dishonesty
- 1** health impairment
- 1** conviction
- 1** out of date medication
- 1** dispensing error (incorrect medication)
- 1** breach of High Court conditions

37

complaints considered by the PPC

2 complaints referred to mediation



4 conditions imposed following fitness to practise hearings

7 inquiries heard before the Professional Conduct Committee



4 callovers took place

Organisational services in numbers

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.

Communication channels

Our Communications Strategy supports effective engagement with all stakeholders. It is designed to ensure patient safety is core to our communications and create awareness and understanding of the PSI's role.

We recognise that our website is an important source of information supporting our mission and meeting stakeholder needs. We continue to assess its content, ensuring we follow Plain English principles and make it as user-friendly and accessible as possible. During the year, we continued to prepare for the re-development of the website, but due to COVID-19, the re-development project was pushed forward to 2021. We plan to implement a contemporary and flexible PSI website that supports and facilitates all PSI digital offerings, aiming to enhance and increase visitor engagement with improved opportunities for awareness-raising about our role for all our customers.

We recognise the changing technology landscape and demand for different types of media, including social media content and videos. We continue to build our profile on social media and provide information on regulatory and public health updates. We use the PSI newsletter to maintain regular contact with PSI 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. The newsletters are archived on the PSI website so that they can be usefully referenced. We updated registrants on a range of topics by email throughout the year and ensured information was available about our events and 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 and other requests for information from various stakeholders throughout the year.

In July, the PSI and Sport Ireland signed a Memorandum of Understanding to assist joint working between the agencies, particularly when there are overlapping interests or areas of mutual concern.

Human resources

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

In 2020, the sudden transition to a remote working set-up was managed successfully. Employee satisfaction and engagement levels were high throughout the year, as evidenced through regular staff surveys and other engagements. New ways of working have emerged, and several key HR processes are now fully operational online.

Several working groups are collaborating closely with our HR Office on wellbeing and staff engagement related topics. An Equality, Diversity and Inclusion Working Group was created in 2020 to advise the organisation in these areas and to help ensure that we continue to meet our statutory obligations and that we are promoting a culture of equality, diversity, and inclusion.

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 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.

We implemented Microsoft Teams in January 2020, which enabled us to transition to remote working in a highly efficient manner.

Business Transformation

We established a Business Transformation Office to lead on delivering an organisation-wide strategic and transformative programme aimed at achieving the PSI's strategic and developmental objectives. A significant part of the business transformation programme is the delivery of a new digital platform to serve as our single customer view. This will streamline and modernise many of our processes in relation to registration, complaint and query management, and inspections and will deliver efficiencies for the PSI and registrants. The programme will also deliver improved data quality across all systems, supporting our risk-based approach to regulation.

Organisational services in numbers



354,189 website sessions

236,233 website users

635, 690 unique page views



22 media queries dealt with

6 press releases issued

4 newsletters issued

29 communications sent to registrants on COVID-19



97%

of pharmacists applied for their continued registration online



Governance and Accountability

How we ensured high standards of internal governance

State bodies should act prudently, ethically, and with transparency and conduct their activities consistent with their statutory responsibilities. All PSI staff and officeholders, Council and Committee members have a role to play in assuring the good governance of the PSI, including maintaining a high standard of compliance with Government guidelines and clear evidence of transparency in 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 2020.

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. 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. During 2020 an independent performance evaluation of the Council was carried out and an action plan developed to implement recommendations that were identified. The PSI Council held a total of eight meetings in 2020.

All Council members who held office during 2020 are listed on page 32, along with records of attendance, fees and expenses paid.

PSI Council members 2020

Council Member (as at 31 December 2020)	Number of meetings attended ¹	Date of first appointment	Fees paid in 2020 ²	Expenses paid in 2020 ³
Mr Hugo Bonar**	8/8	29 October 2015	7,695	0
Ms Nicola Cantwell*	8/8	18 June 2013	7,695	0
Ms Geraldine Crowley**	5/8	18 June 2019	0	0
Ms Dorothy Donovan**	7/8	16 May 2018	7,695	0
Mr Fintan Foy**	8/8	17 June 2015	7,695	0
Dr Paul Gorecki**	8/8	31 January 2014	7,695	0
Mr Roy Hogan*	6/8	18 June 2019	7,695	0
Mr Mark Jordan*	7/8	18 June 2019	7,695	357
Ms Joanne Kissane* President	8/8	17 June 2015	11,970	0
Prof Brian Kirby*	7/8	18 June 2019	7,695	0
Mr Graham Knowles**	8/8	17 June 2015	7,695	1,372
Mr Michael Lyons* Vice-President	8/8	21 June 2017	7,695	581
Dr Shane McCarthy**	6/8	13 March 2014	7,695	2,508
Ms Muireann Ní Shuilleabháin*	7/8	17 June 2015	7,695	745
Ms Marie Louisa Power *	7/8	21 June 2017	0	86
Dr Ailis Quinlan**	7/8	21 June 2017	7,695	659
Mr Sean Reilly*	7/8	21 June 2017	7,695	41
Ms Ann Sheehan**	6/8	17 June 2015	7,695	1,657
Ms Veronica Treacy*	6/8	21 June 2017	7,695	0
Mr Paul Turpin**	6/8	17 June 2015	7,695	0
Ms Fiona Walsh**	6/8	16 May 2018	7,695	0

*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 2020. Council Members employed in the public sector were not paid fees in 2020.

³ Aggregate expenses paid up to 31 December 2020.

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. Each Committee meets throughout the year and reports to the Council on the work they have undertaken.

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 complaints and disciplinary process of the PSI. The Committees assess whether or not disciplinary action needs to be taken in circumstances where a registered pharmacist has not met the standards required of a member of the profession, as outlined in the Pharmacy Act 2007. Further information on the work carried out by these committees can be found in the Fitness to Practise section of this report.

PSI Advisory Committee members 2020

Audit and Risk Committee	
Committee member	Meetings attended
Chair: Paul Turpin	4/4
Liam Burke	4/4
Wendy Kennedy	4/4
Marie Louisa Power	3/4
Fiona Walsh	4/4
Niamh O'Regan	3/4
Veronica Treacy	4/4

Special Purposes Committee	
Committee member	Meetings attended
Chair: Joanne Kissane	1/1
Graham Knowles	1/1
Michael Lyons	1/1
Muireann Ní Shuilleabháin	1/1
Paul Turpin	1/1

Regulatory and Professional Policy Committee	
Committee member	Meetings attended
Chair: Muireann Ní Shuilleabháin	5/5
Hugo Bonar	5/5
Paul Gorecki	5/5
Brian Kirby	4/5
Ailis Quinlan	4/5
Sean Reilly	5/5
Ann Sheehan	2/5

Performance and Resources Committee	
Committee member	Meetings attended
Chair: Graham Knowles	4/4
Geraldine Crowley	2/4
Dorothy Donovan	3/4
Fintan Foy	4/4
Roy Hogan	4/4
Mark Jordan	3/4
Shane McCarthy	2/4

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, as they are aligned with our core function to maintain and promote the health and safety of the public. The PSI has a child protection policy in place to guide its staff and officeholders. The PSI also has a designated liaison person and deputy to oversee compliance with the policy and to act as the first 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 2020, we continued to monitor performance against the standards set out in the Customer Charter and identify areas for improvement.

Data Protection

The PSI, the pharmacy regulator, 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 23 data sharing requests and three subject access requests in 2020.

Disability Act

The PSI is committed to meeting the target set for public bodies in Part 5 of the Act, that 3% of its staff have disabilities. Further information on compliance with the Disability Act in the PSI can be found on page 36.

Energy Efficiency and Conservation

The PSI is 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 2020, the PSI consumed 471,763 kWh of energy, consisting of 196,300 kWh of electricity and 275,463 kWh of gas. In comparison, the PSI consumed 526,614 kWh of energy, consisting of 227,000kWh of electricity and 299,614kWh of gas in 2019.

The PSI notes a 14% reduction in electricity and a 9% reduction in gas in 2020. We can attribute this mainly to the ongoing COVID-19 crisis, which meant that our staff worked remotely from mid-March 2020. 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 2020, we ensured compliance with the legislation by responding in a timely manner to FOI requests and reporting on our engagement with the legislation. In 2020, we processed eight freedom of information requests and one internal review request.

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 workplace safety 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 Return to Work Safely Protocol, the PSI issued and implemented in full a 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 are 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 was given to all staff on measures to prevent the spread of COVID-19 and wearing of Personal Protective Equipment. 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 publishes any document setting out public policy proposals; its annual report; its audited account or financial statement; and any statement of strategy required to be prepared under section 5 of the Public Service Management Act 1997 in Irish, and will engage in the Irish language with those who wish to do so. For those seeking information on the PSI's official complaints process, information is available both in Irish and English, including the complaint form.

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 2020, six potential protected disclosures were received by the PSI under Section 7 of the Act. No protected disclosures were made under section 6 of the Act.

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 2020, 54.5% of our creditors had been paid within 15 days and a further 33.5% within 30 days.

Equality, Diversity, and Inclusion Working Group Report

In 2020 the PSI established an Equality, Diversity, and Inclusion (EDI) Working Group, which consists of staff drawn from all levels of the organisation. Its purpose is to progress activities that support, through actions, the values outlined in its Equality Diversity & Inclusion Statement, which is available on the PSI website.

The Group, which develops and promotes an awareness of our EDI obligations as a public body, and monitors EDI projects and goals within the PSI, created an EDI learning resource for PSI staff to celebrate and help raise awareness of equality, diversity, and inclusion, as well as promoting related best practices, across the organisation.

The Group noted that in gender diversity terms, the pharmacy profession continued to be a health sectoral leader, with 64% of all PSI registered 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 fully reflected in the PSI. In 2020, of the 21 members of the PSI Council (Board of Management), 10 were women, and 11 were men. Furthermore, in 2020, 70% of PSI staff, and 57% of the PSI Executive Leadership Team, which comprises the Registrar and six senior managers, were women.

The Group will continue to work to improve levels of representation in these areas in order that the PSI can continue to meet its legal obligation under the Public Sector Equality and Human Rights Duty, as outlined in Section 42 of the Irish Human Rights and Equality Act 2014, which requires all public bodies in Ireland to promote equality, prevent discrimination, and protect the human rights of their employees, customers, service users and everyone affected by their policies and plans.

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 Compliance

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 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 assurance framework includes a programme of internal audits presented to the Committee for consideration and approval. In 2020, the Audit and Risk Committee considered internal audit reports on the PSI's systems of internal control, GDPR systems and processes, as well as commissioning a high-level review of the PSI's internal controls.

The Committee received regular reports from the PSI's Executive Leadership Team on progress regarding the implementation of recommendations of previous internal audit reports and briefings on the PSI's quarterly financial position and the management of staffing, resources, and superannuation.

The Committee noted that the emergence of COVID-19 in 2020 presented the organisation with a series of new challenges and rapidly evolving risks, which had to be managed at pace. Overall, the Committee's view is that the organisation was successful in 2020 in mitigating these risks 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 2020 conducted a deep dive of the following PSI department's risk registers:

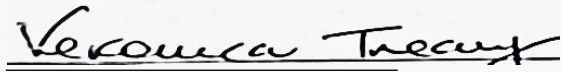
- Pharmacy Practice Development,
- Regulation,
- Operations, and
- Education and Registration.

In 2020 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 continues to monitor risks, both from external sources, such as the on-going COVID-19 pandemic, internal risks relating to the PSI's staffing levels, and those that may arise in the course of the PSI's Business Transformation and Organisational Change Projects, currently underway.

The Committee reviewed, with the External Auditor, 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 controls 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 towards the end of 2020, I would like to acknowledge the hard work and commitment of the former Chair, Mr. Paul Turpin.

A handwritten signature in black ink, reading "Veronica Treacy", is written over a horizontal line. The signature is cursive and fluid.

Veronica Treacy

Chair of the Audit and Risk Committee

Our Risk Management Report

The PSI manages risk through a process of reviewing the known risks it faces, the likelihood these will materialise, their possible consequences should they materialise, and the measures needed to mitigate them.

We have a risk management policy in place and related risk management processes that operate across the organisation.

The PSI Council has ultimate responsibility for the PSI's system of internal control, including risk management, and is advised by the Audit and Risk Committee with regard to these.

The Council is responsible for approving the organisation's risk management framework, including setting its risk appetite, reviewing its business continuity plan, and with the assistance from 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 patient safety and public protection, the PSI seeks to manage and mitigate risks that have the potential to affect its ability to effectively carry out and achieve its functions and objectives.

A corporate risk register identifies key risks for the organisation, and in 2020 risk updates were considered by the Executive Leadership Team, the Audit and Risk Committee and the Council. The PSI Council has considered the nature and extent of the risks it is willing to take to achieve the PSI's strategic objectives.

A summary of the PSI's principal risks and uncertainties as of 31 December 2020 is provided below.

- The PSI has a responsibility to ensure the 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.
- Risks were identified in 2020 in relation to the COVID-19 pandemic, and in seeking to mitigate those risks, the PSI engaged with the Department of Health, the HSE, the pharmacy profession, and the public.
- The PSI must ensure it has requisite resources, both financial and staff, to achieve our regulatory responsibilities. Risk in this context is mitigated by setting an annual Service Plan and budget and monitoring performance at management, Committee and Council level, by reviewing our priorities on an ongoing basis against resource availability and risk exposure, and by following financial policy, procedure, cash flow and value for money strategies. The business transformation project (2019-2021) is intended to achieve better ways of working across the PSI, to ensure we use our technology and our people in the best way possible. A key project in 2020 included a strategic funding assessment which will also inform our next corporate strategy.

- The PSI Council has deliberated 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 2007. To mitigate this risk, the Council proposed a draft set of statutory rules to the Minister for Health in 2019. However, the outcome of a Judicial Review in relation to the rules is still awaited, and until this is resolved, further progress on those rules cannot be made. The Council is clear that the absence of rules remains a risk for the public and the PSI.
- A new programme of education was introduced by the PSI in recent years for pharmacists qualifying in Ireland. Risks relating to the bedding-in of the five-year MPharm programme, the availability of placements for students and the continued delivery of a high-quality pharmacy education are risks under review by the PSI. To mitigate these risks, the PSI has accreditation standards in place, undertakes accreditation visits on a regular basis, engages with the higher education institutions and their shared service, the Affiliation for Pharmacy Practice Experiential Learning (APPEL), and with students, where appropriate. The PSI engages with the Department of Health as necessary.
- 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 our ageing ICT systems while new infrastructure is being developed, and risk to the PSI's business continuity should this be impacted by malicious cyber activity. To mitigate these risks the PSI has taken steps that ensure ongoing systems updates and testing occur. A business continuity plan is in place together with antivirus software and cybersecurity infrastructure. A security awareness and training programme is in place for all staff. The PSI Council has adopted a digital - first policy statement. It has approved a multi-phase business transformation project, together with project investment, to deliver on a new registration and e-enabling system for the organisation. This project has commenced with the dedicated support of a Business Transformation Office and oversight by a project programme board that reports to the PSI Council.
- Despite significant planning and consideration by the PSI and the Department of Health and others, there remain business and process risks that may impact the organisation arising from the United Kingdom exiting the EU. This remains an area under review by the PSI. The PSI has engaged with Government departments, regulatory counterparts in the UK, and others in relation to changes that will impact the PSI's functions, and the wider health and pharmacy environment

Our Financial Report

The 2020 annual accounts of the PSI have been audited by JPA Brenson Lawlor, and the details of the accounts are shown in the financial statements for the year ended 31 December 2020.

Income

The total income in 2020 was €7.885m, which is in line with 2019 income of €7.822m. 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 (IIOIP).

The total fee income for 2020 of €7.285m is in-line with the 2019 figure.

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 the 31 December 2020 was €5.844m (€6.010 in 2019) and is reflected in the cash held at that date in the Statement of Financial Position.

In 2020, funding of €0.600m was received from the Department of Health in respect of the IIOIP. The drawdown of €0.600m represents the full allocation of funds from the Department of Health for 2020.

Cost of operations

The total cost of operations decreased by €489k in 2020 to €6,986m, compared to €7.475m in the previous year. This was due to the pandemic and resulted in lower than budgeted expenditure on organisational costs, HR Costs, Legal Fees, and project expenditure as a result of changed work practices (home working) and compliance with government guidance.

Pay costs

The level of permanent whole-time staff approved by the Department of Health in 2020 was not exceeded. The average number of staff on payroll during the year was 43. In 2020, 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 2020, were €3.666m, a decrease of €0.048m on the 2019 cost of €3.714m. Direct pay costs amounted to €2.938m for the year, which is a decrease of €0.101m on the 2019 cost of €3,040m.

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 2020, in accordance with the directive of the Department of Public Expenditure and Reform.

The level of absenteeism of PSI staff continued to be low in 2020 at 0.45%, well below the figure of 1.50% in 2019. 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 from March 2020.

Non-pay costs

The total non-pay costs in 2020 were €3.320m (2019: €3.761m). The major elements were:

	2020	2019
	€m	€m
• Legal fees	0.466	0.526
• Tax and financial advisory fees	0.017	0.020
• Public affairs / marketing fees	0.028	0.044
• Pensions and human resources	0.012	0.009
• Consultancy & Professional fees	0.035	0.071
• ICT costs	0.410	0.357
• Printing, postage, and stationery	0.090	0.143
• Repairs, maintenance, and other property costs	0.149	0.135
• Depreciation	0.072	0.066
• Other education costs	0.045	0.034
• Institute of Pharmacy (IOP)	1.202	1.297
• Affiliation for Pharmacy Practice Experiential Learning (APPEL)	0.002	0.067

The IIOF operated for a full calendar year in 2020 and drew down €1,202,389 of its full operating budget allocation of €1,283,752. This amount was offset by €600,000 Department of Health funding received.

The PSI continued to use its approved Procurement Policy and the 2020 annual procurement plan to ensure that best value for money was achieved and costs contained to the best of our ability.

Financial results 2020 against budget

The table below outlines the operating income and expenditure result for 2020 against the original 2020 budget. These figures exclude capital related transactions, which are accounted for in the Balance Sheet.

Outturns for the year 2020 from operating activities against original budget

	Original Budget €	Outturn €	Variance €	Variance %
Total income	7,732,450	7,885,037	152,587	1.97%
Expenditure				
Pay costs	3,848,282	3,665,773	182,509	4.74%
Non-pay costs	4,637,729	3,320,547	1,317,182	28.40%
Total expenditure	8,486,011	6,986,320	1,499,691	17.68
(Deficit) surplus from operating activities	(753,561)	898,717	1,652,278	219.26%
Interest income	-	4,532	4,532	-
(Deficit) / surplus	(753,561)	903,249	1,656,810	219.86%
Funding from reserves	399,544	56,745	(342,799)	85.79%
Adjusted (deficit) / Surplus for the year	(354,017)	959,994	1,314,011	317.11%

Statement of financial position

The PSI's Statement of Financial Position as at the 31 December 2020 shows that total assets exceeded total liabilities by €24.643m compared to €23.740m at 31 December 2019. This is the net assets of the PSI including PSI House. It is represented in the Statement of Financial Position as follows:

	2020	2019
	€m	€m
Income and expenditure account	10.729	9.826
Revaluation reserve	11.414	11.414
Designated legal reserve	2.500	2.500
Closing reserves	<u>24.643</u>	<u>23.740</u>

The cash balance in the Statement of Financial Position at 31 December 2020 was €18.017m. 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 €5.844m (€6.010m in 2019).

The cash balance includes the following commitments:

	2020
	€m
Deferred income (prepayment of fees)	5.844
Statutory staff superannuation scheme funds	5.019
Designated legal reserve	2.500
Income and expenditure reserve minimum level – circa 30% of registration fees	2.124
Total cash committed	<u>15.504</u>
Unrestricted cash	<u>2.790</u>
	<u>18.294</u>

The PSI's statutory staff superannuation scheme fund of €5.019 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 a designated deposit account 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, JPA Brenson Lawlor, 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 2020, and of its results for the year 2020. 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 2019 were undertaken for the PSI by the firm Crowleys DFK, 5 Lapps Quay Cork, T12 RW7D.

The PSI's appointed external auditors in 2020 were JPA Brenson Lawlor, Brenson Lawlor House, Argyle Square, Morehampton Road, Dublin 4.

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Financial Statements 2020

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Council information

President	Ms Joanne Kissane
Vice-president	Mr Michael Lyons
Council members	Mr Hugo Bonar Ms Nicola Cantwell Ms Geraldine Crowley Ms Dorothy Donovan Mr Fintan Foy Dr Paul Gorecki Mr Roy Hogan Mr Mark Jordan Prof Brian Kirby Mr Graham Knowles Dr Shane McCarthy Ms Muireann Ní Shúilleabháin Ms Marie Louisa Power Dr Ailis Quinlan Mr Sean Reilly Ms Ann Sheehan Ms Veronica Treacy Mr Paul Turpin Ms Fiona Walsh
Registrar	Mr Niall Byrne
Head office	PSI House 15-19 Fenian Street Dublin 2
Auditors	JPA Brenson Lawlor Brenson Lawlor House Argyle Square Morehampton 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)
The Capel Building
Mary's Abbey
Dublin 7

O'Connor's Solicitors
8 Clare Street
Dublin 2

Council's report

The Council presents its annual report and the audited financial statements for the year ended 31 December 2020.

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 four occasions during 2020. The Committee is responsible for reviewing internal control matters, together with any other issues raised by the Internal Auditors, External Auditors and Committee members.

Remuneration policy

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

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

Financial results

The financial results for 2020 show an operating surplus of €903,249 (in 2019, the surplus was €357,769). The income for the year at €7.885m is a 1% increase on 2019 income of €7.822m.

In terms of annual reported expenditure, operating expenditure decreased by €488k to €6.986m in 2020 compared to 2019 (€7.475m). The challenges arising from the pandemic and the PSI's redirected focus to respond contributed to this result. The PSI continues to place emphasis on operating a model which endeavours to work as efficiently as possible and on cost management to ensure value for money across the organisation.

The Council authorised the use of the Income & Expenditure (I&E) Reserve to fund a number of projects amounting to €399,544, of which €56,745 was spent in 2020. €30,000 of this money was spent on the Organisation Development Project, €24,600 on a software upgrade for the outsourced Irish Institute of Pharmacy services and €2,145 on seed-funding for the Affiliation for Pharmacy Practice Experiential Learning (APPEL).

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 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.

Auditors

JPA Brenson Lawlor were reappointed as the company's auditor in 2020, in accordance with section 383(2) of the Companies Act 2014.

This report was approved by the Council on 25 March 2021 and signed on its behalf.



Joanne Kissane
President



Michael Lyons
Vice-president

Statement of Council's responsibilities

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 Irish Generally Accepted Accounting Practice in Ireland, including Financial Reporting Standard 102 'The Financial Reporting Standard applicable in the UK and Republic of Ireland' and promulgated by Chartered Accountants Ireland and Irish law.

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 profit or loss 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 25 March 2021:



Joanne Kissane
President



Michael Lyons
Vice-president

Report from the President

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 2020.
- ii. All appropriate procedures for financial reporting, internal audit, travel, procurement, and asset disposals are being carried out.
- iii. The Corporate Governance Framework also outlines that the PSI complies with disposal procedures for assets as outlined in the Code of Practice for the Governance of State Bodies. The Pharmacy Act 2007 states that any surplus following disposal of assets can be allocated to the development of education, research or any other public purpose connected with pharmacy.
- iv. A statement on the Systems of Internal Control has been included as part of this Financial Statements.
- v. Codes of Conduct for Council, Advisory Committee members and employees of the PSI are in place and are being adhered to.
- vi. Government policy on the pay of Chief Executives and all State body employees is being complied with. The PSI also complies with Government guidelines on the payment of Council Members' fees.
- vii. The Guidelines for the Appraisal and Management of Capital Expenditure Proposals in the Public Sector are being complied with.
- viii. The PSI is primarily self-funding in relation to the vast majority of its expenditure. An annual €600,000 Department of Health grant is allocated via the PSI to part-fund services provided by the Irish Institute of Pharmacy (IIOP). Detailed oversight procedures are in place between the PSI and Department, and contract and governance arrangements in place between the PSI and the IIOP service provider, which specify use of that funding for specific, and approved, work programmes related to initiatives and training for public health benefit. The PSI complies with its value for money strategy, and appropriate governance and procurement arrangements, where applicable, in keeping with the Public Spending Code and procurement procedures for public bodies.

- ix. The PSI is in compliance with Circular 25/2016 on the Protocol for the Provision of Information to Members of the Oireachtas by State Bodies.
- x. There are procedures in place for the making of protected disclosures in accordance with section 21(1) of the Protected Disclosures Act 2014. Details on protected disclosures made to the PSI in 2020 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 2019-2020 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.
- xvii. Gender Balance in the Council membership as at 31 December 2020:
 - 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.
 - No appointments were made to the Council in 2020.
 - The following measures are planned 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 will highlight the gender composition of the Council.

This report has been formally approved by the PSI Council on 25 March 2021 and signed by the President.



Joanne Kissane
President

Statement on the systems of internal control

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.

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 2020 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 2018-2020.
- 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 2020 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 2019 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
 - Review of GDPR systems and processes
 - High level review of internal controls

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. No breaches were reported for 2020. All elements of the control system were operational. No material losses or frauds occurred in 2020.

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

This statement of internal control has been formally reviewed and approved by the PSI Council on 25 March 2021 and signed on its behalf by the President:



Joanne Kissane
President

Independent Auditor's report

Opinion

We have audited the financial statements of the PSI for the year ended 31 December 2020, which comprise the Income Statement, Statement of Comprehensive Income, Statement of Financial position, Statement of Cash Flows and related notes. The relevant financial reporting framework that has been applied in their preparation is FRS 102, the Financial Reporting Standard applicable in the UK and Republic of Ireland issued by the Financial Reporting Council and promulgated by Chartered Accountants Ireland.

In our opinion the financial statements:

- give a true and fair view of the state of the PSI's affairs as at 31 December 2020 and of its results for the year then ended;
- have been properly prepared in accordance with FRS 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 56 to 57 reflects the PSI's compliance with the requirements of paragraph 1.9 (iv) of the Code of Practice for the Governance of State Bodies 2016 and is consistent with the information gathered during our audit.

Basis for opinion

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

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

Emphasis of matter - treatment of retirement pension

In forming our opinion, which is not qualified, we have considered the adequacy of the disclosures in Note 20 to the financial statements concerning the accounting treatment for retirement benefits. The PSI has not been advised on how best to administer the funds of the defined benefit pension scheme as the Department of Public Expenditure and Reform has yet to approve the funding mechanism for the scheme.

The pension scheme has been accounted for in the financial statements as if it were a defined contributions scheme. Should the pension scheme have been accounted for under FRS 102 Section 28 the actuarial gain / loss would be recognised in the Statement of Comprehensive Income and the surplus / deficit of the funds' assets over its liabilities would be recognised in the Statement of Financial Position as an asset or liability.

Conclusions on going concern

In auditing the financial statements, we have concluded that the PSI's use of the going concern basis of accounting in the preparation of the financial statements is appropriate. Based on the work we have performed, we have not identified any material uncertainties relating to events or conditions that, individually or collectively, may cast significant doubt on the PSI's ability to continue as a going concern for a period of at least twelve months from the date when the financial statements are authorised for issue. Our responsibilities and the responsibilities of the Council with respect to going concern are described in the relevant sections of this report.

Other information

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

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

We have nothing to report in this regard.

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

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

Matter 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 in accordance with Schedule 1, paragraph 16, of the Pharmacy Act 2007 and the accounting standards issued by the Financial Reporting Council and promulgated by Chartered Accountants Ireland (Generally Accepted Accounting Practice in Ireland), and for being satisfied that they give a true and fair view, and for such internal control as the directors determine 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.

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.



Thomas McDonald
for and on behalf of JPA Brenson Lawlor
Chartered Accountants
Argyle Square
Morehampton Road
Donnybrook
Dublin 4
25 March 2021

Statement of comprehensive income

	Notes	2020 €	2019 €
Income	3	7,885,037	7,822,156
Operating expenses		(6,986,320)	(7,474,735)
Operating surplus		898,717	347,421
Interest receivable	9	4,532	10,348
Surplus before taxation		903,249	357,769
Taxation	11	-	-
Surplus for the financial year		903,249	357,769

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

The notes on pages 64 to 79 form part of these financial statements.

Statement of financial position

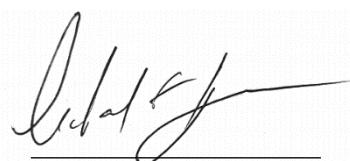
	Notes	2020 €	2019 €
Fixed assets			
Tangible assets	12	18,365,172	17,916,193
		18,365,172	17,916,193
Current assets			
Debtors	14	198,350	175,313
Cash at bank and in hand	15	18,017,338	17,293,778
		18,215,688	17,469,091
Creditors: amounts falling due within one year	17	(11,937,607)	(11,645,282)
Net current assets		6,278,080	5,823,809
Total assets less current liabilities		24,643,253	23,740,002
Reserves			
Revaluation reserves	18	11,413,635	11,413,635
Designated legal reserve	18	2,500,000	2,500,000
Income and expenditure reserve	18	10,729,616	9,826,367
Closing reserves		24,643,253	23,740,002

The financial statements were approved and authorised for issue by the Council on 25 March 2021.

Signed on behalf of Council:



Joanne Kissane
President



Michael Lyons
Vice-president

Statement of cash flows

	2020	2019
€	€	€
Cash flows from operating activities		
Surplus for the financial year	903,249	357,769
Depreciation on tangible assets	72,228	65,891
Interest received	(4,532)	(10,348)
Decrease/(increase) in debtors	(23,029)	(122,217)
Increase/(decrease) in creditors due within one year	292,325	511,064
Net cash flows from operating activities	1,240,241	802,159
Cash flows from investing activities		
Payments for tangible fixed assets	(521,213)	(146,740)
Interest received	4,532	10,348
Net cash flows from investing activities	(516,681)	(136,392)
Net (decrease)/increase in cash and cash equivalents	723,560	665,767
Cash and cash equivalents at beginning of financial year	17,293,778	16,628,011
Cash and cash equivalents at end of financial year	18,017,338	17,293,778
Relating to:	18,017,338	17,293,778
Cash at bank and in hand		

The notes on pages 64 to 79 form part of these financial statements

Notes to the Financial Statements

1. Accounting policies

1.1. Compliance with accounting standards and basis of preparation

The financial statements have been prepared in accordance with FRS 102, the Financial Reporting Standard applicable in the Republic of Ireland issued by the Financial Reporting Council and promulgated by Chartered Accountants Ireland, 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 first phase of the Business Transformation Project (BTP) is projected to be completed by end Q2 2021. Depreciation will start once the first phase of the BTP has been completed.

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.

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. Debtors

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

1.6. 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.

1.7. 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.

1.8. 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.

1.9. 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 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.

1.10. 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.

1.11. Interest income

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

1.12. 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.

1.13. 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.

1.14. Taxation

The Finance Act 2013, section 35, amends the Schedule to the Taxes Consolidation Act 1997 to include the PSI 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.

	2020 €	2019 €
Registration of pharmacists	2,630,633	2,496,115
Registration of retail pharmacy business	4,507,532	4,584,750
Administration charges and other registration costs	113,583	119,851
Other fees	33,289	21,440
Department of Health funding for Irish Institute of Pharmacy	600,000	6000,000
	7,885,037	7,822,156

4. Operating surplus

Operating surplus for the year is calculated after charging:

	2020 €	2019 €
Depreciation of tangible assets	72,228	65,891
Other pension costs	485,285	443,802
Audit remuneration (including VAT)		
-Audit fees	11,378	11,378
	568,891	521,071

5. Employees

5.1. Average numbers

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

	2020	2019
Office and management	43	40

5.2. Aggregate remuneration

Their aggregate remuneration comprised:

	2020 €	2019 €
Wages and salaries	2,938,064	3,039,562
Social insurance costs	242,424	230,323
Pension costs	485,285	443,802
	3,665,773	3,713,687

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:

	2020	2019
€60,000 to €70,000	11	8
€70,000 to €80,000	3	3
€80,000 to €90,000	1	2
€90,000 to €100,000	1	2
€100,000 to €110,000	2	-
€110,000 to €120,000	-	1
€120,000 to €130,000	1	-
	19	16

5.4. Key management personnel

The remuneration of key management personnel was as follows:

	2020 €	2019 €
Wages and salaries	610,062	599,988
Pension costs	138,352	134,636
	<hr/>	<hr/>
	748,414	734,624
	<hr/>	<hr/>

5.5. Registrar remuneration

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

	2020 €	2019 €
Niall Byrne	122,959	119,616
	<hr/>	<hr/>
	122,959	119,616
	<hr/>	<hr/>

6. Other staff costs

6.1. Staff travel and subsistence

	2020 €	2019 €
Domestic	13,847	34,416
International	3,193	19,344
	<hr/>	<hr/>
	17,040	53,760
	<hr/>	<hr/>

6.2. Hospitality expenditure

	2020 €	2019 €
Staff hospitality	245	2,432
	<hr/>	<hr/>
	245	2,432
	<hr/>	<hr/>

7. Council/Committee members' remuneration

	2020 €	2019 €
Council/Committee members' remuneration	193,070	200,496
	193,070	200,496

8. Council/Committee members' travel and subsistence

	2020 €	2019 €
Domestic	16,103	78,752
International	-	1,403
	16,103	80,155

9. Interest receivable

	2020 €	2019 €
Bank interest receivable	4,532	10,348
	4,532	10,348

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.

	2020 €
General legal advice	27,510
Financial advice	12,522
Public affairs	25,509
Procurement	34,291
Other	6,587
	<hr/>
	106,419
	<hr/>
Consultancy costs capitalised	-
Consultancy costs charge to the income and expenditure and retained earnings reserves	106,419
	<hr/>
	106,419
	<hr/>

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.

	2020 €
Legal fees	438,270
Conciliation and arbitration payments settlements	-
	<hr/>

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 2020, legal fees amounted to €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 2020, 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 2020 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 2020	17,700,000	21,795	10,431	246,489	337,112	18,315,827
Additions		13,784		8,651	498,779	521,213
Cost of disposal	-	-	-		(11,480)	(11,480)
At 31 December 2020	17,700,000	35,579	10,431	255,139	824,410	18,825,559
Depreciation and impairment						
At 1 January 2020	-	9,043	-	193,175	197,416	399,634
Depreciation eliminated on disposals	-	-	-		(11,480)	(11,480)
Depreciation charged in the year	-	3,299	-	30,024	38,906	72,228
As 31 December 2020	-	12,342	-	223,199	224,841	460,383
Carrying amount						
At 1 January 2020	17,700,000	12,752	10,431	53,314	139,696	17,916,193
At 31 December 2020	17,700,000	23,237	10,431	31,940	599,569	18,365,177

Included in Computer and Software is an amount of €539,592, which relates to the business transformation project. This will not be depreciated until the system goes live in Q2 2021.

13. Financial instruments

	2020 €	2019 €
Financial assets		
Bank and cash balances	18,017,338	17,293,778
Financial liabilities		
Trade creditors	184, 588	279,164

14. Debtors

	2020 €	2019 €
Prepayments and accrued income	198,350	175,313

15. Cash and cash equivalents

	2020 €	2019 €
Cash at bank and in hand	18,017,338	17,293,778

16. Cash

	2020	2019
	€	€
Cash at hand	273	368
Current accounts	4,911,049	4,218,933
Superannuation funds deposit account	5,019,092	4,660,758
Fixed term deposits	8,086,923	8,413,719
	18,017,338	17,293,778

Cash held in fixed term deposits contains the designated legal reserve fund of €2,500,000 and an Income and Expenditure minimum reserve of 30% of Registration Fee Income (approximately €2,000,000).

17. Creditors: amounts falling due within one year

	2020	2019
	€	€
Trade creditors	184,588	279,164
Other creditors	34,341	24,458
PAYE/PRSI	119,718	32,091
VAT	40	-
PSWT	7,255	5,616
Deferred income	5,844,686	6,009,925
Accruals	727,887	633,270
PSI Superannuation Scheme	5,019,092	4,660,758
	11,937,607	11,645,282

18. Reserves

18.1. Revaluation reserve

The freehold property was valued by Murphy Mulhall Chartered Surveyors, on 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 2020.

18.2. 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.

18.3. 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.

19. Movements in reserves

	Revaluation reserve	Designated legal reserve	Income & expenditure reserve	Total reserves
At 1 January 2020	11,413,635	2,500,000	9,826,367	23,740,002
Surplus for the year	-	-	903,249	903,249
At 31 December 2020	11,413,635	2,500,000	10,729,616	24,643,252

20. Pension commitments

The Pharmaceutical Society of Ireland Superannuation Scheme 2016

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

An actuarial valuation under FRS102 rules was performed on the scheme position as at 31 December 2018. The valuation showed an overall scheme liability of €6.819m. There was no actuarial report available as at the 31 December 2020. As the PSI holds cash assets of €5.019m on behalf of the scheme, this results in a net scheme deficit of €1.8m. However, for the reasons outlined below, the PSI is of the opinion that provision should not be made for this deficit in the financial statements.

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 10 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 no 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.

21. Events after the balance sheet date

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

22. Related parties

There were no transactions with related parties that require disclosure.

23. Controlling party

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

24. Approval of the financial statements

The Council approved and authorised these financial statements for issue on 25 March 2021.
